BUILDING A CULTURE OF PATIENT SAFETY

REPORT OF THE COMMISSION ON PATIENT SAFETY AND QUALITY ASSURANCE

JULY 2008
A Message from the Minister for Health and Children

I am delighted to welcome this Report, aptly titled ‘Building a Culture of Patient Safety’, which sets out a comprehensive framework for safety and quality in our health service.

I established the Commission on Patient Safety and Quality Assurance in January 2007 to develop clear and practical recommendations which would ensure that the safety of patients and the delivery of high quality health and personal social services would be paramount within our health service.

I want to thank the Chairperson of the Commission, Dr Deirdre Madden, all the members of the Group and the support staff for their tireless work and commitment to this task over the last eighteen months.

We live in an imperfect world: as human beings we all make mistakes and no system is perfect. However, all of us working in the delivery of healthcare owe it to our patients and to ourselves to do all that we can to minimise errors and maximise quality. The best way to do this is to accept and describe honestly where and how mistakes and failures have occurred in order to learn and to improve. A blame-free reporting and management culture is in the best interests of patients and those delivering services.

We can have different perspectives on many aspects of our health system – finance, staffing, service configuration, etc. - but patient safety and quality of care are at the core of what we all want to achieve. They can, therefore, be very powerful drivers of reform and improvement in services. Important improvements have already been made and others are underway. I am convinced that a collaborative approach between those using our services and those providing them, whether in the public or private system, will help to bring about a new era in Irish healthcare: an era of patient safety and quality of care.

Mary Harney TD
Minister for Health and Children
Foreword

We look for medicine to be an orderly field of knowledge and procedure. But it is not. It is an imperfect science, an enterprise of constantly changing knowledge, uncertain information, fallible individuals, and at the same time lives on the line.

Atul Gawande (2002), Complications: A Surgeon’s Notes on an Imperfect Science

From the beginning of their training, healthcare professionals are taught that errors are unacceptable: no diagnosis, allergy or previous medical problem can be missed, every test must be tracked down, every medication dose must be exactly right. Despite this, in every healthcare system errors do happen, sometimes with serious or even fatal consequences for patients and their families. When such adverse events occur there must be a system in place that ensures that all those affected are informed and cared for, and that there is analysis and learning from the error to try to prevent the recurrence of such an event. The dissemination of learning throughout the system is crucial to minimising error and protecting future patients.

As patients we are entitled to expect to be treated by competent professionals who are appropriately skilled and up-to-date with developments in their field, in facilities that are fit for purpose and subject to regulatory oversight to ensure that appropriate standards are complied with. We are entitled to be partners in our own healthcare, kept informed about our treatment and treated with honesty and respect if something goes wrong. Meeting those expectations on a daily basis is undoubtedly a challenge facing every health system which seeks to provide safe high quality care to all who need it.

The aim of the Commission on Patient Safety and Quality Assurance is to provide recommendations for a framework of patient safety and quality which will lead to effectively governed healthcare facilities, increased involvement of patients and service-users in healthcare decision making at all levels of the system, and the development of local and national leadership with clear accountability and reporting relationships. The Commission’s objective is to make recommendations for organisational, regulatory and educational reform which will create a culture of patient safety for our health system. Such a culture will drive clinical effectiveness where best practice will be based on national and international evidence, and audit will be the norm in every healthcare facility and for every healthcare professional. A patient safety culture will develop open communication with patients, and ensure learning throughout the system when things go wrong.

The Commission acknowledges the work already undertaken by a number of organisations, regulatory bodies and individuals in Ireland in the area of safety and quality and hopes that the recommendations in this Report will build upon that work through a national focus on patient safety. We are grateful to all those who responded to our
invitation to make submissions in which their concerns and priorities were highlighted, and to those who met with us to discuss particular aspects of our Terms of Reference.

I would like to acknowledge the hard work and co-operation of my fellow Commission members and the breadth of knowledge and expertise that they brought to our deliberations; it was a privilege and a pleasure to work with them. Their commitment to patient safety and quality was evident throughout our work and their professional experience and wisdom was invaluable in the writing of this Report.

On behalf of the Commission I would also like to express our immense gratitude to the researchers who gave their time and expertise to this work, and who made a vital contribution to our deliberations and to the writing of the Report.

Finally, on my own behalf and on behalf of my colleagues on the Commission, I would like to thank most sincerely the staff of the Patient Safety Unit in the Department of Health and Children who provided administrative support for the Commission, and whose efficiency, professionalism and commitment to the work at hand was always matched by patience and good humour.

Dr Deirdre Madden
Chairperson
July 2008
Commission Membership

Chair: Dr Deirdre Madden, Senior Lecturer, Faculty of Law, University College Cork
Dr Richard Brennan, General Practitioner, Kilkenny
Dr Tracey Cooper, CEO, Health Information and Quality Authority
Dr Eibhlín Connolly, Deputy Chief Medical Officer, Department of Health and Children*
Mr Tim Delaney, Head of Pharmacy, Adelaide & Meath Hospitals, Dublin incorporating the National Children’s Hospital, Tallaght
Ms Mary Duff, Director of Nursing, St Vincent’s University Hospital, Dublin
Ms Edwina Dunne, National Head of Quality and Risk, Office of the CEO, Health Service Executive
Mr Paul Fox, Process Engineering Manager, Bausch and Lomb, Waterford
Professor Muiris X. FitzGerald, Physician**
Dr Mary Hynes, Director of Quality and Risk, National Hospitals Office, Health Service Executive
Ms Margaret Murphy, Patient/Carer representative, Cork City
Dr Alf Nicholson, Consultant Paediatrician, Our Lady of Lourdes Hospital, Drogheda
Mr Tiberius Pereira, Patient/Carer representative, Dublin
Dr Ailis Quinlan, Head of Clinical Indemnity Scheme
Dr Gabriel Scally, Regional Director of Public Health for the South West Region of England, Bristol
Mr Dermot Smyth, Assistant Secretary, Department of Health and Children

*Dr Eibhlín Connolly replaced Dr Philip Crowley
**Professor Muiris X. FitzGerald replaced Professor Fergal Malone
Terms of Reference

Having regard to the findings of the Lourdes Inquiry and to responses to health system failures in other jurisdictions, the Commission will develop proposals for a health service-wide (encompassing both the public and the private sectors) system of governance based on corporate accountability for the safety and quality of health services. These proposals should constitute a framework which includes mechanisms and arrangements that will enable the verifiable implementation of nationally agreed managerial and clinical standards. The framework should include any necessary legal, managerial, administrative, technical and human resource measures.

As a component of any proposed framework, the Commission will *inter alia* examine and make recommendations in relation to:

- a system of leadership for clinicians and managers which would underpin robust corporate accountability for institutional and clinical performance
- a statutory system of licensing for public and private healthcare providers and services
- the process of quality assurance of clinical services (with an emphasis on clinical outcomes) for public and private healthcare providers and services
- procedures for healthcare professionals and managers to anticipate risks and promote good performance through effective risk identification, near-miss and adverse event reporting
- the participation of patients and carers and support staff in engaging with healthcare providers on health services planning and the quality of care received
- the participation by all healthcare staff in audit programmes which will aim to ensure quality improvement and that trends in adverse clinical events, complaints, adverse drug reactions and adverse events with medical devices are effectively analysed and disseminated
- the means to ensure that evidence-based practice is supported and applied routinely in everyday practice
- the governance of regulatory bodies in the health system and ways in which effective integration can be enabled between the various bodies.
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Chapter One

Executive Summary and Recommendations

Executive Summary

1. Introduction

Patient safety and quality are at the heart of the delivery of healthcare. For every patient, carer, family member and healthcare professional, safety is pivotal to diagnosis, treatment and care. Doctors, nurses and all those who work in the health system are committed to treating, helping, comforting and caring for patients and to excellence in the provision of health services for all who need them. There has been significant investment in recent years in the improvement of services, the enhancement of the capacity of the system, the recruitment of highly trained professionals and the provision of new technologies and treatments. Yet the Irish health system, in common with many others across the world, has faced challenges dealing with unsafe practices, incompetent healthcare professionals, poor governance of healthcare service delivery, errors in diagnosis and treatment and non-compliance with standards. These challenges are referred to throughout this Report.

Despite a professionally trained and highly motivated workforce in the health system, as well as huge investment in healthcare services over recent years in particular, the Irish healthcare system does not yet appear to have the framework in place to lessen the likelihood of errors occurring, the means by which to respond quickly or effectively to errors by analysing them and disseminating learning, nor sufficient regulation in place to ensure as far as possible that patients receive the highest possible quality of care throughout their journey through the health system.

It is important to acknowledge that despite our best efforts, medicine will never be a risk-free enterprise. What we must do in our efforts to make the system as safe as possible for patients and staff is to ensure that we have the right checks and balances in place to detect errant practices, identify and re-train clinicians whose competence falls below appropriate standards, provide the means by which to analyse and learn from mistakes when they do occur and develop standards against which to measure the competence of healthcare providers who seek to provide services to the public.

In this Report the word ‘patient’ is intended to include all people who use health and social care services. The word ‘clinician’ is intended to refer to all healthcare professionals involved in clinical work.

2. Background to the establishment of the Commission

The background to the establishment of this Commission is set out in Chapter Two of this Report. Some of the context in which the Commission has considered the issues within its Terms of Reference has been shaped by the review of highly publicised adverse events in the Irish health system. The failures identified by the reports that were published following these events point to a clear need to address these issues, not only at a local or institutional level, but also at a national or system-wide level in order to ensure that the
Building a Culture of Patient Safety

lessons of the past are learned and acted upon for the future. Therefore, although the Commission was established in the wake of some of these adverse events, this Report is not simply reactionary but rather intends to set a course for proactively dealing with current and future challenges to the delivery of safe and high quality healthcare services.

Patient safety has become both a national and international imperative in recent years, with increased emphasis across the world on patient safety in policy reform, legislative changes and development of standards of care driven by quality improvement initiatives. Studies of adverse events in numerous countries around the world demonstrate that between 4% and 16% of patients admitted to hospital experience one or more adverse events, of which up to half are preventable. Understanding why preventable errors occur is key to developing strategies by which they can be addressed and minimised. This focus forms the basis of much of the work of the Commission and the recommendations throughout this Report.

Analysis of the current situation in the Irish health service demonstrates the significant increase in recent years in the number of healthcare services delivered on a daily basis in hospitals, out-patient clinics and primary and social care settings across the country. New ways of working have emerged and new technologies have been developed and continue to be refined. This places continuing demands on multi-disciplinary teams delivering care to ensure that they are informed of best practice, have the flexibility to respond to new developments and put systems in place to monitor and evaluate the care provided so that high quality care in accordance with best practice is delivered.

There have been a number of developments in healthcare reform in Ireland over the last number of years, with the publication by the Department of Health and Children of the National Health Strategy, the Primary Care Strategy, the Prospectus Report, the Brennan Report and the Health Reform Programme in 2003. The Health Service Executive (HSE) was established in 2005; the Health Information and Quality Authority (HIQA) was established in 2007; legislation has been enacted to reform the regulation of medical practitioners, health and social care professionals and pharmacists; and detailed proposals for a Nursing Bill are expected to be published later this year.

A number of investigations and reports into adverse events in the Irish health service in recent years have identified a range of issues relevant to the work of this Commission. These include weak governance structures, poor communication processes, failure to develop or implement clinical audit, poor working relations between clinicians and management, lack of senior clinical leadership within organisations and nationally, poor team working, lack of structured incident reporting systems, inconsistent analysis of adverse events, lack of clarity on reporting relationships and failure to participate in continuous professional development. In its deliberations, the Commission took account of the findings of these investigations and the recommendations made in the reports.

3. Public consultation

The Commission undertook a public consultation exercise to gather information from those working in the healthcare system, patients, service-users and any member of the
Building a Culture of Patient Safety

public with views on the issues within its Terms of Reference. Submissions received by the Commission prioritised concerns as follows: risk management; participation of patients, carers and the public; audit; quality assurance systems; licensing; clinical governance and leadership; evidence-based practice; collaboration between healthcare regulators; medication safety; use of information technology; education and continuing professional development; physical environment and resources; and some others. These submissions are summarised in Section 2.8 of the Report and the Commission is grateful to those who took the time to respond to its invitation.

4. Development of a patient safety and quality framework in Ireland

The Commission agreed that the vision or framework around which the Irish health system should be based is as follows:

Knowledgeable patients receiving safe and effective care from skilled professionals in appropriate environments with assessed outcomes

The values underpinning this framework include openness, patient centredness, learning, effectiveness and efficiency, good governance, leadership, evidence-based practice, accountability and patient/family involvement. In many of the reports surrounding adverse events in Ireland and elsewhere, poor governance structures have been identified as major contributory factors in the analysis of how and why those events occurred. Governance is a broad concept which encompasses a number of different elements including advocating for positive attitudes and values about safety and quality, planning and organising governance structures for safety and quality, organising and using data and evidence and ensuring a patient focus. The various components of these elements are further discussed in Section 3.2.2 of the Report. The Commission agreed that governance is a framework composed of many elements that combine to drive a culture of continuous improvement in the safety and quality of services for all service-users, service providers and the wider community.

5. Patient and service-user involvement

Patients, carers and family members are and must be at the centre of all that is done in the Irish health service. Their voices must be heard more effectively in the future in relation to the development of policy for service delivery, development and evaluation. In particular, the health system needs to develop a national framework and network of patient advocates who will work in partnership with healthcare organisations to improve patient safety and to contribute to the education and continuing professional development of healthcare professionals. The means by which the integration of patients, carers and family members into healthcare decision-making can be achieved is set out in Section 4.1.2 of the Report.
Patients and service-users have faced an explosion in easily accessible medical information in recent years with increased information available on the Internet and through other sources. However, sometimes such information can be inaccurate and misleading and care must be taken to ensure as far as possible that patients are given accurate information about their condition, the care that is most appropriate for them and the ways in which they can access the services they need when they need them. Recommendations to support the concept of the ‘knowledgeable patient’ are set out in Section 4.2.1 of the Report.

6. Open communication with patients and carers

Unfortunately, sometimes things do go wrong in the delivery of healthcare. Ireland is no different in this respect from other countries. When adverse events occur which caused harm or could have caused harm to a patient, sometimes healthcare professionals and organisations are unsure how to react to the patient, how open they should be and how they should protect their patients and themselves. The system of compensation for medical negligence in existence in Ireland is not conducive to an open and honest communication process in these circumstances. Clinicians and risk managers are fearful of the consequences if they inform patients of an adverse event and often the event remains undisclosed and therefore the lessons from the event are never learned or shared with others who may be in similar situations in the future.

As a general principle, the Commission was of the view that every patient is entitled to open and honest communication regarding his/her healthcare; every patient is entitled to be informed regarding diagnosis and prognosis, treatment options and chances of recovery if possible. If something happens to a patient in the course of treatment and care which impacts or could impact on the person’s health or quality of life, that patient should be informed of this event, given an adequate explanation of the event and reassured that measures have been taken to prevent such an event occurring again in the future to him/her or to anyone else. Such disclosure is in keeping with the modern interpretation of the doctor-patient relationship which is built on partnership, open communication, dialogue and honesty. The Commission acknowledges that challenges exist in relation to the fear of litigation and the need to develop national standards for such disclosure and supports for clinicians and patients in the aftermath of an adverse event. However, it believes that these challenges are not insurmountable. This issue is further explored in the conclusions and recommendations of the Commission in Section 4.3.6, and adverse event reporting systems as a learning tool are explored further in Chapter Seven of the Report.

7. A culture of patient safety

Leadership and accountability are fundamentally important criteria for the delivery of a safe system. It is crucial to strike the right balance in the organisational and structural governance of each healthcare establishment and at local and regional levels of a health system. Patient safety must be seen as not only the business of a named individual whose job description mandates compliance with certain safety and quality standards. Safety and quality is and must be the job of everyone who works in healthcare. In the absence
of effective leadership, however, individuals who may be well motivated may lack the necessary driving force to put their motivation into practice and may become complacent in their actions. Complacency is not conducive to safe high quality patient care.

Although much has been said in recent years about the need to create a ‘fair and just culture’ in order to foster openness and honesty, there is also an argument which supports the holding to account of those whose competence and performance has fallen below what might reasonably be expected of them. Patients and members of the public are entitled to expect the highest possible quality of care from the Irish health system. When the delivery of care falls below that quality, they are entitled to ask why and to want to be assured that measures have been taken to protect them and future patients from similar harm in the future.

Cultural issues are sometimes identified as a barrier to system change both in Ireland and elsewhere. Viewed negatively, these cultural issues refer to professional and organisational attitudes and behaviour that are resistant to perceived interference and embody an antipathy towards change. By contrast, a positive safety culture is characterised by open communication, mutual trust, shared perceptions of the importance of safety and confidence in the efficacy of preventative measures. Increased efforts are required in Ireland to improve national, professional and organisational culture so that patient safety is understood, promoted and supported at all levels.

Experience from other systems shows that effective professional leadership is essential in achieving the culture change necessary to provide safe, high quality services. Leaders bring about change by first examining the current situation, looking ahead to future possibilities and recognising the areas for improvement. They then create a new system or change the system from what it is to what it should be by engaging with and involving the people using their services and those providing them. The Commission acknowledges the need for strong clinical leadership at national and organisational levels in healthcare and recommends the assignment of specific leadership roles for this purpose.

8. Governance framework for patient safety and quality

Accountability is a complex concept in healthcare and is recognised as a key driver for safety and quality of care. One of the key principles of good governance is that there are clear lines of accountability at individual, team and system levels, with accountability to employers, professional bodies, patients and the public. The Commission recommends in Section 5.2.2 that all healthcare organisations should have in place a governance framework that clearly describes responsibilities, delegated levels of authority, reporting relationships and accountability within the organisation. The Chief Executive of each organisation should be made ultimately responsible and accountable for patient safety and quality within that organisation. The Commission also recommends that a senior person be nominated to hold responsibility for safety and quality at all organisational levels. A clear system of accountability should connect the holder of the responsibility at each organisational level through to the top management team or Board of the organisation and, where appropriate, these should be networked at regional and national levels.
The Commission supports the implementation of a system of clinical directorates within all healthcare organisations which would ensure that the clinical director, appointed on a competency basis, would be accountable for all aspects of patient safety and quality within the directorate.

The Commission recommends that governance arrangements across the system should enable a connected and integrated approach at local, regional and national levels that ensures that good governance is in place and that learning occurs and is disseminated effectively. It should be the responsibility of all healthcare organisations to ensure that their governance arrangements specifically address this aspect of service provision. The Commission recognises that the governance structures which will be required of hospitals and other healthcare facilities to fulfil the licensing requirements proposed in Chapter Six of this Report may vary depending on the nature and extent of the services being provided. However, it recommends that in general such governance structures should at least include a Board of Management comprised of representatives of the medical, nursing and other professions involved in the provision of services at the facility as well as lay people who represent the interests of patients, carers and the public.

The Board must review on a regular basis the systems of governance at the facility relating to healthcare safety, quality and performance, including the structures in place for risk management and audit. Legislation should be introduced that would place a clear duty on the Board of each facility or group of facilities to put and keep in place arrangements for the purpose of monitoring and improving the safety and quality of healthcare. A similar statutory duty should be placed on the Chief Executive and Board of the HSE to ensure that all the Boards under its remit are complying with these requirements.

The Commission recognises that the governance structures recommended above may not be appropriate or feasible in relation to healthcare services delivered outside of acute hospital and comparable clinical settings. The Commission therefore suggests that in the rolling out of the licensing framework proposed in this Report to primary and community care, extensive consultation should take place with relevant stakeholders as to how the governance arrangements recommended in this Report should be adapted to the provision of services in those sectors. Further details of the Commission’s recommendations on governance structures are set out in Section 5.3.3.

9. Education, training and research on patient safety

The Commission strongly supports the prioritisation of education, training and research on patient safety. The Commission recommends in Section 5.4.1 that all bodies responsible for the training and continuing professional development of healthcare workers should review their curricula to ensure that both technical and human factors in relation to safety and quality are incorporated into their education modules. Education and training suites and modules on patient safety need to be developed and implemented in collaboration with the professional regulatory and training bodies, the HSE and the Health Research Board (HRB) at undergraduate and postgraduate levels for all healthcare workers.
It is clear that health professionals can no longer be regarded as trained for life. Systems of lifelong learning and professional development with regular competence assurance must be mandated in order to ensure that all members of the workforce remain competent and fit for purpose throughout their working lives. The Commission therefore strongly supports the introduction of Competence Assurance Schemes for all healthcare professionals. Such an innovation recognises the necessity for lifelong commitment to continuing education and training, peer review and clinical audit. The development and implementation of Competence Assurance Schemes by professional regulatory and training bodies should integrate patient safety education and training modules as part of their core elements.

The Commission also recognises the need for specific educational and training requirements and supports for healthcare managers. It therefore recommends in Section 5.5.2 the creation of a specific vocational management training programme aimed not only at producing high quality managers but also at enhancing the management capability of health professionals at all levels of the health system; this programme would also include specific modules on patient safety and quality. The competencies required for health service management should be clearly identified, and the management team up to and including the Chief Executive should demonstrate competence-based training and be subject to ethical and disciplinary codes similar to other health professionals.

10. Regulation of healthcare facilities

As outlined in Chapter Six of this Report, organisational and professional regulation in Irish healthcare is complex. There is currently no licensing, registration or certification system for healthcare facilities other than for residential care centres for older people, children and people with disabilities and those regulations applying to maternity homes and mental health services. Individual practitioners are however required to be registered with professional regulatory bodies. A voluntary accreditation scheme has been in operation in recent years which was overseen initially by the Irish Health Services Accreditation Board and, since 2007, has been integrated into the functions of HIQA.

The Commission carried out extensive research into licensing regimes in operation in other countries including the United Kingdom, Canada, Australia, New Zealand, the Netherlands and the United States. Different terms are used in different countries to describe the process of licensing or mandatory registration in accordance with minimum standards. It is acknowledged that the evidence of the effect of regulation on healthcare is sparse, with no robust evidence of the effectiveness of licensing on the quality of the healthcare. However, it must be remembered that although there is no available evidence on the effectiveness of licensing on the quality of care, the absence of evidence does not imply the absence of effect. Internationally, while there is diversity in methods of regulation, the trend is towards more regulation driven by, amongst other things, the increase in the expansion of private healthcare. In the view of the Commission, licensing as part of a safety and quality framework that also requires demonstration of engagement in a continuous quality improvement process will improve patient safety and quality of care. The Commission’s recommendations in relation to the introduction of licensing for public and private healthcare providers are set out in Section 6.2.6.
11. Professional regulation

The Commission examined the regulation of healthcare professionals in Ireland. Self-regulation has been a typical feature of healthcare professional groups in most jurisdictions until recent times. However, this model has suffered criticism from patients and the public on the basis that it leads to a perceived protection of self-interest by such groups and does not provide strong public accountability. Internationally the role of health professions in society and their self-regulatory status is changing. This is driven by a decline in trust in the professions, challenges to traditional hierarchies by the introduction of multi-disciplinary care and globalisation and increased mobility of the workforce. For these reasons, reform of the regulation of health professions is an important aspect of the policy response to patient safety and quality assurance internationally.

The Commission examined the statutory functions of the professional regulatory bodies in Ireland, the recent legislative changes introduced to regulation of the medical profession, pharmacists, health and social care professionals and the anticipated changes to the regulation of the dental and nursing professions. A common feature of these reforms is to change the membership structure of the regulatory body councils to ensure that a majority of members are not members of the relevant profession and to restructure the membership in favour of appointment rather than election by peers. The Commission carried out research into comparable regulatory arrangements in other jurisdictions including the United Kingdom, the United States, Canada, Australia and New Zealand. It concluded that although regulatory bodies are moving towards a common stated objective of protecting the public, some differences in regulatory interventions and opportunities for collaboration between the regulatory bodies exist, particularly in relation to the development of professional standards and education and training. These are outlined in Section 6.3.4.

The Commission also discussed the exercise of disciplinary functions by professional regulatory bodies. The fundamental purpose of Fitness to Practise inquiries is to promote and safeguard the public interest which involves individual patient protection, the maintenance of public confidence in the profession and declaring and upholding proper standards of conduct. If that fundamental purpose is to be met, there are some basic principles that should be applied to ensure that practitioners receive a fair and public hearing by an independent and impartial tribunal in accordance with the European Convention on Human Rights Act 2003. The Commission took careful note of recent cases in this jurisdiction, the Shipman Report in the United Kingdom and legislative changes recently introduced in this regard.

The Commission is concerned that, in the context of the medical profession, some of the members of the Fitness to Practise Committee who will hear the evidence and submissions in relation to the allegation, and reach conclusions on the allegation of professional misconduct, will be members of the same body that will make the final decision as to professional misconduct (though they will not be part of the final decision-making process). The Commission is of the view that the appearance of separation of function must be matched by the reality of the processes and procedures.
At the present time, Fitness to Practise inquiries are generally heard by a small committee of medical and non-medical members of the regulatory bodies. Such members may sit on inquiries for a number of days per year, and each committee may be comprised of different members. The Commission is concerned that this system does not facilitate the development of expertise in relation to the disciplinary process and may result in inconsistencies in the application of standards.

In addition, the increase in multi-disciplinary team care and treatment of patients may result in complaints being made against a team rather than an individual practitioner. For example, skills extension for nurses has led to the assumption of specifically defined clinical decision-making, drug-prescribing and the performance of medical procedures such as bronchoscopy and colonoscopy. It is important therefore that consensus is reached between the different professional groups in respect of common standards and ethical behaviour that would ensure patient safety, when therapeutic interventions or the performance of procedures can be carried out by different craft groups. The current disciplinary structures in the professional regulatory bodies do not facilitate an investigation and hearing of a complaint pertaining to team care, which may therefore fall between the regulatory bodies.

The Commission concluded that there is a role for a coordinating body in professional healthcare regulation. Potential areas for such a body to add value in terms of patient safety and quality assurance in healthcare include ensuring that professional regulatory bodies pursue a similar objective in protecting the public, requiring professional regulatory bodies to collaborate on areas of common interest, providing a first point of contact for patient concerns in relation to clinical care and ensuring that the initial investigation of complaints is managed using a common framework.

The Commission was of the view that there should be greater separation between the investigation and adjudication functions performed by the professional regulatory bodies so that the public might have greater confidence that the disciplinary functions exercised by those bodies are independent and robust. It recommends in Section 6.3.5 the establishment of a group to make detailed provision for the implementation of the Commission’s recommendations in this regard.

12. Recruitment of healthcare professionals – an information gap

For healthcare providers in an era of corporate governance and compliance, information is critically important. Recruitment decisions taken by healthcare providers have crucial significance in relation to providing safe and high quality clinical services to patients. In recent years, concern has arisen in relation to the fact that employers may not have a complete picture of the track record of the potential employee and may therefore be unaware of problems previously encountered in relation to that person’s clinical competence. Although applicants are required to complete application forms, provide professional references and appear at interview, this system will not necessarily capture information relating to previous competence or conduct. For example, locum doctors are occasionally appointed to fill a gap at short notice and in the circumstances of such
temporary appointments it may often be difficult to comprehensively check the veracity of application forms and references. This system may therefore expose patients to risk. The Commission considered ways in which this situation might be prevented, including a strengthened concept of clinical governance, the recent introduction of competence assurance schemes for registered medical practitioners and a system of credentialing of healthcare staff.

Credentialing is a process whereby healthcare organisations review the qualifications and track record of doctors and other professional staff who are either joining or are already working within their organisations. In the United States credentialing is linked to the concept of privileging which is used by healthcare providers to define the scope of practice of healthcare practitioners. Privileges are related to an individual’s documented experience in categories of treatment areas or procedures, to the results of treatment and to the conclusions drawn from quality assurance activities. The Commission believes that the system of privileging has many potential benefits to offer to a safety and quality framework by ensuring that, for example, doctors who undertake new or novel surgical techniques have been adequately trained in the skills required for the application of such techniques and have been assessed by the relevant training body as competent to undertake such procedures.

In the Irish context, the Medical Council maintains a register of all medical practitioners and also a specialist register. It is not currently a mandatory requirement for consultant posts in the HSE to be filled by those on the specialist register. There are similar registers maintained by the Nursing Board, the Health and Social Care Professionals Council, the Dental Council and the Pharmaceutical Society of Ireland. There is no national system of credentialing, no system of alert notices or no national database to which employers can apply for information relating to the qualifications and competence of healthcare practitioners other than the professional regulatory bodies which record only information relating to the practitioner’s current registration status.

The Commission believes it is of crucial importance that a potential employer should be fully aware of any problems in a professional’s previous employment so that a decision to give someone access to patients is made with as full knowledge of that individual as possible. A system of alert notices has been established in the UK whereby employers of a professional can request the issuing of an alert notice in respect of an employee who they have good reason to believe may pose a significant risk to patients or staff. Alert notices are sent to potential employers so that employment decisions can be made in the light of full knowledge of previous employment experience. The Commission believes that healthcare employers have a duty to other potential employers and patients to consider whether there is a potential risk arising from the practice of a healthcare professional. Whilst contacting the appropriate professional regulatory body they should also take action to bring the matter of serious concern to the attention of other bodies in the healthcare system. The Commission therefore concluded that an alert notice system should be introduced in Ireland.

The Commission’s recommendations in relation to credentialing, privileging and the issuing of alert notices are set out in Section 6.4.4 of this Report.
13. Clinical effectiveness

It is essential in any healthcare system that healthcare professionals, multi-disciplinary teams, organisations and the wider healthcare service are able to use information to monitor the safety and quality of the services that are being provided so as to enable the sharing of good practice, make improvements as required and inform the planning of services. Clinical effectiveness embraces this approach as part of a well governed healthcare system, and involves a number of processes and behaviours at the various levels of healthcare in order to drive safety and quality.

The requirements for good clinical effectiveness include access for healthcare professionals to the most up-to-date information and evidence-based practice relating to the condition or specialty area, and the undertaking of effective clinical audit by individuals, teams, organisations and the wider health system in a well led, organised and effectively managed manner, with strong clinical leadership to support and drive the activity. Clinical effectiveness also includes establishing clinical standards, guidelines and indicators that enable healthcare professionals to monitor their individual, team and organisation’s performance against nationally, and where possible, internationally recognised comparative parameters. It further involves ensuring that staff are supported, educated and trained in clinical audit, information models and the use of information to inform and improve their service. These issues are explored in detail in Chapter Seven of the Report.

14. Evidence-based practice

It is self-evident that safe and effective treatments and care are important in ensuring that patients get the best outcomes from their care. The international evidence also indicates that effective care is often the most efficient care. However, defining what effective care is, ensuring that both professionals and patients are aware of what effective care is and ensuring that effective care and treatments are available in a fair and equitable way across the entire system presents significant challenges. Despite recent initiatives introduced by the HSE, colleges and professional training bodies and the Health Research Board, there is no formal system in place at national level in Ireland which sets quality assurance standards for evidence-based guidelines, and the implementation of guidelines is not systematically monitored or incorporated into routine health service management processes.

The Commission is of the view that supporting evidence-based practice is a critical element of a health system which is to deliver safe and high quality care. While acknowledging that some considerable work in the development of professional guidelines has been carried out to date, value can be added to these initiatives through a strategic, systematic approach, properly resourced and supported, where responsibilities are clearly assigned and where guideline development is quality assured and linked to service delivery priorities. Also, as evidenced in other systems, attention must be directed at ensuring the implementation of evidence-based guidance.

The Commission recommends that a leadership role should be developed in relation to the capture and analysis of international evidence and research, and to the production of evidence-based information and guidance for use in policy-making, system reform
and individual patient and professional interactions. It further recommends that a rolling programme should be developed by the Department of Health and Children, HIQA and the HSE to deliver evidence-based service frameworks covering the major health conditions within the public healthcare system, similar to the National Service Frameworks (NSFs) model in the UK. Such frameworks should be reviewed periodically to encompass new evidence on effectiveness and performance. A substantial strand in publicly funded health research strategies, focused on patient safety and quality, should be developed by the Health Research Board. Evidence-based national standards should be developed with multi-disciplinary input, in both primary and secondary care settings, and for the transition between care settings. The Commission’s recommendations are set out in Section 7.2.3.

15. Clinical audit

It is recognised that clinical audit needs to be at the heart of clinical practice and is something that all health practitioners should be engaged in. Clinical audit is about continuing evaluation and improvement by health professionals working towards delivery of safe, high quality care for patients. It arguably constitutes the single most important method that any healthcare organisation can use to understand and assure the quality of the service that it provides. It is one of the principal methods used to monitor clinical quality, and the results provided by clinical audit are a source of indispensable information to patients, the public, clinicians and healthcare managers. It also provides a powerful mechanism for ongoing quality improvement, highlighting incidences where standards are not met and identifying opportunities for improvement.

Currently there is no national coordinated effort to integrate clinical audit into quality improvement or governance. While clinical audit is being advanced in a number of organisations and there have been some initiatives in recent years by training bodies and professional regulators, clinical audit is not generally linked to service improvements, planning or resource allocation. The Commission examined clinical audit arrangements and requirements in other countries and concluded that clinical audit should be viewed as an essential and integral component of professional practice which will contribute to improved patient outcomes. It acknowledges that there are challenges to clinical audit including fear of litigation through disclosure of data, lack of incentives and lack of resources, especially time and training.

The Commission recommends that all clinicians, both as individuals and as members of teams or networks, must actively participate in clinical audit in compliance with national standards and priorities. As part of the licensing process recommended in Chapter Six of this Report, all licensed healthcare facilities must demonstrate active participation in local and national clinical audit as appropriate to their services. As part of the implementation of this Report, a group should be established to develop national programmes of and standards for clinical and other forms of audit which support the safety and quality of health services and are linked to national health priorities. The Commission recommends the introduction of an exemption from Freedom of Information legislation and the granting of legal protection from disclosure to data related to patient safety and quality improvement.
that are collected and analysed by healthcare organisations for internal use or shared with others solely for purposes of improving safety and quality. Further details of the recommendations in this context are set out in Section 7.3.6.

16. Adverse event reporting

As outlined above, there is significant international evidence regarding the extent of adverse events arising in healthcare. Studies conducted in the US, the UK and Australia found that adverse events occur at rates of between 4% and 16% of hospitalisations. In considering adverse event reporting processes, the Commission agreed that it is essential that the lessons learned in one healthcare establishment are communicated regionally, nationally and internationally. For the purposes of this Report, the Commission adopted the World Health Organisation (WHO) definition of adverse event as ‘an incident which results in harm to a patient’.

A number of different adverse event reporting systems are in place throughout the Irish health service. However, there is no universal system that collects and collates adverse event data from all elements of the health sector. The Commission examined systems in place in Denmark, the United States, the United Kingdom and Australia.

The Commission concluded that it is essential that an effective and patient-centred approach is taken to governance, management, reporting and communication following adverse events. The effectiveness, speed and style of communication of the local response to an adverse event or near-miss are key from the perspective of the patient, his/her family and the staff involved – the culture within the healthcare facility will influence this response and an open and transparent culture within facilities will enhance the communication and learning following such events.

In order to ensure that appropriate action is taken to support the patient and staff member(s) involved, every healthcare facility should have effective arrangements in place to ensure that the process of reporting, investigating, learning and management of adverse events and near-misses is carried out effectively and is a priority of the Board of the facility. However, it is also essential that there is a national surveillance resource that receives reports of serious adverse events from across the system in order to ensure that appropriate action has taken place, that trends are monitored and that learning takes place to inform the existing and future delivery and governance arrangements of healthcare.

The Commission discussed the advantages and disadvantages of both voluntary and mandatory reporting systems. Voluntary reporting systems rely on strong educational initiatives, institutional supports and professional codes of conduct to encourage, promote and support healthcare professionals in reporting adverse events. Mandatory systems seek to make healthcare providers accountable for serious mistakes by requiring that the mistakes be reported, and by providing disincentives such as sanctions for the continuation of unsafe practices. The Commission considered systems in operation in other jurisdictions as well as the current reporting system in place in Ireland under the aegis of the Clinical Indemnity Scheme (CIS).
The Commission concluded that systems that rely wholly on spontaneous or voluntary reporting are ineffective and result in underreporting. It believes that a mandatory system will improve patient safety and ensure greater accountability by requiring specific reports of serious injury to be made by healthcare providers, and disseminating lessons to be learned throughout the system. The development of a complementary voluntary system of reporting of close calls or near-misses will contribute to further learning and dissemination of best practice. This is already in place for enterprises covered by the CIS but should be extended to cover all future licensed facilities. Further detail of the Commission’s recommendations in relation to adverse event reporting is provided in Section 7.4.12.

17. Medication safety

Adverse events involving medication are one of the commonest categories of adverse events in Ireland and elsewhere. The Commission considered specific issues pertaining to medication safety and was of the view that patients are entitled to expect the highest standards of safety, quality and efficacy of medicinal products, their ethical marketing, and the safe use of medicinal products in the hands of healthcare professionals, carers and patients themselves. To that end the Commission strongly encourages pharmaceutical companies to ensure the safety, quality and efficacy of the medicinal product, including ensuring freedom from contamination or counterfeit contents.

The Commission supports the continued promotion of pharmacovigilance by the Irish Medicines Board and the capture of information regarding adverse drug reactions, the provision of effective feedback and the uptake of this information by healthcare professionals and patients. The Commission recommends that there should be a national analysis of the problems and potential solutions to the issues presented in the context of medication safety. Further details of the Commission’s recommendations in this regard are provided in Section 7.5.1.

18. Appropriate environments

It is impossible to consider the concepts of safe and effective care being delivered by skilled professionals in isolation from the physical environment and setting in which that care is provided. Although the Commission did not undertake detailed research into these aspects of care, it is aware of work that is being done within other areas of the healthcare system to identify best practice and make recommendations in respect of both the setting of care and the built environment in which care is delivered to optimise safe, high quality and patient-centred care. The Commission is persuaded by such evidence as has been made available to it and by submissions made on this issue that the implementation of evidence-based design will result in safer and higher quality care for patients, with resultant economic benefits for the health system. It therefore recommends in Section 7.6.1 that the Department of Health and Children should commission an independent report on the principles and implementation of evidence-based design of healthcare facilities for the Irish health system.
19. Health information and health information technology

Information is at the heart of understanding and knowledge. It is fundamental for a healthcare system to have accurate, meaningful and accessible information made available to patients, the public, healthcare professionals, planners and politicians, regarding the safety and quality of the healthcare provided at all levels of the system, the performance of the health service and public health priorities for the future. It is impossible to think about improvements in safety and quality in healthcare, and the development of a high reliability healthcare system, without also considering the health information and health information technology developments that are required to enable and sustain these improvements and further the understanding and knowledge of the health system.

Timely access to relevant information is essential for the delivery of safe, high quality care. Lack of timely access to information may result in patients not receiving the appropriate care. This may result in care that is of a poor standard, has a negative impact on the experience of the patient and contributes to system waste and inefficiencies such as the unnecessary repetition of diagnostic tests and inappropriate admissions.

High quality information should be at the core of decision-making concerning health at all levels, from individual patient care to the planning and management of services at local and national levels. However, access to information in healthcare is frequently limited and fragmented. Patient records in many areas of care are paper-based or, if computerised, are in formats that cannot be shared easily between providers. Health service management information which is collected is usually for financial or administrative purposes rather than being directed at the outcomes of clinical care and the safety and quality of services.

Fit-for-purpose Health Information Technology (HIT), and the necessary Information Communication Technology (ICT) systems, are essential to underpin a modern health system in order to support the provision and accessibility of accurate and meaningful health information. Despite some localised examples of good practice in HIT and health information within the Irish health system, technology for the delivery of clinical care has lagged behind administrative and financial applications. As a result, the available information tends to be limited to financial and administrative information rather than the impact of care on the patients, and therefore meaningful information on the assessed outcomes for patients is restricted.

International experience shows that the effective use of information systems and HIT have the potential to contribute to improved patient safety, patient empowerment and better patient experience of care, the delivery of more evidence-based care and better integrated care across different healthcare sectors and environments, improved training of healthcare professionals, improved health service planning and performance monitoring as well as improvements in the design of services.

Chapter Seven reviews the international and Irish experience to date in this area, and deals with information developments that are most important in terms of patient safety as well as HIT and their potential to enhance safety in the Irish system. The Commission’s recommendations in this regard are set out in Section 7.7.8.
20. Conclusion and implementation

Following comprehensive discussion of the issues within its Terms of Reference, the Commission agreed that there are significant problems with existing internal and external regulatory mechanisms for ensuring patient safety in Ireland. The Commission considered ways in which the gaps in the current system might best be remedied so that responsibility, accountability and safety are clearly embedded as key priorities for all participants in the healthcare system.

The Commission is of the view that there is a need to modify existing mechanisms to create new solutions that can be integrated into the current framework in order to build a comprehensive approach to patient safety and quality assurance. The Commission acknowledges the challenge in trying to find the correct balance between formal and informal strategies to improve safety and quality of care. While regulation is not the answer to every problem, as it may be burdensome in terms of time, resources and financial expenditure, the Commission believes that there are nonetheless distinct advantages in regulating for patient safety in terms of ensuring compliance with agreed national standards and achieving valued policy objectives.

In devising an implementation plan for the recommendations in this Report, the Commission stresses that the ultimate objective must be to provide clear national leadership on patient safety for the Irish health service which will ensure sharing of information and expertise as well as the integration of similar regulatory functions within one agency. The Commission acknowledges that the achievement of this objective will require significant medium to long-term planning for legislative, organisational and structural reform, which will inevitably take some time to implement. The Commission nonetheless believes that this long-term objective would be the most effective means of implementation of the recommendations of this Report.

The option recommended by the Commission envisages the immediate commencement of work by the Department of Health and Children in relation to the introduction of legislation, where this is required, to implement all of the Commission’s recommendations. The implementation plan endorsed by the Commission further recommends the immediate establishment of an Implementation Steering Group (ISG) with clear and regular reporting obligations to the Minister for Health and Children regarding progress on the implementation of the recommendations of the Report. This also requires the establishment of expert sub-groups comprised of representatives of relevant stakeholders, each of which will be required to report to the ISG on the practical and detailed implementation of the recommendations within their remit. Further detail on the composition and terms of reference of these sub-groups is set out in Section 8.1. The ISG and sub-groups must be supported by a full-time executive at senior level within the Department of Health and Children. The Commission further recommends that the progress reports from the ISG to the Minister should be made available to the public.

The Commission strongly believes that full and effective implementation of all of the recommendations in this Report will prioritise patient safety to the extent necessary to ensure a significant and long-lasting effect on the Irish health system.
Recommendations

Chapter Four – Patients, Carers and Service-Users as Partners

Patient, carer and service-user participation

The Commission endorses the recommendations in the *National Strategy for Service User Involvement in the Irish Health Service* (Department of Health and Children and HSE 2008) and further recommends the following:

R4.1 The proposals in the *National Strategy for Service User Involvement in the Irish Health Service* should be implemented as a matter of urgency to ensure that patients and their families can influence policy development, service delivery and health service development and evaluation.

R4.2 A national network of patient advocates who will work in partnership with healthcare organisations and other key players to improve patient safety should be identified, supported and developed through appropriate training programmes; the network should also, where appropriate, have strong links with international/worldwide initiatives.

R4.3 Effective patient and public involvement should be demonstrated in any review of health service performance.

R4.4 Robust and validated patient and public involvement should be a requirement for all healthcare oversight, scrutiny, quality control and other accountability mechanisms.

R4.5 Healthcare organisations must ensure an environment that allows for patients and their families to raise issues at the point of care. Communications and behaviours need to be reinforced to facilitate this and patients should be informed at first point of contact that it is the policy of the organisation that raising concerns about their care will not negatively affect their care or their experience while under care and they should be reassured as necessary throughout their treatment that this is the case.
R4.6 Healthcare organisations must ensure that there is a named lead person who will liaise with patient advocates, service-user representatives, patients and families. This person would be an identified point for patients to provide feedback in relation to their care. Feedback needs to be provided to service-users so that they can see that their views are being taken seriously.

R4.7 Opportunities must be provided for service-users to contribute to the education of future healthcare professionals and to the continuing professional development of existing practitioners.

R4.8 Provision should be made for patient and family involvement in research activities such as measuring patient contribution to bad outcomes, factors that rescue patients from provider error, and factors that mitigate the harm caused by errors.

R4.9 Patients should be offered full access to information relating to their care, including correspondence between healthcare professionals.

R4.10 Patient engagement should be advanced as a recognised patient safety solution. Amongst other things, this will enable a better understanding of what patients and families want in relation to disclosure and learning from adverse events and the development of an appropriate communications process to deal with such events.

R4.11 In relation to complaints handling, patients and carers should have a clear understanding of the procedures and processes involved. Patient involvement in the design of standards and implementation processes is crucial to transparency and effectiveness.

Knowledgeable patients

R4.12 A public information service should be developed by HIQA and the HSE which makes information readily available to patients and their carers about maintaining their health and dealing with illness. Such a system should signpost paths through the healthcare system and guide patients in accessing the care that is most appropriate to them, indicate how to raise any concerns they might have in relation to their treatment and care, and support effective development and access to health literacy information and support networks. It should also provide information in relation to medication, alternative non-medicinal therapies and the safe use of medicinal products.
R4.13 Specific programmes should be developed by the HSE aimed at supporting patients with chronic conditions, helping them to understand and manage their conditions and to participate in decision-making regarding their clinical management.

R4.14 All public information should be easily accessible, available in a variety of formats and media and culturally and socially appropriate; it should enable use of advocacy and interpretation services as appropriate. The information should be quality assured and readily identifiable as being from an authoritative and standardised source.

R4.15 All health policies and plans developed by the Department of Health and Children, the HSE and HIQA should be required to contain a statement on how patients, carers and service-users were involved in the development of the policy.

Open communication with patients following an adverse event

R4.16 National standards for open disclosure of adverse events to patients should be developed and implemented.

R4.17 Legislation should be enacted to provide legal protection/privilege for open disclosure. Such legislation should ensure that open disclosure, which is undertaken in good faith in compliance with national standards developed in accordance with the recommendation above, cannot be used in litigation against the person making the disclosure.

R4.18 Open communication principles, policies and standards should be included in the education curricula of all healthcare professionals and embedded in codes of professional practice.

R4.19 Specific training and support should be provided on open communication for all healthcare professionals.

R4.20 Mechanisms should be developed to monitor, evaluate and review the implementation of disclosure standards through patient feedback on the content and quality of the disclosure process as experienced by them.
R4.21 Research should be undertaken into the impact of adverse events on patients and their families and the findings of such research should be integrated into continuing professional development and ongoing education programmes for all healthcare professionals.

R4.22 Support and counselling programmes should be offered to patients and families in the aftermath of an adverse event.

R4.23 Healthcare facilities should ensure as far as possible that the patient has the support of an advocate at the time of disclosure of an adverse event.

R4.24 Training and support mechanisms should be developed and provided for patient advocates.

R4.25 As part of the implementation of this Report, a group should be established to lead and ensure the effective implementation of the recommendations in Chapter Four.

Chapter Five – Leadership and Accountability

Leadership

R5.1 Key leadership roles must be assigned to designated professionals and agencies at national level for the purpose of providing strong clinical leadership to the system in the area of patient safety and quality. This should be achieved by strengthening existing senior professional roles within the system, such as that of the Chief Medical Officer and the Chief Nursing Officer within the Department of Health and Children and/or the creation of new leadership roles within existing agencies such as HIQA and the HSE. Such leadership roles must include advocacy for safety and quality, the development and dissemination of patient safety knowledge and learning and the promotion of good practice.

R5.2 Universities/Higher Education Institutes, in conjunction with postgraduate training bodies, must design versatile suites of multi-disciplinary education programmes at Diploma, Masters and Doctoral level in Healthcare Leadership.
Accountability

The Commission is of the view that patient safety and quality of care must become core principles in healthcare and recommends the following:

R5.3 Nationally agreed standards of governance must be developed as part of a licensing system. All healthcare organisations must have in place a governance framework which clearly describes responsibilities, delegated levels of authority, reporting relationships and accountability within the organisation. In particular, there must be clear assignment and documentation of responsibility within and between clinical teams involved in the care of individual patients. The governance framework should also include a code of conduct and behaviour for all healthcare workers which should be published and publicly made known to service-users in healthcare facilities through awareness measures such as notice boards, posters, etc.

R5.4 Professional regulatory codes of conduct (clinical and managerial) must prioritise patient safety as the primary duty of all healthcare professionals.

R5.5 Organisational codes of governance must be implemented which clearly identify safety and quality as a core objective and which specify the processes by which these objectives will be achieved. Organisational performance in these areas should be monitored, through, for example, the setting of specific organisational performance indicators and targets in the area of safety and quality and the requirement for regular reports via internal and external accountability mechanisms on delivery against those targets. Patients should be provided with an accessible opportunity to contribute to such accountability mechanisms.

R5.6 There should be a clear system of accountability throughout each healthcare organisation which connects all those with responsibility for patient safety at each level in the organisation through to the Chief Executive of each facility. This reporting relationship should, where appropriate, continue through regional and national levels to the main Board of the organisation.

R5.7 The Chief Executive within each defined healthcare organisation must be ultimately responsible and accountable for patient safety and quality within that organisation.

R5.8 A system of clinical directorates must be implemented within all healthcare organisations which should ensure that the clinical director, appointed on a competency basis, would lead and be accountable for all aspects of patient safety and quality of care within the directorate.
At all times during an episode of care, it should be clearly identified and documented who is the responsible clinician accountable for the patient. The patient, and the patient’s relatives or carers, should be informed and be able to discuss his/her care with that clinician. Where a patient moves into a different clinical environment, and the responsible clinician changes for a period of his/her care, there should be a formal handover of information and accountability for the overall care of that patient. This change should be made explicit and be documented, and the patient, along with his/her relatives or carer, should be informed.

Safety and quality assurance requirements must be integrated as part of individual and service level contractual agreements.

Management and reporting structures

The Commission recognises that the governance structures which will be required of hospitals and other healthcare facilities, to fulfil the licensing requirements proposed in Chapter Six of this Report, may vary depending on the nature and extent of the services being provided. As a minimum the Commission recommends the following:

A Board of Management should be established close to the point of delivery of service to govern the activities of a facility or a networked group of facilities. It should have a code of governance which sets out its role and responsibilities including an oversight role in respect of the safety and quality of health services provided at the facility.

The Board of Management of each facility must include representatives of the medical, nursing and other professions involved in the provision of services at the facility and lay people who would represent the interests of patients, carers and the public.

The Chief Executive, or equivalent, of an organisation must report to the Board of Management on patient safety and quality of care. Where the organisation is part of the HSE, its Chief Executive will also report to the Chief Executive of the HSE.
R5.14 A senior Clinical Leader at Clinical Director level, or equivalent, should be formally appointed and have delegated responsibility and accountability for patient safety and quality throughout the organisation. He/she must report to the Board on all aspects of safety and quality including the facility’s compliance with mandatory standards on medical and nursing services, infection prevention and control, medication safety and systems of audit including clinical audit.

R5.15 The Board of Management of a facility should meet at least once a month and at any other time when called upon by a majority of its members or the licensing authority to meet and deal with any significant issue of patient safety arising at the facility.

R5.16 The Board must review, on a regular basis, the systems of governance, including risk management and audit, relating to healthcare safety, quality and performance. This should include:

- the delivery of clinical services including clinical audit activities
- mandatory standards and key performance indicators applicable to the services provided by the facility including hygiene and infection prevention and control
- policies, procedures and behaviours relating to communications with patients and their families
- adverse events, complaints, claims and near-misses
- information on waiting times across key service areas
- financial and budgetary management aligned to the provision of safe, high quality care.

The patient experience of the quality of care provided has to be ascertained as part of this review process.

R5.17 As part of the licensing framework, a clear legal duty should be imposed on the Board of Management of each facility or group of facilities to put and keep in place arrangements for the purpose of monitoring and improving the safety and quality of healthcare. A similar statutory duty should be placed on the Chief Executive and Board of the HSE to ensure that all the Boards under its remit are complying with these requirements.
Education, training and research on patient safety

**R5.18** All healthcare facilities must provide pre-employment mandatory induction training for all healthcare workers that specifically includes patient safety modules (including the reporting of adverse events). Refresher patient safety training should be provided on a regular basis.

**R5.19** There should be a strong emphasis on safety and quality in the training and education of healthcare professionals. All bodies responsible for the training and continuing development of healthcare professionals should review their curricula to ensure that patient safety and quality, including technical and human factors, is incorporated into the modules.

**R5.20** There should be an active research programme on patient safety and quality issues in healthcare for Ireland.

**R5.21** Education and training suites and modules on patient safety should be developed and implemented in collaboration with the professional regulatory and training bodies and relevant stakeholders at undergraduate and postgraduate levels for all healthcare workers.

**R5.22** The development and implementation of Competence Assurance Schemes by professional regulatory and training bodies should integrate patient safety education and training modules as part of their core elements.

**R5.23** Consideration should be given by the professional regulatory bodies to the development of a means by which patients may be enabled to access information relating to the maintenance of professional competencies by healthcare professionals.

Skilled professionals in management

**R5.24** A specific vocational management training programme should be developed which is aimed not only at producing high quality managers but also at enhancing the management capability of healthcare professionals at all levels of the health system; this programme should also include specific modules on patient safety and quality of care.
R5.25 The competencies required for health service management should be clearly identified and the management team, up to and including the Chief Executive, should demonstrate competence-based training and be subject to ethical and disciplinary codes similar to other healthcare professionals.

R5.26 Appropriate training, coaching and mentoring supports must be provided to develop the managerial skills, change management skills and competencies required for clinicians with managerial responsibilities.

R5.27 Healthcare organisations should put in place human resource processes and strategies which ensure that all professionals employed in the organisation are fully compliant with continuing professional development requirements.

Chapter Six – Organisational and Professional Regulatory Framework

Standards and licensing

R6.1 There should be a mandatory licensing system in Ireland to cover both public and private healthcare providers. It must be an equitable and transparent system, with a review of the licences every three years. It will apply to existing and new bodies, with time being given for compliance.

R6.2 The Mental Health Commission which currently undertakes mandatory inspection of public and private mental health facilities should continue to operate this registration system until the licensing framework has commenced, at which time consideration should be given to whether and how both systems might be appropriately integrated.

R6.3 There should be a licence for hospitals/hospital groups/other healthcare facilities and also service-specific licences within the hospital or facility e.g. radiotherapy, intensive care.
R6.4 The licensing system should commence with application to the acute hospitals and other facilities based on analysis of potential risk to patient safety. This list should include facilities where the following treatments are provided:

- medical treatment under anaesthesia or sedation
- dental treatment under general anaesthesia
- obstetric services
- cosmetic surgery
- techniques and technologies such as laser and intensepulse light therapy, hyperbaric oxygen chambers, private dialysis, *In Vitro* Fertilisation and endoscopies and any others to be prescribed by the Minister for Health and Children.

R6.5 Following the introduction of the licensing framework in the sectors listed above, the licensing system should subsequently be rolled out to other facilities such as primary community and continuing care, following comprehensive consultation with relevant stakeholders in those sectors.

R6.6 Licensing should be linked to compliance with stated standards, enforceable through inspection and imposition of sanctions if necessary. The sanctions should range from warnings, with time limits for compliance, up to withdrawal of licence either for a specific service within the hospital or the hospital itself if required.

R6.7 The licensing system should be self-financing, with a licence fee to be paid according to the size of the facility/number of beds etc.

R6.8 The licensing function should be assigned to HIQA with a provision in legislation requiring it to carry out this function in a manner independent from its other functions so that those responsible for deciding on licence applications do not have any role in the setting or monitoring of healthcare standards to apply to such licences.
In advance of the introduction of legislation providing for licensing, HIQA should progress urgently the development of standards on safety and quality to be applied to hospitals and all future licensed healthcare facilities. HIQA should also be asked to commence work immediately on standards in respect of any area where a high and immediate risk to the health and/or welfare of patients or the public is identified. Subject to current legal provisions, arrangements should be put in place by which private healthcare providers would voluntarily adhere to such standards, agree to be monitored and the resulting reports published. Private health insurers should require all private healthcare facilities to adhere to the standards set by HIQA where such standards exist.

The licensing authority should work with other regulators across health and social care to ensure that, when other regulators are licensing a service within the same facility, the licensing authority and respective regulator(s) work together to co-ordinate the most effective system to reduce the burden of inspection on the provider and to enhance safety and quality for the users of the service.

The regulations that determine the criteria for obtaining a licence should include the following (not an exhaustive list):

- effective governance and management arrangements
- protocols for the transfer of patients to and from other healthcare providers so as to ensure a safe and seamless patient journey
- risk management systems in place
- participation in audit and adverse event reporting systems
- participation in recognised systems of continuous quality improvement e.g. accreditation
- appropriately trained and competent staff
- implementation of evidence-based practice
- participation in continuing medical education (CME) and competency re-validation programmes
- mechanisms for patient participation and feedback
- information management
- meeting health and safety standards
- appropriate structure, equipment and service design.

Applications for a licence must demonstrate compliance with specified core standards in order to be given approval in principle. This will be followed by an assessment (including inspection) by the licensing body which in turn will lead to the granting of a licence.
R6.13 The operation of the licensing process should be reviewed through quantitative and qualitative methodology after three years.

R6.14 The impact of licensing on patient safety and quality in healthcare in Ireland should be reviewed through quantitative and qualitative methodology after three years of operation.

### Regulation of healthcare professionals

R6.15 As part of the implementation of the recommendations in this Report, a group should be established through which the professional regulatory bodies will collaborate on areas of common interest, such as developing a shared understanding of the professional standards that are common to each body and supporting education and training appropriate to the different professionals operating in multi-disciplinary teams.

R6.16 The Group will develop plans for a first point of contact for patient concerns in relation to clinical care, with referral to appropriate regulatory bodies as necessary.

R6.17 The Group will propose the means by which the initial investigation of complaints by the professional regulatory bodies can be managed using a common framework as appropriate and an audit of cases to assure performance in this regard.

R6.18 The Group will review current Fitness to Practise processes across the different professional regulatory bodies in order to develop plans to achieve greater separation between the investigation and adjudication functions performed by the professional regulatory bodies, and in order to devise means by which Fitness to Practise panels can be independently appointed and trained.

R6.19 Healthcare providers not currently covered by any of the regulatory bodies should be identified and included within the existing allied healthcare professionals group. Other non-medically trained practitioners in alternative medicine whose treatments may be unsafe or potentially hazardous to patients should be considered by the Department of Health and Children for some type of regulation.
Credentialing

R6.20 As part of the implementation plan proposed in Chapter Eight, a group should be established to collaborate on the scope, design and implementation of a credentialing system. This system should be commenced on a pilot basis as soon as possible and reviewed after two years with a view to the introduction of legislation to give it statutory effect and universal application in due course to all regulated professionals.

R6.21 The Group should consider the means by which Ireland could proactively participate in an EU-wide credentialing system.

R6.22 The Group should also report on the ways in which a credentialing database could potentially be used as part of a privileging system for healthcare professionals. This should be done in collaboration with the postgraduate training bodies who are best placed to advise on the competency of those who have completed specialist training.

R6.23 The Group should plan a system of alert notices to be established for the exchange of notices between healthcare employers both within Ireland and between Ireland and adjacent jurisdictions in respect of healthcare professionals for whom patient safety issues have arisen.

R6.24 Healthcare employers should only employ in consultant posts medical practitioners who are registered on the Specialist Register in the Medical Council.

Chapter Seven – Quality Improvement and Learning Systems

Evidence-based practice

R7.1 A leadership role in relation to the analysis of international evidence and research, and to the production of evidence-based information and guidance for use in policy-making, system reform, and individual patient and professional interactions should be developed.
R7.2 A rolling programme should be developed by the Department of Health and Children, HIQA and the HSE to deliver evidence-based service frameworks covering the major health conditions within the public healthcare system, similar to the National Service Frameworks model in the UK. Such frameworks should be reviewed periodically to encompass new evidence on effectiveness and performance.

R7.3 A substantial strand in publicly funded health research strategies, focusing on patient safety and quality, should be developed by the Health Research Board.

R7.4 Evidence-based national standards should be developed, with multi-disciplinary input, in both primary and secondary care settings, and for the transition between care settings.

Clinical audit

R7.5 All clinicians, both as individuals and as members of teams or networks, must actively participate in clinical audit in compliance with national standards and priorities.

R7.6 As part of the licensing process recommended in this Report, all licensed healthcare facilities must demonstrate active participation in local and national clinical audit as appropriate to their services.

R7.7 Clinical audit should be considered within an integrated safety and quality governance framework and should be linked to service plans and to local, national and professional priorities. An integrated governance framework for primary care teams should include audit of access, process, quality and outcomes for patients.

R7.8 Every healthcare facility should develop and implement an Annual Clinical Audit Forward Plan as part of its annual planning and delivery cycle for clinical audit activities and the facility’s safety and quality governance framework. This Plan should reflect the national, organisational, team and individual audit requirements on the facility. It should be the responsibility of the Clinical Leader, with accountability for safety and quality at Board level, to ensure that the Plan is developed and implemented with effective clinical engagement and reported to the Board of the facility.

R7.9 Clinical audit data should be risk-adjusted and clinician-validated.
### Building a Culture of Patient Safety

<table>
<thead>
<tr>
<th>R7.10</th>
<th>As part of the implementation of this Report, a group should be established to develop national programmes of and standards for clinical and other forms of audit which support the safety and quality of health services and are linked to national health priorities.</th>
</tr>
</thead>
<tbody>
<tr>
<td>R7.11</td>
<td>Legislation should be enacted to give exemption from Freedom of Information legislation and to grant legal protection from disclosure to data related to patient safety and quality improvement that are collected and analysed by healthcare organisations for internal use or shared with others solely for purposes of improving safety and quality.</td>
</tr>
<tr>
<td>R7.12</td>
<td>If clinical audit is to be granted any such exemption or legal privilege, organisations or clinicians who participate in clinical audit must publish aggregated information about clinical audit.</td>
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<tr>
<td>R7.13</td>
<td>Such legislation must include routes to refer to appropriate professional regulatory bodies where there is evidence that there are serious and continued variations in performance from agreed standards of care.</td>
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<tr>
<td>R7.14</td>
<td>Such legislation must also include the obligation to refer to other legal authorities such as An Garda Síochána where there is evidence that a serious offence has been committed.</td>
</tr>
<tr>
<td>R7.15</td>
<td>Adequate administrative and IT supports must be allocated to ensure the implementation of these recommendations across all health sectors. In particular, support systems must be established in primary care to encourage, educate, assist and support general practitioners and other healthcare providers to participate in audit.</td>
</tr>
<tr>
<td>R7.16</td>
<td>Clinical audit should be integrated into all healthcare professional education and training curricula.</td>
</tr>
<tr>
<td>R7.17</td>
<td>Research should be undertaken into appropriate audit systems, especially in those areas not already subject to audit.</td>
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</table>
Confidential enquiries

R7.18 The Department of Health and Children should seek to negotiate the participation of Ireland in the three Confidential Enquiries in operation in the United Kingdom, namely the Confidential Enquiry into Maternal and Child Health (CEMACH), the National Confidential Enquiry into Patient Outcome and Death (NCEPOD) and the National Confidential Inquiry into Suicide and Homicide by People with Mental Illness (NCISH) as well as any future such enquiries.

Reporting, managing and learning from adverse events

R7.19 The WHO standardised taxonomy, which describes definitions of adverse events, should be adopted on a national basis.

R7.20 Standards should be developed for adverse event reporting across both public and private healthcare providers.

R7.21 A national mandatory reporting system should be introduced for the collection of standardised information on adverse events that result in death or serious harm. The system must clearly delineate the events which must be reported, such as those listed in the National Quality Forum’s 28 Never Events, but should not be confined to those events. The system should include provision for the voluntary reporting of other non-serious adverse events and ‘near-misses’.

R7.22 In order to be effective, the collection and dissemination of this information must be the responsibility of a national agency that can provide national leadership on learning from errors. The agency should provide analysis and feedback in order to ensure that lessons are learned and models of best practice are implemented effectively.

R7.23 Effective governance arrangements should be put in place to ensure that the Clinical Leaders responsible for safety and quality in healthcare facilities, and other relevant individuals, should exchange learning and improvements resulting from adverse events and near-misses at regional and national levels. Where these are employees of facilities within the Health Service Executive, these arrangements should connect seamlessly into the HSE’s corporate governance arrangements.
R7.24 A group should be established to collaborate and report on the detailed implementation of these recommendations and in particular the most appropriate repository for the maintenance of such a comprehensive database and the dissemination of learning throughout the system including the facilitation of rapid alerts as necessary.

R7.25 The national reporting system should be compatible with and capture data from all existing incident reporting systems, or may replace local systems. The information collected in this database should inform all safety and quality initiatives, policies and clinical protocols.

R7.26 Every healthcare facility must have a serious adverse event policy which is immediately triggered when a serious adverse event takes place. The Group needs to consider the reporting arrangements and timeframe for reporting such events into the proposed national system.

R7.27 Every healthcare facility should ensure that, as part of its safety and quality governance arrangements, the reporting, investigating, monitoring, learning and management of adverse events and near-misses is discharged effectively and reported to the Board of the facility.

R7.28 Professional regulatory bodies should include mandatory reporting as an ethical obligation within their Codes of Professional Practice.

R7.29 Professional regulatory bodies should collaborate to develop clear guidelines for health professionals in relation to reporting of adverse events and unsafe practices.

R7.30 The design of the reporting system must also facilitate patient and family reporting of adverse events, and patients should be advised accordingly.

R7.31 Aggregated validated data should be made available to the public in the form of annual reports.

R7.32 Information collected under the reporting system (both mandatory and voluntary) must be strictly confidential, protected from legal discovery and exempted from Freedom of Information legislation.
R7.33 Such legislation must require disclosure to appropriate professional regulatory bodies where there is evidence of significant deviation from agreed standards of care. If a criminal act has taken place, the appropriate legal authorities must be notified.

R7.34 There must be adequate administrative and IT resources in place to support the reporting system.

R7.35 Education and training supports in relation to reporting systems, including the development of appropriate skills for dealing with adverse events, must be provided at all levels of the health system, from undergraduate and postgraduate education to continuing professional development programmes.

R7.36 There should be continued research on the impact of adverse events on healthcare workers, the results of which must be integrated into continuing professional development and ongoing education programmes. This research will be complementary to that recommended in R4.21 in Chapter Four on the impact of adverse events on patients and their families.

Medication safety

R7.37 There should be national analysis of the problems and potential solutions to the issues surrounding unlicensed medicines and medicine shortages by the Irish Medicines Board (IMB), the Irish Pharmaceutical Healthcare Association (IPHA) and other key stakeholders such as the Health Service Executive (HSE).

R7.38 The powers of the IMB should be enhanced to ensure that all medicinal products, herbal, homeopathic and traditional remedies undergo rigorous control of safety, quality and efficacy, both at the licensing stage and post-marketing.

R7.39 The licensing requirements of the IMB should include risk assessments of the medicinal product in use, in order to identify risks in prescribing, dispensing, administration in primary and secondary care and patient evaluation of the information in patient information leaflets (currently included in requirements), packaging and labelling. Risks identified should be minimised and user testing repeated to ensure risk reduction is brought to an acceptable level.
R7.40 Problems identified with products on the market through emergence of medication errors where product name, labelling and packaging were contributory factors should be monitored, collated and result in rapid changes where appropriate. Communication, coordination and cooperation between all agencies involved will be necessary.

R7.41 Communication structures between all bodies with a stake in the medication use process or in medication safety should be clearly established e.g. the IMB, pharmaceutical companies, professional societies and regulatory bodies and the CIS. There should be linkages between the pharmaceutical industry and the IMB to ensure that safety issues identified which may be improved by changes to pharmaceutical products (e.g. packaging, labelling, patient information) are acted upon as a matter of urgency. Linkages with all professional bodies are needed to ensure that safety messages are being promoted through professional channels as well as by the safety body.

R7.42 As part of the safety and quality governance framework, healthcare organisations must prioritise the implementation of formal medication reconciliation systems. This would include regular tracking audits and the deployment of suitable resources for this purpose.

Appropriate environment/setting

R7.43 Having regard to the need to balance accessibility, safety and effectiveness, care should ideally be delivered as close as possible to where the patient lives. Standards should be set for built healthcare environments in the State, in public, private and voluntary health and social care facilities, and those standards should be governed by considerations of safety and quality.

R7.44 The Department of Health and Children should commission an independent report on the principles and implementation of evidence-based design of healthcare facilities for the Irish health system.
Health information and health information technology (HIT)

R7.45 The National Health Information Strategy (NHIS) which was published in 2004 and is still not fully implemented should be reviewed in order to clarify the roles and responsibilities of the Department of Health and Children, the HSE and HIQA and the recently established Health Information Inter-Agency Group should ensure that these key bodies work together to progress the implementation of the Strategy as quickly as possible.

R7.46 The planning of health information and HIT developments should be an integral part of the planning of health service developments to ensure that the full potential of health information and HIT to improve patient safety is realised. This should be driven by a patient-centred approach, with full clinical engagement learning systems design, in order to enable the delivery of health services to the patient in whatever setting.

R7.47 The underlying information communication technology (ICT) infrastructure, and applications within all aspects of healthcare, should be recognised as the foundation for all patient-centred systems. The infrastructure should therefore be seen as a key enabler of patient safety and quality and ICT infrastructure standards should be set at a national level to ensure good levels of reliability, performance, security and interoperability.

R7.48 All healthcare ICT projects, including those driven within the HSE, should formally consider the impact that the information system(s) will have on the patient journey, to include safety, quality and benefits to be realised, and should be planned and implemented in the context of the overall National Health Information Strategy.

R7.49 Immediate development priorities in health information and HIT in areas of high risk, from a patient safety perspective, should be identified and implemented rapidly in order to create engagement across the relevant stakeholders and continue to build the momentum of improved patient safety and quality through health information and HIT.

R7.50 Rapid progress must be made on the development and implementation of a unique identifier for the health system.
R7.51 There must be a standards-based approach to HIT developments that will be led by HIQA. These standards should apply in areas such as clinical terms, coding and classification as well as messaging and electronic health record. Such standards are necessary requirements for the effective interoperability of HIT systems, i.e. the ability to share information that has a consistently understood meaning and interpretation wherever and by whomever it is accessed, and this approach will enable reliability, performance, security and interoperability.

R7.52 The health system must commit itself to the full implementation of an appropriate standards-based electronic health record, with appropriate sharing of information within and between providers so that critical information about the care of patients is available at the point of care. This should include the sharing of critical clinical information between the public and private sectors.

R7.53 An effective information governance framework, and underpinning legislation, should be developed and implemented across the health system. This should include the requirement of providers to implement clear plans and the allocation of responsibility that forms the basis of business rules governing how health information is exchanged and utilised.

R7.54 The NHIS review should consider the ICT requirements, skills and tools necessary to support healthcare professionals in implementing the recommendations in this Report.

R7.55 A managed approach to health surveillance which includes patient safety data should be developed across Ireland. This should involve the coherent collation, interpretation, learning and dissemination of sources of information from across the system, including information from the national mandatory reporting system for adverse events.
Chapter Eight – Conclusion and Implementation

R8.1 The drafting of all the legislative changes necessary to implement the recommendations of this Report should begin as soon as possible.

R8.2 An Implementation Steering Group (ISG), with a clear reporting relationship to the Minister for Health and Children, should be established to oversee the implementation of all the recommendations in this Report.

R8.3 A number of specialised sub-groups should be established comprising service providers, regulators, education and training bodies, indemnity providers and patient advocacy representatives. These sub-groups should have clear and regular reporting relationships to the ISG.
Chapter Two

Setting the Scene

2.1 Background to the Commission on Patient Safety and Quality Assurance

Recent decades have seen an improvement in our understanding of the effectiveness of healthcare in improving patient outcomes; however, there is also growing recognition that the healthcare that patients receive is not always consistent with this evidence, and so fails to secure the best possible outcomes. A number of international studies have highlighted the burden of injury caused by adverse events in health and social care settings, with significant impact on patients, their families and the health system, and many countries have experienced high profile adverse events that have highlighted failings in healthcare delivery. Public expectation of high performing services is legitimately developing and people are increasingly empowered to demand safe, high quality healthcare. As a result of these trends, improving the safety and assuring the quality of healthcare has emerged in recent years as a key challenge facing health systems internationally.

This is a challenge that has been recognised in the Irish health system. A number of high profile adverse events have resulted in inquiries and reports which have placed patient safety and quality high on the policy agenda in Ireland. Similar inquiries have been undertaken in other countries arising from significant system, management and clinical failures. All of these reports have proposed new organisational arrangements to improve clinical quality incorporating national standards, comprehensive adverse event reporting, clinical audit, accountability of senior clinicians, performance monitoring and clinical governance. The reports have proposed the promotion of a no-blame learning and questioning culture, executive leadership to promote quality, staff involvement and partnership with patients. The findings of these reports are summarised later in this chapter.

The most recent reports in Ireland relating to the misdiagnosis of cancer have highlighted yet again similar weaknesses and in particular also point strongly to poor management, governance and communications especially in circumstances where a serious adverse event takes place.

There are already a number of local and national initiatives underway to address some of these issues. However, the failures in the healthcare system identified by these reports demand a system-wide response to address healthcare quality and healthcare outcomes. In recognition of this, the Commission on Patient Safety and Quality Assurance was established by the Minister for Health and Children in January 2007.

There is a clear national and international imperative for policy development in the area of patient safety and quality in healthcare, and the Commission has been charged with developing proposals for the Irish health system. The current context of the health system in Ireland and existing initiatives in patient safety and quality provide a platform for the necessary change arising from these proposals. Given this context, the Commission must determine where the health system in Ireland should be with regard to patient safety and quality, and how it should get there.
This is a challenge that has been faced in other jurisdictions. The path of health system reform is dependent on the history of the system’s development and its current structure and function. This context is unique to each health system, and no single system can provide a blueprint for the development of policy proposals in Ireland. However, a review of how the challenge of patient safety and quality in healthcare has been met in other jurisdictions can offer much to the necessary debate that will form the basis of the Commission’s proposals.

2.2 Work of the Commission

The Commission met 20 times between 2007 and 2008. The Commission membership is made up of medical, nursing, management and patient representatives.

Secretariat to the Commission was provided by the Patient Safety and Quality Unit of the Department of Health and Children.

The Commission undertook a public consultation exercise between September and November 2007 which requested written submissions from the public and interested stakeholders. In excess of 50 written submissions (see Appendix D for list of those who made submissions) were received and the contents were used to inform this Report.

The Commission also convened four sub-groups from within its membership to provide further, detailed input and research on various aspects of the Report. These sub-groups were supported by the following researchers:

Ms Hilary Coates, Head of Safety and Learning, HIQA
Ms Debbie Dunne, Clinical Risk Adviser, Clinical Indemnity Scheme
Dr Paul Kavanagh, Specialist Registrar in Public Health Medicine, DoHC/HSE
Ms Ciara Kirke, Drug Safety Co-ordinator, Adelaide and Meath Hospital, Dublin incorporating the National Children’s Hospital, Tallaght, Dublin 24
Dr Deirdre Mulholland, Specialist Registrar in Public Health Medicine, DoHC/HSE,
Dr Aidan O’Hora, Specialist Registrar in Public Health Medicine, DoHC/HSE
Dr Aidan Ryan, Specialist Registrar in Public Health Medicine, DoHC/HSE

The research undertaken on behalf of the Commission analysed a number of different jurisdictions in relation to various aspects of the Terms of Reference. The findings of this research are integrated throughout this Report where relevant. Although no one health system provides a perfect template for the Irish context, there are undoubtedly lessons that we can learn from the experiences of other jurisdictions in terms of what works and what does not work in this area.

2.3 Evolution of patient safety as a global health policy issue

Around the world, health systems have become increasingly concerned about the need to improve the quality of care provided to service-users including the safety, effectiveness, appropriateness, access, efficiency and acceptability of that care.
Building a Culture of Patient Safety

The evolution of patient safety as a health policy issue arose from the release of a number of seminal reports internationally, particularly the *Quality in Australian Healthcare Study* (1995) and the *To Err is Human* report (2000) from the Institute of Medicine (IOM) in the United States. The Institute of Medicine estimated that at least 44,000 people, and perhaps as many as 98,000 people in the US, die in hospitals each year as a result of medical errors that could have been prevented.

Studies of adverse events in the United States, Australia, the United Kingdom and Canada have indicated that between 4% and 16% of patients admitted to hospital experience one or more adverse events, of which up to half are preventable. Errors are not only costly in terms of human suffering and mortality; they also result in loss of trust in the healthcare system by patients and diminished satisfaction by both patients and health professionals. Adverse events are also very costly in financial terms on healthcare systems. Adverse events were estimated in 1999 to result in total costs (including the expense of additional care necessitated by the errors, lost income and household productivity, and disability) of between $17 billion and $29 billion per year in hospitals in the US.

Understanding why preventable adverse events occur is key to devising strategies by which they can be addressed and minimised. *‘To Err is Human’* concluded that the majority of medical errors did not result from individual recklessness or the actions of a particular group, i.e. it was not a ‘bad apple’ problem, but that errors are caused by faulty systems, processes and conditions that lead people to make mistakes or fail to prevent them. Thus, the report concluded that mistakes can best be prevented by designing a health system that at all levels is safer, making it harder for people to do something wrong and easier for them to do it right. This ‘systems’ view of patient safety is now widely accepted internationally and mirrors the approach taken in many other major risk industries such as the aviation industry.

The IOM report recommended a tiered approach:

- establishing a national focus to create leadership, research, tools and protocols to enhance the knowledge base about safety
- identifying and learning from errors through immediate and strong mandatory reporting efforts, as well as the encouragement of voluntary efforts, both with the aim of making sure the system continues to be made safer for patients
- raising standards and expectations for improvements in safety through the actions of oversight organisations, group purchasers and professional groups
- creating safety systems inside healthcare organisations through the implementation of safe practices at the delivery level.

These seminal patient safety reports, together with high profile reports in the media of deaths caused by health system error, consumer demand and political pressure have prompted the development of national patient safety and quality policies in a number of countries, particularly the United Kingdom, the United States, Australia and Canada. The publication of *‘An Organisation with a Memory’* in the UK in 2000 is a key example. These
strategies recognise that adverse events cannot be eliminated from modern patient care, but assert that healthcare systems can be designed that learn from the mistakes of the past and minimise the risk of such events happening in the future. They provide plans and direction for policy-makers, healthcare leaders, clinicians and regulators regarding system changes necessary to improve patient safety practices, to create cultures of patient safety, and to support research, knowledge generation and translation around patient safety practices.

The international literature reports that the most common adverse events in healthcare can be classed into similar types of event categories.

The most common adverse events are reported as those:
- due to medication events
- due to hospital-acquired infections
- due to surgical complications
- related to falls.

In 2004 the World Health Organisation (WHO) established a World Alliance for Patient Safety whose remit is to raise awareness and political commitment to improving the safety of care and facilitate the development of patient safety policies and practices in all WHO member states. Each year, the Alliance delivers a number of programmes covering systemic and technical aspects to improve patient safety around the world e.g. programmes on clean care practices and safe surgery.

Adverse medication events

Among the most common adverse events reported internationally are adverse medication events. Adverse medication events or medication errors can be described as preventable mistakes in prescribing and delivering medication to patients such as prescribing two or more drugs whose interaction is known to produce side effects, or prescribing a drug to which the patient is known to be allergic.

A study by the Agency for Healthcare Research and Quality (AHRQ) in the United States found that adverse medication events caused one out of five injuries or deaths per year to patients in the hospitals that were studied (Leape, Laird N, et al, 1991).

Much research is being carried out internationally to characterise preventable adverse drug events and to develop methods to prevent them. The Prescription for Change series, published in the US in 2000 (Clinical Initiatives Centre, 2000), evaluated the efficacy and cost of practices to improve medication safety in the hospital setting. The most effective, least expensive strategies are pharmacy-managed protocols and pharmacist interview (admission history taking or checking by a pharmacist), dispensing protocols (involving double checks at nearly all points in process), dedicated observers (observational studies to check accuracy of administration) and pharmacist order entry. At greater expense, recommended strategies are: computerised prescribing, code reconciliation (medication scanned against prescription), automated dispensing systems (pharmacy robots dispense medication).
Health Care Associated Infections (HCAIs)

Infections acquired during healthcare present many of the characteristics of a major patient safety problem i.e. it has multiple causes relating to both the systems and the processes of care provision as well as to behavioural practices. There is evidence that some HCAIs are avoidable but all are costly to the health service and to patients. At any time over 1.4 million people are suffering worldwide from infections acquired in hospital. Between 5% and 10% of patients admitted to modern hospitals in the developed world acquire one or more infections (World Alliance for Patient Safety 2005).

In the United States, one out of every 136 hospital patients becomes seriously ill as a result of acquiring an infection in hospital; this is equivalent to two million cases and about 80,000 deaths a year. In England, more than 100,000 cases of healthcare-associated infection lead to over 5,000 deaths directly attributed to infection each year (World Alliance for Patient Safety 2005).

The prevalence of HCAIs in acute-hospital patients reported in studies conducted in European countries since 1990 suggest a HCAI prevalence of around 3.5% to 9.0% although the HCAI case definitions used varied and the accuracy and validity of the data collection is unknown.

Surgical adverse events

Surgical care and its safe delivery affect the lives of millions of people. About 234 million major operations are performed worldwide every year (World Alliance for Patient Safety 2008). The change in disease patterns worldwide is increasing the need for surgical services considerably. Ensuring better access to surgical care and its safe delivery is crucial for its effectiveness. The available evidence suggests that as many as half of the complications and deaths arising from surgery could be avoided if certain basic standards of care were followed (World Alliance for Patient Safety 2008). Studies suggest that complications following surgery result in disability or prolonged stay in 3% to 25% of hospitalised patients, depending upon the complexity of surgery and the hospital setting (World Alliance for Patient Safety 2008).

Adverse event reporting in Ireland

In Ireland, the electronic incident reporting system of the Clinical Indemnity Scheme (CIS), established in 2004, lists the most common incident types reported annually. In 2007 the common incidents reported were slips/trips and falls (36%) followed by medication incidents (10%), violence, harassment and aggression (8%) and treatment incidents (7%). Infection control incidents made up 6% of the incidents reported to the CIS.

Adverse medication events in Ireland

Irish data on medication error and adverse drug reactions in four hospitals recorded 510 events/near-misses in a three-month period in 2006 (Kirke et al 2007). The most common event/near-miss types were wrong dose, frequency/rate and dose/drug omission, with
monitoring, omission and wrong frequency/rate being the most common categories for adverse drug events i.e. resulting in patient harm. Seven per cent of the reports involved patient harm due to adverse drug reactions or medication error.

A recent Irish publication shows that one third of patients over 65 admitted to Cork University Hospital’s accident and emergency department were on inappropriate medication (Gallagher et al 2008).

Strategies that are considered best practice internationally have been implemented in some hospitals in Ireland. Pharmacist admission history taking and interview is carried out in some hospitals e.g. the Adelaide and Meath Hospital, Dublin incorporating the National Children’s Hospital, Tallaght. HAZMAT protocols are in place in most hospitals for chemotherapy preparation and dispensing. Pharmacist order entry is carried out in some hospitals e.g. the Mater Misericordiae University Hospital.

Health Care Associated Infections (HCAIs) in Ireland

In Ireland healthcare associated infections are an increasingly important issue and cause of concern to healthcare professionals and the general public. Recent media coverage surrounding the extent and spread of meticillin-resistant *Staphylococcus aureus* (MRSA) and *Clostridium difficile* in Ireland is an example of the heightened awareness of HCAIs in this country. Any improvements in preventing and reducing the rates of HCAIs in Irish healthcare settings will lead to better care and reduced healthcare costs.

A survey of adult patients was conducted in February 2006 to May 2006 in acute hospitals across England, Wales, Northern Ireland and the Republic of Ireland, to estimate the prevalence of healthcare-associated infections (Smyth et al 2008). The survey found that HCAI prevalence in the Republic of Ireland was 4.89%, in England was 8.19%, in Wales 6.35%, and in Northern Ireland 5.43%. The most common HCAIs were gastrointestinal (20.6% of all HCAIs), urinary tract (19.9%), surgical site (14.5%), pneumonia (14.1%), skin and soft tissue (10.4%) and primary bloodstream (7.0%). Prevalence of MRSA was 1.15%, with MRSA being the causative organism in 15.8% of all system infections, and prevalence of *Clostridium difficile* was 1.21%.

As part of the HSE strategy for prevention and control of HCAIs launched in March 2007, the Health Protection Surveillance Centre (HPSC) is developing and coordinating the collection and analysis of surveillance data relating to HCAIs and antimicrobial resistance (AMR) for acute public hospitals in Ireland.

At the time of the publication of this Report, HIQA had published draft standards for Infection, Prevention and Control for the Irish health system. These will be mandated when concluded and services providing healthcare will be monitored against these standards through an ongoing programme of review.
2.4 Delivery of Irish health services

Every day in Ireland life-saving, or life-enhancing, services are being delivered by those who work in the health service. In 2007 the public acute hospital services alone dealt with over 600,000 in-patient discharges, over 590,000 day cases, over 1.1 million A&E attendances and over 3 million out-patient attendances. There are also an estimated 17 million consultations with General Practitioners annually.

The HSE has also introduced a range of community services including:

- GP direct access diagnosis. About 30,000 x-rays and ultrasounds were carried out in 2007 under this project.
- Community Intervention Teams. A total of 3,068 referrals were dealt with last year by these teams. They provide an early response to patients, thereby reducing unnecessary referrals to hospitals.
- Expanded GP out-of-hours services. This service dealt with about 830,000 calls last year, an increase of 11%. About 90% of the population is now covered by this service.
- A national information line. This provides information to the public on all matters relating to the health service. There was an increase of 47% last year in such calls, representing over 70,000 calls.

Also, there were 97 primary care teams in development throughout the country last year. These will provide services such as physiotherapy, public health nursing and general practice.

In addition, there were over 8,000 people in receipt of homecare packages. The packages include public health nursing, physiotherapy, occupational therapy and attendance at a day-care centre. Homecare packages are targeted at people who would otherwise be admitted to long-term care or who would be admitted to acute hospitals unnecessarily. They are also targeted at patients who are waiting to be discharged home from hospital. At the end of 2007, there were over 50,000 people benefiting from more than 12 million home-help hours.

There has been an explosion in healthcare knowledge in recent decades, not just in knowledge about specific treatments and procedures but also in systems knowledge about how care should be delivered and how professionals should be trained and organised to work together more effectively and to provide improved patient care.

This increase in healthcare knowledge has presented a number of challenges. It is clear that health professionals can no longer regard themselves as ‘trained’ when they complete professional learning, but must engage in lifelong learning to keep abreast of new developments. Equally important is the need for the healthcare system to meet this challenge by:
ensuring that health professionals are kept informed of relevant best practice
having the appropriate organisational flexibility to respond to new developments
putting the systems in place to monitor and evaluate the care provided so that high quality care in accordance with best practice is assured.

New ways of working and new technologies continue to develop in response to new knowledge and to changes in population health needs. In particular, as the population ages, the number of patients with chronic care needs (e.g. diabetes, cardiovascular disease, cancers, etc) has increased. This increase in chronic care needs requires a reorientation in the way that care is delivered. Internationally it has been shown that these conditions are best treated using a planned systematic approach, with an emphasis on the information and self-management needs of patients. Multi-disciplinary teams involving the full range of professionals from which the patient requires care have been shown to provide better care than the traditional isolated approach. Extensive coordination and communication is required between different disciplines and clinicians across settings and over time during the course of the patient journey.

A culture of highly specialised professionals across a wide range of disciplines has developed in health systems in every country. While specialisation is necessary to create excellence in service delivery it must be accompanied by a recognition that health services are provided by professionals who are dependent on each other to deliver safe, high quality care and treatment to patients. For these patients and their families it is vital to know that the specialists are working together to give the appropriate care and treatment. This means that issues like clinical audit and risk management are the shared responsibility of those who deliver the services.

Equally, the healthcare professionals must recognise that patients and their families have a right to know why specific treatments are being proposed for them so that the patients can, in a positive manner, have some control over their treatment. In recent years the public has become better informed in relation to health matters generally which supports the development of a wider cultural change based on a relationship of trust between the healthcare professional and the patient.

A number of policy documents in recent years, particularly the Primary Care Strategy (2001) and the Acute Hospital Bed Capacity Review (2007), undertaken by the HSE, have indicated the need for a reorientation of Irish healthcare away from a focus on hospital-provided services. The vast majority of healthcare is provided in the primary care and community setting and there is evidence that much of the care currently provided in hospitals would be more appropriately delivered nearer to the patient.

In October 2007 the Department of Health and Children published Health in Ireland: Key Trends 2007. This provides a guide to trends in health and healthcare over the past decade. The following month, the Organisation for Economic Co-operation and Development (OECD) published its Health at a Glance, 2007, an authoritative source of comparable data on health and health systems up to and including 2005 in OECD countries.
Among the key trends which emerge from these publications and other authoritative sources are the following:

- There has been a rapid increase in life expectancy since 1999, unmatched by any other EU country; life expectancy in Ireland exceeded the EU 27 average for the first time in 2002 and is now more than a year above the average, at 79.6 years.
- The percentage of people in Ireland reporting good or very good health is the highest in the EU.
- There have been very significant reductions in mortality from circulatory system disease; specifically, there has been a reduction of 38% since 1997 and a reduction of 50% over the last 30 years. For all major causes of death there have been significant reductions since 1997 and our rates of improvement are about double the average for the EU; this includes reductions in mortality from cancer.
- For breast cancer, the five-year relative survival rate in Ireland is nearly 80% for the period 1999 to 2004 compared to 73% for the period 1994 to 1998, although it is still below the OECD average.
- Infant mortality rates in Ireland have fallen dramatically over the last few decades: the rate is 4 deaths per 1,000 live births in 2005, lower than the OECD average of 5.4; our maternal mortality rates are among the lowest in the world.
- The mortality rate from suicide in Ireland is 10 per 100,000, below the OECD average of 12.1, and it has shown a welcome sign of reduction in more recent years.
- Total expenditure on health in 2005 accounted for 8.8% of Gross National Income, which puts Ireland close to the OECD average of 9% of GDP.
- Between 1997 and 2006 the number of day cases in Irish hospitals has more than doubled, from 243,000 in 1997 to over 550,000 in 2006.
- The use and provision of community mental health services has increased over the period, with numbers attending mental health day centres increasing by 84% and the number of places in community residences rising by 9%.

A number of these trends have highlighted positive developments. However, it is acknowledged that there are serious deficiencies in our current health system that must be dealt with. There is also an ever increasing movement across the EU and worldwide towards the patient safety and quality agenda.

2.5 Health Service Reform Programme

2.5.1 National Health Strategy

A new National Health Strategy, *Quality and Fairness: A Health System for You*, was published in 2001. A National Health Strategy Consultative Forum, representative of key stakeholders in the health services, including health professionals, management and consumers, was established to advise on the development of the Strategy. The need to embed quality more deliberately into our health services by developing a quality culture, which will allow the provision of high quality homogenous health services with the patient as the central tenet, is identified through a number of actions in the Strategy:
Action 63: Quality systems will be integrated and expanded throughout the health system

Action 68: Decisions across the health system will be based on best available evidence

Action 70: Accountability will be strengthened through further development of the service planning process

Action 110: Health Boards will be responsible for driving change, including a stronger focus on accountability linked to service plans, outputs and quality standards.

Following publication of the National Health Strategy and the associated strategy for Primary Care, *Primary Care: A New Direction*, (2001) the Health Reform Programme was developed to translate the vision into reality and implement the actions set out in the Strategy. It was clear that new structures and supporting processes were required to best meet current and future health needs as expressed in the goals and objectives of the Strategy.

Prospectus Strategy Consultants conducted an independent *Audit of Structures and Functions of the Health System* (2003), and at the same time the Minister for Finance established a Commission on Financial Management and Controls in the Health Service (2003), chaired by Professor Niamh Brennan. Both reports independently arrived at similar conclusions about the system and made comparable recommendations which provide the background for the government decisions on the Health Service Reform Programme. The main findings and recommendations were as follows:

- The multiplicity of health boards and specialist agencies operating in the public health sector had resulted in a complex and fragmented system.
- There was a need for rationalisation, standardisation and much improved co-ordination within the system.
- There was a need for greater clarity of roles, accountability and responsibility throughout the system, including the roles of the Department and the delivery system.
- There was a need to enhance needs assessment and service planning, with stronger links to funding, activity and outcome measurement.

Another report was commissioned on the staffing requirements of acute hospital services. The outputs from all this work culminated in the announcement of the Health Service Reform Programme in June 2003. The main elements of the Reform Programme were: structural reform, legislation, modernisation and improvement coupled with increased investment and enhanced governance and accountability.

2.5.2 Structural reform

The structural aspects of the Reform Programme which emerged largely from the recommendations in the Prospectus and Brennan Commission reports were:
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- rationalisation of health service agencies to reduce fragmentation, including abolition of the health board/health authority structure
- establishment of the Health Service Executive (HSE) as a single national entity to manage the health services
- restructuring of the Department of Health and Children
- establishment of the Health Information and Quality Authority (HIQA).

The HSE was established on 1 January 2005 under the Health Act 2004 and HIQA was established on 15 May 2007 under the Health Act 2007. The Department of Health and Children was restructured to take account of these changes and reflects its current core roles of national policy development and oversight of the operations of the state bodies under its aegis.

HIQA was established to underpin patient safety and quality in the new restructured health service. A core function of the Authority is to set standards on safety and quality of services and to monitor enforcement of these standards in an open and transparent way.

Other functions of the Authority include:

- undertaking investigations into the safety, quality and standards of services where it is believed that there is a serious risk to the health or welfare of a person receiving services
- carrying out reviews to ensure best outcomes/value for money for the resources available to the HSE
- inspecting and registering designated residential care services for older people, (e.g. nursing homes), for children and for people with disabilities. Monitoring of foster care services, day facilities and children’s detention centres
- undertaking Health Technology Assessments to inform the decision-making for safety and quality
- adopting a central role in health information development and implementation of the recommendations set out in the National Health Information Strategy
- evaluating information available on services provided by the HSE and other service providers and on the health and welfare of the population, identifying information deficiencies, and advising the HSE and Minister accordingly.

2.5.3 Legislation

In addition to establishing the HSE, the Health Act 2004 provided the legal framework for Regional Health Forums established by regulation to allow public representatives to share their views with the HSE on how services are being delivered and managed. It has also established a statutory complaints framework to help ensure a high standard of complaints management within the health service. The Health Act 2007 provided for protected disclosures or ‘whistleblowing’ safeguards: employees making protected disclosures in good faith and on reasonable grounds about issues of patient safety or patient welfare are protected from penalisation in the workplace and from civil liability.
Other important pieces of legislation introduced to support the reform programme include the Health and Social Care Professionals Act 2005, the Pharmacy Act 2007 and the Medical Practitioners Act 2007.

Health and Social Care Professionals Act 2005
The Health and Social Care Professionals Act 2005 provides for a system of statutory registration for twelve health and social care professions to ensure that members of the public can be confident that health and social care professionals providing services are properly qualified, competent and fit to practise. There is an overarching Health and Social Care Professionals Council, with separate registration boards for each profession. The first Council was established on 26 March 2007.

Pharmacy Act 2007
The Pharmacy Act 2007 reforms the regulation of pharmacy practice by setting new standards of governance, fitness to practise and registration for pharmacy. It also lifts restrictions on qualified EU pharmacists setting up in Ireland.

Medical Practitioners Act 2007
The Medical Practitioners Act 2007 provides for an enhanced system of regulation of the medical profession in Ireland. Some of the important changes introduced by the Act include increased non-medical membership on the Medical Council and the statutory obligation on medical practitioners to maintain their professional competence throughout their careers by participation in competence assurance schemes which include peer review and clinical audit.

2.6 Recent developments on risk management, patient safety and quality, adverse event reporting and learning

2.6.1 HSE quality and risk initiative
The Health Service Executive (HSE) was established in January 2005 as the single body responsible for meeting Ireland’s health and social care needs. Prior to this, healthcare services were delivered through a range of different agencies, each of which was independently answerable to the Department of Health and Children. This was a complex structure that made it difficult to provide nationally consistent health services.

As part of the establishment of the HSE, the Office of Quality and Risk was established to support the assurance of good governance in respect of all services provided by the HSE.

The HSE is engaged in an integrated system-wide process of implementing a Quality and Risk Management Standard which conforms to the requirements of the Australian/New Zealand Risk Management Standard. This standard provides as follows:
‘Healthcare quality and risk are effectively managed through implementation of an integrated quality and risk management system that ensures continuous quality improvement.’

The aim of the Standard is to provide a common set of requirements that will apply across all service providers to ensure that health and social services are both safe and of an acceptable quality. In response to this standard, the National Hospitals Office (NHO) and Primary, Community and Continuing Care (PCCC) directorates, which are responsible for service delivery in the HSE, have developed a Quality and Risk Framework which will:

- ensure that there is an appropriate framework for the management of quality, safety and risk across service delivery
- drive programmes of work in quality, safety and risk management such as clinical effectiveness, service-user and community involvement, risk management and patient safety, continuous professional development and service improvement
- ensure that appropriate accountability and oversight arrangements are in place to monitor quality and risk performance and to support the provision of assurance to the Directors of the NHO and PCCC and to the HSE Board.

2.6.2 Initiatives by Health Information and Quality Authority

The object of the Authority as set out in legislation is ‘to promote safety and quality in the provision of health and personal social services for the benefit of the health and welfare of the public’. The Authority is undertaking a range of work programmes that include its mandatory functions and is engaged in a range of activities that facilitate collaborative working with statutory, voluntary, educational, professional, advocacy and patient organisations. These activities currently include:

- the development of standards in collaboration with relevant patient representative organisations, academia, service providers, statutory agencies, professional bodies, special interest groups
- undertaking national quality assurance reviews of priority service areas e.g. symptomatic breast disease and hygiene
- carrying out investigations into serious adverse events with involvement from the relevant specialty experts and lay people
- participation in international projects and networks on patient safety dealing with issues such as open communication and safe surgery
- participation in the Health and Social Care Regulatory Forum.

2.6.3 Developments by State Claims Agency

The Clinical Indemnity Scheme (CIS) was established following enactment of legislation in 2002, with a dual remit to (a) manage all claims relating to professional clinical services in the Irish public health sector and (b) lead and support the development of clinical risk management in this sector.
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National clinical incident reporting

National clinical incident data are now available for the first time. A confidential web-based clinical incident reporting system, STARSWeb, designed to capture all clinical incidents and near-misses, has been rolled out nationally. The number of incidents notified via STARSWeb continues to rise each year. From January 2004 up to the end of March 2008, over 160,000 clinical incidents, the most common of which were slips/trips and falls, had been notified via the system. This system supports local risk management initiatives at enterprise level and also allows for national trend analysis.

Sharing of learning to support patient safety

A very important objective for the CIS is sharing of learning to support patient safety. This is done in a variety of ways: as claims are closed, they are subjected to analysis in order to capture any learning from them. Feedback is provided to the individual enterprise and any generic lessons are fed back into the system through workshops, seminars, the CIS website or newsletter.

2.7 Reports on adverse events in the Irish health system in recent years

As mentioned above, a number of investigations have been carried out in recent years in Ireland following adverse clinical events. The Commission received copies of the reports published in relation to these investigations and also heard presentations in relation to some of these events. These reports included the following:

- Review of a clinical adverse event in December 2002, in which a pregnant patient attended Monaghan General Hospital and was transferred to Cavan General Hospital. Delivery of a pre-term infant occurred during transfer and the infant subsequently died at Cavan General Hospital
- Report of the Panel reviewing the events surrounding the death of Roisin Rudden in July 2003
- Report into the circumstances pertaining to the death of Frances Sheridan in February 2004
- Report into the death of Patrick J Walsh, October 2005
- Report of Judge Maureen Harding Clark S.C. following the Inquiry into peripartum hysterectomy at Our Lady of Lourdes Hospital, Drogheda, 2006
- Report into the circumstances that led to the decision by the HSE in August 2007 to suspend breast radiology services, initiate a clinical review of symptomatic breast radiology services and place a consultant radiologist on administrative leave at the Midland Regional Hospital, Portlaoise
- Management, governance and communications issues arising from the review of breast radiology services at the Midland Regional Hospital, Portlaoise, February 2008
Report of the HIQA investigation into the circumstances surrounding the provision of care to Rebecca O’Malley, in relation to her symptomatic breast disease, the Pathology Services at Cork University Hospital and Symptomatic Breast Disease Services at the Mid Western Regional Hospital, Limerick.

It is not intended to repeat in detail the circumstances of the events in each of these reports, or to list the specific findings and recommendations which were made in the context of each report. Although many of these may have been remedied in the particular hospitals in which the event occurred, it is nonetheless important to highlight the general findings from these reports which the Commission considered relevant to its remit in relation to the development of an integrated patient safety framework. These include:

- poor communication processes with patients and their families following adverse events
- deficits in staff knowledge of hospital policy
- insufficient induction of healthcare staff
- lack of appropriately skilled senior personnel in acute care specialties
- lack of senior clinical leadership within hospitals or on a national level
- poor team working within hospitals and lack of integration of primary care professionals in the medical team
- lack of protocols within hospital departments to deal with referrals between departments
- insufficient communication with General Practitioners following hospital discharge
- lack of structured adverse event reporting, or monitoring systems
- inconsistent system of root cause analysis of adverse events and complaints
- poor management skills
- dysfunctional processes, interpersonal relationships and management structures within hospitals
- lack of engagement/poor working relations between management and clinicians
- poor communication/protocols within and between hospitals regarding transfer of patients
- lack of networking links between hospitals to share knowledge and experience
- lack of clerical support for consultants with clinical leadership and educational roles
- difficulties in relation to availability of medical records in emergency cases
- under-developed/absence of leadership of or responsibility for clinical governance programmes
- lack of/failure to implement formal risk management policies
- absence of internal and external audits
- lack of clarity in relation to accountability and reporting relationships within hospitals
- failure to develop or implement clinical audit processes
- failure to participate in continuous professional development programmes.

The Commission also took careful note of the recommendations included in these reports where these were relevant to its Terms of Reference. In particular, the Commission
considered the recommendations contained in the Report of Judge Maureen Harding Clark SC, following the Inquiry into peripartum hysterectomy at Our Lady of Lourdes Hospital (The Lourdes Hospital Report), as this report was instrumental in leading to the establishment of the Commission. The main recommendations, insofar as they are relevant to the work of the Commission, are summarised as follows:

- Safeguards must be in place to identify questionable or outdated practices carried out by doctors and to quickly retrain or remove such doctors to protect the public.
- The work of all doctors must be effectively reviewed by way of peer review and independent audit.
- There should be regular multi-disciplinary reviews of patient throughput with participation from junior and senior clinicians and nursing staff, and other members of the team as appropriate.
- All healthcare staff should be aware of the importance of continuous learning, competence assurance, adverse event reporting and audit.
- Change, analysis, review and learning are the keys to best practice. All procedures must be measured against outcomes, modern literature and accepted benchmarks.
- Leadership, training and knowledge must be recognised as key elements in every successful hospital.
- Professional bodies must play a fuller role in evaluating competence.
- Management structures need serious changes in training, continuity and accountability. They also should be subject to audit and review.
- There should be a lead clinician in each unit, with responsibility for budgetary planning and management, and this person should be part of the management team. The lead clinician should be responsible for organising regular clinical audit meetings, clinical pathological conferences, clinical governance, clinical adverse event reporting policies and continuing education. The lead clinician should liaise regularly with the lead clinicians in other departments and should sit on the hospital Medical Board.
- Consideration should be given to entering key data of sentinel events on a daily basis into a national integrated monitoring system and into an internal computer auditing system.
- There should be induction for all new trainees to include information on the hospital layout, hospital policies, clinical standards, conduct and communication with colleagues and patients.
- All registrars and consultants should attend courses in clinical governance and risk management.
- Research and audit projects by all clinicians should be actively encouraged and facilitated.
- All consultants should undergo rigorous independent clinical competence appraisal and evaluation every five years, and arrangements should be put in place for training and development on a needs basis in specialist centres of learning.
- There should be a comprehensive, effective, user-friendly IT system in place.
- All patient records should be in standard format from which key data can be extracted for internal and external audit.
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Before any consultant engages in a particular procedure the Medical Council must certify that he/she is competent in that area. This power can be delegated to the recognised professional training bodies.

Persons appointed as managers should be highly skilled and experienced in hospital management, and be paid a salary commensurate to skill, experience and responsibility.

There should be legislation in place to protect clinical governance records and risk management clinical adverse event report forms from the application of the Freedom of Information (FOI) Act. Unless these documents are protected from FOI or discovery, they are unlikely to be created, and opportunities for learning from mistakes will be lost.

There should be clear, effective, accessible complaints processes in place and rights and responsibilities publicised.

The Commission also took cognisance of reports into adverse events in other jurisdictions. In particular, the Commission noted the findings of the Report of the public inquiry into children’s heart surgery at the Bristol Royal Infirmary 1984 – 1995, (2001) (the Bristol Report) in which similar failings were highlighted such as: lack of clinical leadership; poor teamwork; poor communication; lack of formal quality assurance systems; absence of standards for evaluating performance; confusion about responsibility for monitoring the quality of care; the existence of a ‘club culture’ within hospital environments; poor hospital organisation; failure to maintain clinical competency; poor buildings and equipment; unwillingness to acknowledge and learn from errors; cultural barriers to openness; lack of clarity regarding accountability.

In the view of the Commission, these reports clearly point to the need for:

- effective governance to ensure that the environment in which healthcare takes place is supportive of safe and good quality care
- greater accountability of institutions and their management for institutional performance
- greater accountability in the different bodies that regulate clinical practice
- a strengthened system of information on adverse clinical events and complaints
- patient reporting to be formalised, thereby providing a stronger role for patients and carers in feeding back on care received.

2.8 Consultation process

As part of its deliberations the Commission undertook a public consultation exercise to gather information from stakeholders and the public on the issues within the Commission’s remit. The Call for Submissions was advertised in the national and medical press, with a closing date of 9 November 2007. The advertisement identified the key issues under consideration by the Commission as including: the role of the patient/public in safety and quality issues affecting the delivery of health services, clinical and managerial leadership and accountability, open disclosure of adverse events to patients, adverse event reporting, statutory licensing of public and private healthcare providers and the governance of regulatory bodies.
The Commission asked that those making submissions identify five key priorities from the Commission’s Terms of Reference, state the most important elements of each priority identified, the main arguments in favour of the author’s views and how the author would like to see those priorities addressed.

The Commission received over 50 submissions from a range of interested persons and bodies (see Appendix D for list of those who made submissions). The main themes in the submissions, identified below in order of priority given, related to the following issues:

- Risk management
- Participation of patients, carers and the public
- Audit
- Quality assurance systems
- Licensing
- Clinical governance and leadership
- Evidence-based practice
- Collaboration between healthcare regulators
- Medication safety
- Use of information technology
- Education and continuing professional development
- Physical environment and resources
- Others – health promotion; continuity of care in the community; requirement for a single overarching regulatory body; regulation of health service managers; efficiency of the complaints process; credentialing; health technology assessments; radiation safety.

It is not intended to give an exhaustive list here of the many important questions and points raised in these submissions. However, a reflection of some of the issues raised will illustrate the concerns held by the authors of the submissions and the value of their personal experiences as recipients of health services or healthcare workers.

- In the area of risk management, the following issues were stressed: the need for mandatory adverse event reporting and root cause analysis; the need for dedicated staff to identify sources and trends; national co-ordination of a reporting system; the need to monitor corrective actions; reporting of near-misses; medication errors; pharmacist review; open disclosure of errors to patients accompanied by the provision of information and counselling; how to drive culture change so that the system becomes one of learning, not blame; the potential replacement of the tort system with a redress scheme; the issue of legal protection; the need for strong leadership within institutions; an inter-disciplinary approach; effective medical equipment management; local policies/training to guide staff so that each staff member has a responsibility to identify and report risk; clear reporting relationships; positive incentives and education in relation to reporting; resources.

- In relation to the participation of patients, carers and the public, many submissions emphasised the unique contribution of patients through patient forums and
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expert patient groups in engagement in service design, planning and evaluation; the inclusion particularly of ‘hard to reach’ groups; the need for an accessible complaints system that can be clearly and easily navigated; training of patient advocates and staff; representation on clinical governance committees, audit project teams, focus groups; standardised national patient surveys; charters and mission statements; the need to communicate to the public in relation to standards; readability of information for patients and carers, particularly in relation to medication.

- On the issue of **audit**, the submissions mentioned a range of audits which should include clinical outcomes, patient safety, hygiene, infection, staffing, qualifications and medical equipment; continuous trend analysis; the need for a national audit committee to set standards and benchmark against international standards; the requirement for a structured multi-disciplinary approach, including managers and service-users; means by which to encourage participation from professionals could include reference to audit in codes of conduct and contracts; the need for training in relation to the skills necessary for effective audit; time and resources; the need for institutional commitment, IT resources, ring-fenced funding and support from managers and hospital boards; current legal impediments in relation to disclosure of results as an inhibitor to learning; the necessity for re-audit to ensure change.

- **Quality assurance systems**: the submissions stressed the need for continuous quality assurance (QA) of clinical services; a multi-disciplinary approach should be taken which will yield high quality data on clinical outcomes per procedure and specialty; must also measure inputs; there should be a second/peer review within departments; standards must be based on national and international evidence; there must be accessible reliable indicators of quality which will assist in flagging potential problems; should be a national QA panel to identify trends and deal with poor performance; healthcare providers should have a statutory responsibility to meet standards; there should be a dedicated QA budget and local co-ordinator in each hospital; there must be a systems approach, with the patient at the centre; payment for services should be based on quality audit; integrate QA into education and continuous professional development; there should be an evaluation of progress over time and an assessment of the useful levers for change.

- **Licensing**: the submissions favoured a licensing system which applied to all facilities where health interventions take place, both public and private; all providers must meet minimum standards and be engaged in continuous quality improvement through existing accreditation systems or otherwise; there should be a multi-disciplinary assessment, with lay involvement and collaboration with regulators and voluntary bodies; there must be regular inspection, review and power to revoke a licence; the system must be proportionate; clear criteria must be set by an independent and appropriate body; the system could commence with a self-assessment/self-declaration followed by inspection; standards should focus on leadership and management and embed accountability in the healthcare system.
Governance and clinical leadership: the submissions included the following points – there should be a clinical leadership team in each hospital and PCCC area, with a named manager and clinical director and clinical governance committees; there should be a national clinical leader; there must be a streamlined and robust system, with clear lines of accountability and reporting structures; recruitment of health service managers should be based on competence and advocacy skills as well as ability in terms of performance management and implementation of change; managers should be accountable for their contractual, statutory and professional responsibilities; there should be a statutory registration system for managers by which they would have to demonstrate compliance with codes; there should be a structured operational plan, skilled staff and appropriate resources, responsibility for ongoing audit and risk management; managers should foster an open and team work approach; there should be a statutory requirement for organisations to assure patient safety; there should not be a ‘one size fits all’ approach but rather a focus on key governance outcomes and statutory responsibilities in priority areas; there should be investment in training and development and more consultation with service-users and the public.

Evidence-based practice: some submissions were of the view that there are few services supported by strongest evidence actually delivered and that there is too much spending on activities that do not improve health; there must be accessible international data such as WHO and Institute for Healthcare Improvement (IHI) lists of high impact safe practices with sound evidence base; these must be implemented across the system; continuing professional development (CPD) is essential to the cycle of learning; there should be more collaboration with medical schools as regards incorporation of medico-legal and clinical risk management theory.

Collaboration between regulators: there should be regular formal interaction on common issues and a sharing of expertise and experience; there should be a clearer understanding of the statutory remit of each body and a mechanism to address interface and avoid duplication; registration and disciplinary issues should be streamlined, with agreement in relation to terminology and definitions of misconduct; there should be a co-ordinated approach to audit and quality indicators; a multi-agency steering group should be established to develop codes of practice for regulatory bodies; regulators should ensure education in relation to patient safety and quality improvement methods for all staff; there should be an overarching regulator/patient safety agency.

Medication safety: evidence-based practice and continuing professional development is essential; regular audits; risk identification and a national adverse event reporting system is necessary; quality standards for hospital pharmacy aseptic compounding units; accreditation programmes and licensing; pharmacists must be treated as members of multi-disciplinary teams; pharmacist-led medication management; need for greater standardisation of hospital pharmacy staffing levels based on clarity about what services they are expected to deliver; danger re counterfeit medicines; packaging issues; personal information packs; health promotion; readability studies for patient information sheets; the use of a unique patient identifier across the system; need for hospitals to adopt the use of bar-code technology for the dispensing and administration
of medicines; electronic prescribing; need for the introduction of automated dispensing systems in hospital pharmacies; seamless care between hospital and community; participation of patients and carers in relation to supply and administration of medicine; review by community pharmacists of patient compliance with medication; need for a national strategy for pharmaceutical care in hospital.

- **Use of information technology:** there is a need for a robust health information infrastructure for improving quality; bar-coding of medication; unique patient identifiers; automatic information and data capture; specimen identification and tracking; electronic patient records; electronic prescribing; automated dispensing; there should be a map intelligence system which would allow hospitals to compare results nationally and internationally.

- **Education and continuing professional development:** there should be education in relation to patient safety at undergraduate level; incorporate medico-legal and clinical risk management theory into teaching; CPD essential; investment in training and development; must be education in relation to audit and reporting mechanisms; education of the public in relation to health promotion.

- **Physical environment and resources:** facilities must be fit for purpose; inspection as part of licensing system; design of infrastructure and facilities to ensure hygiene, privacy, equipment, etc; standards needed in relation to specialised infusion centres and healthcare in the home; mental health facilities inadequate; evidence-based design of hospitals would minimise risk, facilitate infection control and help to provide quality end-of-life care; basic requirements such as CT scans for hospitals admitting acute patients; staffing levels are not conducive to patient safety – nursing and pharmacy in particular; training.

- **Other issues:** health promotion; continuity of care in community; national patient safety agency; regulation of health service managers; efficient complaints process; credentialing; health technology assessment; radiation safety.

These submissions were of immense value to the Commission in its deliberations and the Commission members are grateful to all those who took the time to respond to the Commission’s invitation.
Chapter Three

Governance Framework for Patient Safety and Quality

3.1 Vision of health system-wide governance framework for patient safety and quality

In the course of its deliberations the Commission agreed that the following represents the vision around which a health system-wide governance framework for patient safety should be based:

Knowledgeable patients receiving safe and effective care from skilled professionals in appropriate environments with assessed outcomes

The principles or values underpinning the Commission’s work and proposed framework which are integral to this vision include:

- openness
- patient centredness
- learning from mistakes – safety and quality must be embedded in the system
- maximising benefit to patients – effectiveness and efficiency based on good governance and leadership, modern data management systems and evidence-based practice
- accountability
- patient/family involvement.

3.2 Governance

A significant element of health service reform is the strengthening of governance and accountability arrangements across the health system. The Prospectus Report (Department of Health and Children 2003) stated:

‘To date in Ireland the mechanisms that are central to effective clinical governance have generally been patchy in their development...’

Internationally, a central finding of many of the health system reviews of safety and quality failures that have been undertaken is that of weak systems of leadership, governance and accountability in healthcare, i.e. the view that ‘no-one was in charge’, with confused lines of responsibility and accountability between professional and managerial staff and often with parallel lines of responsibility for different professional groups within the one
organisation. Similar findings of weak accountability structures have been made in reviews in Ireland e.g. in the Lourdes Hospital Report, in the report of the Comptroller and Auditor General into the Consultants’ Contract, in the HIQA Hospital Hygiene Audit, 2007 and in the reports around a number of reviews of serious adverse events carried out by the HSE and HIQA generally in the area of cancer services in 2007 and 2008.

The development of governance in healthcare has been a worldwide phenomenon and, although governance systems vary internationally, there are components of good governance that are common to many of the systems.

3.2.1 Concepts and definitions

Many definitions and concepts of governance have developed and evolved internationally over the last decade. These may be summarised under the headings of: Corporate governance, Clinical governance and Integrated governance.

Corporate governance. This is the system by which organisations direct and control their functions in order to achieve organisational objectives, manage their business processes, meet required standards of accountability, integrity and propriety and relate to their external stakeholders. Given the complexity of healthcare, particularly the many strands of professional and managerial accountabilities that are inherent in its organisation and processes, and the imperative to achieve safe and reliable services, specific models of governance in healthcare have evolved.

Clinical governance. One of the first definitions of clinical governance was described within the National Health Service Framework in the UK in 1998 and it is one of the most widely cited definitions. Clinical governance is:

‘a framework through which NHS organisations are accountable for continuously improving the quality of their services and safeguarding high standards of care by creating an environment in which excellence in clinical care will flourish.’ (Scally and Donaldson 1998)

This definition is intended to embody three key attributes:

- recognisably high standards of care
- transparent responsibility and accountability for those standards
- constant dynamic of improvement.

Clinical governance defines the culture, the values, the processes and the procedures that must be put in place in order to achieve sustained quality of care in healthcare organisations. Clinical governance involves moving towards a culture where safe, high quality patient-centred care is ensured by all those involved in the patient’s journey. Clinical governance must be a core concern of the Board and CEO of a healthcare organisation.
Initially the term ‘clinical governance’ as described included all aspects of healthcare i.e. clinical, non-clinical and administrative, etc. However, in practice there has been an emphasis on the implications of the term for the governance of the clinical aspects of care. It is clear that all aspects of governance of an organisation have a reciprocal impact upon each other and recently, the concept of *integrated governance* has been developed to refocus governance on all aspects of healthcare.

**Integrated governance.** This refers to the corporate governance and clinical governance duties of healthcare organisations. The term ‘integrated governance’ is widely used, e.g. in the UK, and is being further developed, supported and implemented. Integrated governance can be described as:

‘Systems, processes and behaviours by which health service organisations lead, direct and control their functions in order to achieve organisational objectives, safety and quality of service and in which they relate to patients and carers, the wider community and partner organisations.’

(Dept of Health, UK 2006)

The Department of Health in the UK stipulates that the Boards of Trusts in the UK, including Primary Care Trusts, need to ensure that they have in place key structural elements for clinical governance:

- clear arrangements for accountability and reporting with ultimate Board-level responsibility for arrangements to assure and improve quality
- a coherent programme of quality improvement activity
- risk management processes, including mechanisms for detecting and dealing with poor professional performance.

### 3.2.2 Elements of governance

Governance is an umbrella term which encompasses several key elements and themes, all of which, when effective, combine to support and foster a culture of effective governance that drives patient safety and quality. Governance systems should be established in a standardised way nationally and within organisations, facilitating systematic quality control of clinical practice throughout primary and secondary care, including oversight of medication safety.

Governance of all types begins at the highest level, and it is a leadership issue to set organisational agendas for corporate and clinical governance. Good governance requires effective leadership throughout the organisation, including the Board, Chair and non-executive directors, chief executive and executive directors, managers, clinicians and administrative staff.
Central issues have been identified in the literature as key to effective governance. These include:

- ensuring that links are made between health services clinical and corporate governance
- the use of governance to promote safety and quality through a focus on quality assurance and continuous improvement
- the creation of governance structures to improve safety and quality and manage risk and performance
- the development of strategies to ensure the effective exchange of data, knowledge and expertise
- the sponsoring of a patient-centred approach to service delivery.

The Commission has described governance under four broad headings:

1. **Advocating for positive attitudes and values about safety and quality** includes leadership, accountability, continuous improvement strategies to improve safety and quality, continuous education, focus on ethics.
2. **Planning and organising governance structures for safety and quality** includes performance management; managing risk; reporting and managing adverse events; credentialing healthcare professionals; standards; accreditation.
3. **Organising and using data and evidence** includes clinical effectiveness; evidence-based practice; clinical indicators; audit; managing knowledge effectively.
4. **Patient focus** includes service-user participation; focus on patient safety; open disclosure; informed patient consent; managing complaints effectively.

(Adapted from Braithwaite and Travaglia 2008)

A diagrammatic representation of the elements of governance is set out on the next page:
Diagram of the elements of governance
Advocating for positive attitudes and values about safety and quality

At the core of governance strategies lies a commitment to the principles of safety and quality. The key values which board members as well as clinicians and managers need to encourage, support and display, in order to achieve high quality and high reliability services are: leadership, accountability, continuous improvement, quality assurance, continuous education and focus on ethics (Adapted from Braithwaite and Travaglia 2008).

- **Leadership**
  Good governance requires effective leadership at all levels of the organisation. Therefore leadership and leadership skills should be supported and developed at all levels including at Board and Chief Executive level.

- **Accountability**
  Accountability seeks to specify who is responsible and for what they are answerable. Ultimately, in principle Boards and Chief Executives should be accountable for the standard of service delivered.

- **Continuous improvement**
  Continuous improvements are those clinical and organisational initiatives and strategies instituted by organisations to enhance the safety and quality of their services on an ongoing basis.

- **Quality assurance**
  Quality assurance is the process, programmes or activities intended to assure or improve the quality of care in healthcare. The concept includes the assessment or evaluation of the quality of care; the identification of problems or shortcomings in the delivery of care; the designing of activities and structures to overcome these deficiencies and the follow-up monitoring to ensure the effectiveness of the corrective steps. Boards, managers and clinicians should be committed to maintaining and improving quality standards and this should be an underlying value and principle of every healthcare organisation.

- **Continuous education**
  The recommended approach is to promote continuous improvement of services and the quality of care, and therefore there should be systems in place to encourage staff to engage in continuous education and this should be embedded as part of the culture. Boards and executives can help establish the lifelong learning agenda in many ways, for example by taking a lead in personally embracing continuous education, valuing education for others and promoting openings for people to participate in appropriate and relevant educational and learning opportunities.

- **A focus on ethics**
  Governance could be described as an ethical issue as it involves the delivery of appropriate care within budgetary allocations in a timely way to patients without harming them. Boards and executives need to act in a fiscally responsible and ethically
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appropriate way, and they need to ensure such values throughout the workplace for which they are responsible.

Planning and organising governance structures for safety and quality

The enactment of governance is dependent upon a culture of effective planning and management. The key elements are: managing performance, managing risk, reporting and managing adverse events, credentialing health professionals, applying standards and learning from and engaging with service-users (Adapted from Braithwaite and Travaglia 2008).

- Managing performance
  Good management practice suggests that the performance of individuals and groups needs to be reviewed at regular intervals and aligned with the overall organisational mission. Performance management seeks to align organisational goals with group and individual goals and it provides feedback on performance progress within an appropriate framework. Ideally, an effective performance management system covers what it is intended to achieve, what is being achieved, how it is being achieved and the extent to which people are meeting their goals. Boards and executives should ensure that relevant systems are in place and they should provide leadership by participating in performance management.

- Managing risk
  Boards and executives have an obligation to make sure that an effective risk management plan is developed and implemented in healthcare organisations.

- Reporting and managing adverse events
  There should be a system of regular review and reporting of adverse events and potential adverse events to the Board and the executive management group. Identified learning and dissemination and implementation of improvements need to be demonstrated.

- Credentialing health professionals
  Care should only be provided by qualified professionals whose performance is maintained at an acceptable level. This can be done through the process of credentialing which is used in some countries e.g. Australia.

- Applying standards
  There are many standards in healthcare – for individuals, for services and for organisations. Standards are usually evidence-based and are designed to be consistently applied across many different kinds of organisations and/or professional groups. They should also take account of the patient experience in order to identify gaps between the safety measures possible and the actual level of safety being experienced by patients. Healthcare boards and executives should ensure that their organisations participate in the appropriate processes (e.g. accreditation) to fulfil these standards.
Organising and using data and evidence

The sharing of data, knowledge and expertise are essential to the effectiveness of governance and the effectiveness of health services as a whole. There should be a systematic collection of clinical and other data and a purposeful use of intelligent information derived from it, subject to ensuring that the necessary safeguards are in place to protect the privacy of an individual’s health information from unauthorised access or disclosure. The key methods of information sharing are: improving the sharing of information, encouraging clinical effectiveness, promoting evidence-based practices, using clinical indicators, audit and managing knowledge effectively (Adapted from Braithwaite and Travaglia 2008).

- Improving the sharing of information
  Data management and reporting systems should be developed and improved. Methods to encourage decision-making groups at all levels to use and share information should be supported and developed.

- Encouraging clinical effectiveness
  At its simplest, clinical effectiveness is about striving to ensure that practice is based on the best available data and evidence on effectiveness. Clinicians need to be supported to engage in ongoing education and encouraged to keep informed about developments in their specialty area.

- Promoting evidence-based practices
  Evidence-based practice should be embedded throughout healthcare and should be supported through structures such as access to online evidence thus enabling clinicians to keep abreast of the evidence and the promotion at every opportunity of the importance of both effective practice and the systematic use of evidence.

- Using clinical indicators
  Clinical indicators can be used to map performance of a particular unit or organisation over time or to benchmark performance with, for example, another local provider or a provider with an international reputation for the highest quality services. High level clinical indicator data should be reviewed regularly by boards and executive groups in order to track organisational and clinical performance and progress.

- Audit
  Clinical audits involve aspects of the structure, processes and outcomes of care being selected and systematically evaluated against explicit criteria. Where indicated, changes are implemented at an individual, team or service level and further monitoring is used to confirm improvement in healthcare delivery. While clinical audit is led by clinicians, Boards and executives should ensure that regular and widespread clinical audit activity is occurring throughout healthcare organisations within their ambit of responsibility.
Managing knowledge effectively
Knowledge management involves actively striving to promote the sharing and use of information or the adoption of new ideas, ways of working or technology.

Sponsoring a patient focus
Boards and executives of healthcare organisations should endorse a commitment to patient-centred care and oversee strategies that ensure the rights and involvement of patients. The key elements are: encouraging service-users to participate in decisions affecting their care, focusing on patient safety, supporting open disclosure, seeking informed patient consent and dealing with complaints effectively (Adapted from Braithwaite and Travaglia 2008).

Encouraging service-users to participate in decisions affecting their care
In healthcare, it is important to design the health system so that service-users are more educated and informed about the decisions affecting them. In healthcare organisations there should be structures, approaches and attitudes in place to encourage patients to participate in health service planning and review, and for health professionals to co-operate in joint decision-making models with patients, relatives and carers.

Focusing on patient safety
Good governance structures in healthcare should focus on patient safety in healthcare. An example of one structural suggestion to develop this focus is to organise clinicians into groups of patient-focused service configurations, commonly known as clinical streams or clinical directorates.

Supporting open disclosure
Open disclosure following an adverse event should be supported through appropriate policies and practices which are well publicised and instituted widely.

Obtaining patient consent
In all jurisdictions there are policies and procedures requiring appropriate patient consent to have been obtained and any disclosure of material risk to have been made before treatment being initiated. Boards and executives need to take these responsibilities seriously as to do otherwise would be an infringement of patients’ rights. There is also substantial exposure to legal risk involved both to attending practitioners and to healthcare organisations if consent has not been obtained or disclosure not made.

Dealing with complaints effectively
Appropriate complaint-handling systems should be supported and developed and complaints should be dealt with effectively and judiciously.
3.3 Conclusions

From the review of international evidence it is clear that every health system requires effective and clear governance arrangements that provide the necessary framework, structure, systems and processes to enable and demonstrate the provision and management of high quality and safe services. The sophistication of such arrangements is in their simplicity and it is imperative that governance arrangements are clear, cohesive and connect the various levels of a health system in a logical manner that enables learning and knowledge to drive improvements.

However, governance systems and processes are only as effective as the people who work within them. Therefore, at the heart of effective governance is the culture of healthcare. What is required is a culture where patients are put first and at the centre of their care, staff are suitably skilled and developed, behaviours are respectful, relationships are built on trust, team working is effective and active, and open and effective communication is the norm.

An open and supportive culture, which is effectively governed, has to be led and continually reinforced by strong leadership and accountability at all levels of a health system.

The following chapters cover the components that drive effective governance for safety and quality in healthcare and make recommendations that should ensure that the Irish health system develops a strong and effectively governed healthcare service for the future.
Chapter Four

Patients, Carers and Service-Users as Partners

4.1 Patient, carer and service-user participation

In the health system, patients, carers and service-users are at the heart of patient safety. When things go wrong, they and their families suffer from the harm caused. Such harm is often made worse by the defensive and secretive way that many healthcare organisations respond in the aftermath of a serious event. Around the world, healthcare organisations that are most successful in improving patient safety are those that encourage close cooperation with patients and their families. Patients and their families have a unique perspective on their experience of healthcare and can provide information and insights that healthcare workers may not otherwise have known. Partnership must be a key theme: patients, health professionals, policy-makers and healthcare leaders should be working together to prevent avoidable harm in healthcare.

Taking account of the perspective of patients and their families is crucial to articulating the reality and identifying the gaps between the patient safety measures possible and the levels of safety being experienced by patients. Integration of the patient’s perspective is necessary to ensure that services are driven by patient need and are authentically patient-centred, as well as being a useful validation tool in relation to the implementation of guidelines, processes and protocols.

Increased integration of the patient’s perspective will build trust and confidence in the health service and embed key safety guarantees into the care pathways where patients and families can alert staff in relation to inaccurate communication of information across transfers of patient care, anomalies in prescribing, deterioration in patient well-being etc. Patient and carer participation will also help to ensure that adverse events or failures in care are adequately dealt with when they arise.

Current health policy strongly endorses the role of patients. The Health Strategy, Quality and Fairness (2001), places the patient at the centre, and the Primary Care Strategy, Primary Care: A New Direction (2001), commits to user involvement in primary care teams. The Health Act 2004 states ‘The Executive may take such steps as it considers appropriate to consult with local communities or other groups about health and personal social services.’ The Act also allows for the establishment of the National Consultative Forum, Regional Health Fora and Advisory Panels.

The National Strategy for Service User Involvement in the Irish Health Service 2008-2013 (Department of Health and Children and the HSE 2008) lays out clear commitments to engaging service-users in order to improve the safety, quality and responsiveness of health services.
4.1.1 Current policies

The *National Strategy for Service User Involvement in the Irish Health Service* (2008) defines the term ‘service-user’ to include:

- people who use health and social care services as patients
- carers, parents and guardians
- organisations and communities that represent the interests of people who use health and social care services
- members of the public and communities who are potential recipients of health promotion programmes and social care interventions.

The strategy establishes a useful set of principles for working with service-users:

- Service-users, especially those whose voices are seldom heard, have a right to be involved in the development of the health and social services that they use and this is a key element in the delivery of patient-centred care.
- Commitment of management at all levels is essential to ensure leadership and delivery on this strategy.
- Health and social services need to be truly patient-centred.
- Service-users should be centrally involved in their own care.
- Open dialogue, trust and mutual respect are key ingredients of successful service-user involvement.
- Involvement must be based on inclusion, diversity and equity – health services must engage socially excluded groups including those who are socio-economically disadvantaged, ethnic minorities and Travellers, people with disabilities, lesbian, gay, bisexual and transgendered people, children, young people and older people and users of mental health services.
- Clear channels of communication with the health service for service-users are essential to effective involvement.
- Accurate and timely feedback and information to service-users are key elements of successful user involvement.
- Service-user involvement initiatives must be systematically evaluated and learning from service-user involvement initiatives must be disseminated across the health and social services.

The HSE has also developed a programme of service-user involvement in healthcare, ‘*Your Service – Your Say*’, through which a national policy for the management of complaints in all publicly funded healthcare settings is now in operation.

4.1.2 Recommendations

The Commission endorses the recommendations in the *National Strategy for Service User Involvement in the Irish Health Service* (Department of Health and Children and HSE 2008) and further recommends the following:
R4.1 The proposals in the *National Strategy for Service User Involvement in the Irish Health Service* should be implemented as a matter of urgency to ensure that patients and their families can influence policy development, service delivery and health service development and evaluation.

R4.2 A national network of patient advocates who will work in partnership with healthcare organisations and other key players to improve patient safety should be identified, supported and developed through appropriate training programmes; the network should also, where appropriate, have strong links with international/worldwide initiatives.

R4.3 Effective patient and public involvement should be demonstrated in any review of health service performance.

R4.4 Robust and validated patient and public involvement should be a requirement for all healthcare oversight, scrutiny, quality control and other accountability mechanisms.

R4.5 Healthcare organisations must ensure an environment that allows for patients and their families to raise issues at the point of care. Communications and behaviours need to be reinforced to facilitate this and patients should be informed at first point of contact that it is the policy of the organisation that raising concerns about their care will not negatively affect their care or their experience while under care and they should be reassured as necessary throughout their treatment that this is the case.

R4.6 Healthcare organisations must ensure that there is a named lead person who will liaise with patient advocates, service-user representatives, patients and families. This person would be an identified point for patients to provide feedback in relation to their care. Feedback needs to be provided to service-users so that they can see that their views are being taken seriously.

R4.7 Opportunities must be provided for service-users to contribute to the education of future healthcare professionals and to the continuing professional development of existing practitioners.

R4.8 Provision should be made for patient and family involvement in research activities such as measuring patient contribution to bad outcomes, factors that rescue patients from provider error, and factors that mitigate the harm caused by errors.
R4.9 Patients should be offered full access to information relating to their care, including correspondence between healthcare professionals.

R4.10 Patient engagement should be advanced as a recognised patient safety solution. Amongst other things this will enable a better understanding of what patients and families want in relation to disclosure and learning from adverse events and the development of an appropriate communications process to deal with such events.

R4.11 In relation to complaints handling, patients and carers should have a clear understanding of the procedures and processes involved. Patient involvement in the design of standards and implementation processes is crucial to transparency and effectiveness.

4.2 Knowledgeable patients

The achievement of knowledgeable patients requires a change of attitude and culture to the way care is delivered. Care should be delivered in a culture of openness, honesty and trust; caregivers should ensure that patients have the information they need to make informed choices; and to enable patients to become equal partners with healthcare professionals in making decisions about treatment and care.

For patients to be knowledgeable they need to know about:

The health system
- structure
- how to access the system
- how local services compare with services in other areas
- their rights
- their responsibilities
- how to complain; who is in charge
- what to do when things go wrong

Their condition
- access to information and correspondence about their condition/illness
- how to prevent/manage it
- options for treatment
- prognosis
- wider implications of their condition (including family and occupational implications).

Further discussion on the information to support knowledgeable patients can be found in Section 7.7.4 of this Report.
4.2.1 Recommendations

The Commission recommends the following:

**R4.12** A public information service should be developed by HIQA and the HSE which makes information readily available to patients and their carers about maintaining their health and dealing with illness. Such a system should signpost paths through the healthcare system and guide patients in accessing the care that is most appropriate to them, indicate how to raise any concerns they might have in relation to their treatment and care, and support effective development and access to health literacy information and support networks. It should also provide information in relation to medication, alternative non-medication therapies and the safe use of medicinal products.

**R4.13** Specific programmes should be developed by the HSE aimed at supporting patients with chronic conditions, helping them to understand and manage their conditions and to participate in decision-making regarding their clinical management.

**R4.14** All public information should be easily accessible, available in a variety of formats and media and culturally and socially appropriate; it should enable use of advocacy and interpretation services as appropriate. The information should be quality assured and readily identifiable as being from an authoritative and standardised source.

**R4.15** All health policies and plans developed by the Department of Health and Children, the HSE and HIQA should be required to contain a statement on how patients, carers and service-users were involved in the development of the policy.

4.3 Open communication with patients following an adverse event

Research in recent years has indicated that significant levels of error occur in healthcare that often result in injury to patients, in large part due to the complex nature of healthcare delivery. The best-known study on this issue, *To Err is Human*, was published by the Institute of Medicine (IOM) of the National Academy of Sciences in the United States in 2000. The report claimed that 4% of patients incur adverse outcome of treatment and that between 44,000 and 98,000 Americans die each year from preventable errors in hospitals. According to estimates from the IOM report, healthcare errors are the fifth leading cause of death in the US and result in annual costs of up $29 billion. Although there are no available statistics for Ireland in this context, it must be assumed that the rate of preventable error in Ireland match those described above.
As a result of the above-mentioned study and others which demonstrate similar statistics, there is now an increased focus in many jurisdictions on the issue of patient safety. There are a number of definitions of adverse events in common usage in Ireland and elsewhere. For example, the World Health Organisation defines a patient safety incident as an event or circumstance which could have resulted, or did result, in unnecessary harm to a patient. Incidents may arise from both unintended and intended acts. WHO defines an adverse event as an incident which results in harm to a patient. Harm implies impairment of structure or function of the body and/or any deleterious effect arising therefrom. It includes disease, injury, suffering, disability and death and may thus be physical, social or psychological (WHO 2007).

4.3.1 Patients’ experiences of patient safety events

The Commission considered research studies conducted in relation to patients’ experiences of patient safety. Although these studies were carried out in other countries, their findings are illustrative of patient concerns in relation to patient safety events and what patients say they would like to happen in the aftermath of such an event.

In one survey of patients about their experiences of patient safety events while in hospital, 39% reported that they had experienced at least one of seven listed concerns during their hospital stay, most commonly medication errors (17%), nursing mistakes (15%), problems with medical equipment (10%), misdiagnosis (10%) and mistakes by physicians (10%) (Burroughs et al 2007). Another study reveals that patients consider factors such as: physicians not having enough time with patients; overwork, stress or fatigue on the part of health professionals; failure of health professionals to work together or communicate as a team; and understaffing of nurses in hospitals to be the most important causes of patient safety events/medical errors (Blendon et al 2002).

Focus group studies indicate that patients experience physical, emotional and financial trauma following an adverse medical event (Duclos et al 2005; Gallagher et al 2003). Patients describe having a variety of emotional responses after a patient safety event. Hearing that a patient safety event occurred commonly makes patients feel sad, anxious, depressed or traumatised. They fear additional errors, may be angry that their recovery has been prolonged, and are frustrated that the error was preventable. Patients reported being especially disturbed about patient safety events they thought were caused by practitioners being careless (Gallagher et al 2003).

Focus group studies also suggest that the emotional trauma experienced by patients varies according to the communication process with their healthcare providers. For example, one study observed that participants who experienced what they felt was good communication (respect, active listening and caring) with their healthcare provider experienced less emotional trauma. Participants described the importance of having information to help them to cope with the adverse medical event but highlighted that they often had great trouble obtaining it (Duclos et al 2005).
4.3.2 Expectations of patients in the aftermath of a patient safety event

Disclosure
Studies indicate that patients and families want disclosure following a patient safety event. In one study of six focus groups with 52 adult patients, a unanimous desire was expressed to be told about any error that caused them harm (Gallagher et al 2003). However, the study group had mixed opinions about whether they should be told about near-misses. Some patients thought that hearing about a near-miss would alert them to what errors they should watch for and would reassure them that the systems to prevent errors from reaching patients were working. Other patients thought that hearing about a near-miss would be upsetting as it might spark fears of what might go wrong in the future.

Other surveys on this topic reveal similar mixed opinions. For example, over 90% of patients in one study were of the opinion that patients should always be told if an error is made even if the patient is not injured or harmed (Mazor et al 2004). However, another study highlighted that certain patients would only want to know about a mistake/error if it could or did affect their health (Hobgood et al 2002).

Information requirements
Research suggests that patients have specific information requirements following a patient safety event such as: an explanation of what happened, how and why it happened (Bismark et al 2006; Espin et al 2006; Gallagher et al 2003; Mazor et al 2004); the implications for their health (Hingorani et al 1999; Hobgood et al 2002); and how future incidents/errors will be prevented (Bismark et al 2006; Mazor et al 2004).

Apology
Focus group studies highlight that patients may also have a desire for an apology following a patient safety incident (Duclos et al 2005; Gallagher et al 2003). For example, in one study patients indicated that they wanted to know that the practitioner and institution regret what happened to them. They believed that the way an adverse event/error was disclosed to them directly affected their emotional experience after the adverse event/error. Many patients revealed that they would be less upset if the physician disclosed the error honestly and compassionately and apologised. Patients thought that explanations of an error that were incomplete or evasive would increase their distress (Gallagher et al 2003).

Correspondingly, 87% of patients in another study indicated that they would like the doctor to tell them that he or she was sincerely sorry for a medical error (Mazor et al 2004), while 10% of complainants to the Health and Disability Commissioner (HDC) in New Zealand wanted an apology or assurances that someone had accepted responsibility (Bismark et al 2006).
4.3.3 Time of communication

Research indicates that, as a general rule, communication in relation to the adverse event should be conducted as soon as possible after it has been discovered or detected (Hingorani et al 1999; Hobgood et al 2002; Mazor et al 2004). However, one study of patients and families revealed that 23% would prefer to learn about a patient safety incident or error only when the full extent of it is known (Hobgood et al 2002).

4.3.4 The ethics of disclosure

Medical and nursing students are traditionally educated along the dictum of ‘first, do no harm’. However, as the studies outlined above clearly demonstrate, a substantial number of patients suffer injuries due to medical interventions while in hospital. When the causes are investigated it is found that most of such injuries are due to errors and are therefore potentially preventable. Injuries in fact do not represent the full spectrum of errors since most errors do not result in patient injury.

When an error or adverse event occurs, healthcare professionals may be faced with a difficult dilemma in deciding whether and what to tell the patient. On the one hand disclosure is advocated by patients, safety experts and ethicists; yet on the other hand professionals are conscious and fearful of potential litigation. Although such fears are understandable, studies show that error disclosure reduces patients’ inclination to sue. Many patients who believe they have been the victim of incompetent care take legal action simply to find out exactly what happened to them and to prevent recurrence. International evidence shows that the vast majority of patients who are injured by medical errors never sue. Although no approach to disclosure is without risk, there is no evidence to suggest that a policy of open disclosure increases liability.

Over the last two decades there has been growing support in the international literature for the concept that doctors should make full disclosure of medical errors to their patients. As well as enhancing patient safety by the acknowledgement that an error occurred, it is also in keeping with the ethical commitment of honesty to patients. Failure to communicate effectively with patients following errors therefore damages the integrity of the profession. Studies show that openness can decrease the trauma felt by patients following an adverse event and that patients often forgive the medical error when it is disclosed promptly, fully and compassionately and action is taken to make sure it does not happen to another patient.

Disclosure may be seen in five parts: acknowledgement of the event; explanation; expression of remorse; reparation; assurance as to how recurrences will be prevented. It has been suggested that a number of healing mechanisms arise when effective disclosure takes place:
Research indicates that clinicians support disclosure to patients and/or their families following a patient safety incident/adverse event (Finkelstein et al. 1997; Gallagher et al. 2003; Gallagher et al. 2006; Hobgood et al. 2006; Garbutt et al. 2007). A recent survey of US and Canadian physicians revealed that disclosure attitudes were similar in both countries, with 98% of those surveyed agreeing that serious errors should be disclosed and 78% supporting disclosing minor errors to patients (Gallagher et al. 2006b). In another study 99% of surveyed paediatricians endorsed reporting serious errors to patients’ families, while 90% supported the disclosure of minor errors (Garbutt et al. 2007).

Most hospitals and healthcare organisations have an underlying philosophy regarding patient care. Terms such as ‘mutual respect’, ‘trust’, ‘responsibility’ and ‘partnership’ are commonly used to describe the healthcare relationship.

Other jurisdictions have dealt with the issue of open disclosure by legislation or national standards. In the United Kingdom, the National Patient Safety Agency (NPSA) introduced a policy in 2005 called Being Open, which provides guidelines on how to apologise to patients and their families/carer following an error that led to moderate or severe harm or death. The policy does not include near-misses or no-harm events. In 2003 the Australian Council for Safety and Quality in Healthcare introduced a National Open Disclosure Standard which has been implemented across the healthcare system.

There is currently no national open disclosure policy in Ireland. As part of their serious incident management procedures, the HSE operates a policy of informing patients/service-users at the earliest possible time in the event of a serious incident. HIQA is currently
involved in a project with the WHO’s World Alliance for Patient Safety in developing international consensus guidance that will identify best practice for communicating with and supporting patients, their families and clinicians in the aftermath of a patient safety incident.

4.3.5 Barriers to disclosure

Despite theoretical support from clinicians for open communication to patients, a number of studies suggest that this does not always happen in reality. Only 24% of house officers who had been involved in a mistake reported discussing the mistake with the patient or the patient’s family (Wu et al. 1991), while 28% of surveyed emergency medicine residents revealed that they disclosed an error to a patient or family (Hobgood et al. 2005). Parallel national surveys of practising physicians and members of the public in the US revealed that about a third (30%) of respondents in both groups who reported experience with an error had been told of the error by the healthcare professional involved (Blendon et al. 2002).

Clearly, therefore, there are significant barriers to communicating with patients and families after a patient safety event. These have been identified as including the belief that there was no need to disclose an error if the harm was trivial or if the patient was unaware that the error had taken place; belief that certain patients would not want to know about an error and that informing these patients of an error would diminish patients’ trust in their physician (Gallagher et al. 2003). There may be psychological reasons for non-disclosure as acknowledging an error may damage a physician’s confidence and self-esteem, and render him/her less effective. Junior and senior physicians may have different reasons for non-disclosure. Junior physicians may be concerned about their professional advancement while senior physicians may have particular concerns about admitting error because they may fear that this will diminish their authority (Finkelstein et al. 1997).

Fear of litigation has also been identified as an important barrier to disclosure. For example, a survey of US and Canadian physicians revealed that physicians’ individual beliefs about malpractice affected their support for disclosing serious errors. In both countries, physicians who believed that disclosure decreased malpractice risk were considerably more supportive of disclosure (Gallagher et al. 2006b). In addition, physicians who reported that fear of a lawsuit would reduce their willingness to disclose were also less supportive of disclosure. Not surprisingly, fear of medical malpractice litigation was the most commonly cited institutional barrier (77%) to developing and implementing disclosure policies in a survey of US hospital risk managers (Lamb et al. 2003).

A further barrier to disclosure may be a lack of knowledge of how best to proceed in addressing such sensitive issues (Wears and Wu 2002). Twenty-three per cent of surveyed physicians in training revealed that they are uncomfortable disclosing adverse events to patients and families. However, the results imply that they may become more comfortable with such conversations over time (Sorokin et al. 2005). Correspondingly, a majority of
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surveyed physicians in the US (92.9%) expressed a desire for further training in how to handle medical errors (Robinson et al. 2002).

In addition to the challenges posed above, a number of studies also imply that there is a gap between the information patients and/or their families desire and what is actually provided (Chan et al. 2005; Espin et al. 2006; Gallagher et al. 2003 and 2006b). Physicians who may be committed to being truthful with patients also want to put the most positive ‘spin’ on the event as possible. They also want to choose their words carefully when talking with patients about errors. Most often, this careful choice of words involves mentioning the adverse event but not explicitly stating that an error took place (Gallagher et al. 2003).

A quantitative survey of US and Canadian physicians illustrated that there was wide variation regarding what information respondents would disclose. For instance, 56% of those surveyed chose statements that mentioned the adverse event but not the error, while 42% would explicitly state that an error occurred. It also highlighted that some physicians disclosed little information: 19% would not volunteer any information about the error’s cause, and 63% would not provide specific information about preventing future errors (Gallagher et al. 2006b). Similarly, a study of patients and operating room team members (surgeons, nurses and anaesthesiologists) revealed that, although patients more frequently advocated full disclosure (what happened and how), team members preferred partial disclosure (what happened but not how) (Espin et al. 2006).

4.3.6 Conclusions and Recommendations

The Commission considered the research outlined above as well as the submissions received in relation to this issue and is aware of the variance in how organisations currently respond to patients and their families following adverse events. The Commission agreed that the absence of national standards on disclosure hinders the development of open communication policies. It is acknowledged that fear of litigation arising as a possible consequence of disclosure may inhibit healthcare professionals and organisations in this regard. However, the Commission was of the view that, in line with developments in other countries as outlined in the research studies referred to above, such fears may be allayed by a combination of education and training approaches to support healthcare professionals, and appropriate legislation to protect such disclosures being used in the context of litigation. The overriding principle accepted by the Commission is that patients are entitled to expect honest and open communication in relation to adverse events that may have caused them harm.
The Commission therefore recommends the following:

**R4.16** National standards for open disclosure of adverse events to patients should be developed and implemented.

**R4.17** Legislation should be enacted to provide legal protection/privilege for open disclosure. Such legislation should ensure that open disclosure, which is undertaken in good faith in compliance with national standards developed in accordance with the recommendation above, cannot be used in litigation against the person making the disclosure.

**R4.18** Open communication principles, policies and standards should be included in the education curricula of all healthcare professionals and embedded in codes of professional practice.

**R4.19** Specific training and support should be provided on open communication for all healthcare professionals.

**R4.20** Mechanisms should be developed to monitor, evaluate and review the implementation of disclosure standards through patient feedback on the content and quality of the disclosure process as experienced by them.

**R4.21** Research should be undertaken into the impact of adverse events on patients and their families and the findings of such research should be integrated into continuing professional development and ongoing education programmes for all healthcare professionals.

**R4.22** Support and counselling programmes should be offered to patients and families in the aftermath of an adverse event.

**R4.23** Healthcare facilities should ensure as far as possible that the patient has the support of an advocate at the time of disclosure of an adverse event.

**R4.24** Training and support mechanisms should be developed and provided for patient advocates.

**R4.25** As part of the implementation of this Report, a group should be established to lead and ensure the effective implementation of the recommendations in Chapter Four.
Chapter Five
Leadership and Accountability

5.1 Leadership

International evidence and best practice supports the principle that patient safety and quality should be a core principle of healthcare and should not be an add-on to the business of health service delivery. This embedding of patient safety and quality as core to healthcare requires leadership at all levels, from government and national level to frontline delivery services. The Lourdes Hospital Report (2006) stated that many consultants do not understand the concept of clinical governance and do not welcome risk management and clinical audit systems. It stated:

‘...any isolated institution which fails to have in place a process of outcome review by peers and benchmark comparators can produce similar scandals as those which occurred in the Lourdes Hospital. Clinical independence should no longer be interpreted as a licence for arrogance, disregard for patient choice, dignity and need or freedom from accountability.’

In the Bristol Report (2001) the Chief Executive was described as:

‘...both thoughtful and principled in his development of a management system for what was one of the newest and largest trusts in England. He succeeded in meeting the principal obligation of balancing the books. Sadly, a system of separate and virtually independent clinical directorates, combined with a message that problems were not to be brought to the Chief Executive for discussion and resolution, meant that there was power but no leadership. The environment was one in which problems were neither adequately identified nor addressed.’

The Bristol Report stressed that patients are entitled to expect that both the NHS and the hospital in which they are cared for is well led. In relation to leadership it recommended the following:

- The highest priority needs to be given to improving the leadership and management of the health system at every level.
- The role of government in relation to the quality of care is twofold: to manage the health system, and to organise good, comprehensive and independent systems to regulate the quality of healthcare.
- Chief executives of trusts, particularly now that they are legally responsible for monitoring and improving the quality of healthcare, must be supported and enabled to carry out this duty. In particular, all employees, including consultants, must have a similar employment relationship with the trust.
Trust boards must be able to lead healthcare at the local level. Executive directors should be selected on agreed criteria and be appropriately trained. Non-executives should play an active role in the affairs of the trust.

The quality of healthcare should be regulated through bodies such as the National Institute for Clinical Excellence and the Commission for Health Improvement. These bodies should be independent of government. There should be an independent overarching body, the Council for the Quality of Healthcare, to co-ordinate and integrate the activities of these bodies. This Council would report both to the Department of Health and to Parliament.

Although the Bristol Report was written in the specific context of the NHS healthcare system in the UK, it is nonetheless noteworthy in identifying lessons that may be learned in the Irish context. In Ireland, the reports into adverse events mentioned in Chapter Two also highlight local or institutional leadership as instrumental in driving patient safety and quality in healthcare. The Lourdes Hospital Report (2006) stated:

‘Leadership, training and knowledge must be recognised as key elements in every successful hospital’.

5.1.1 The importance of a safety culture

Cultural issues in healthcare have also been identified as a particular barrier to system change. In a negative sense these cultural issues refer to professional and organisational attitudes and behaviour which are typically characterised by resistance to perceived interference with clinical autonomy and managerial capacity, and antipathy towards change. By contrast, the safety culture of an organisation may be described as the product of individual and group values, attitudes, perceptions, competencies and patterns of behaviour that determine the commitment to, and the style and proficiency of an organisation’s health and safety management. Organisations with a positive safety culture are characterised by communications founded on mutual trust, by shared perceptions of the importance of safety, and by confidence in the efficacy of preventative measures.

Efforts are required to improve national, professional and organisational culture to ensure that patient safety culture is understood, promoted and supported at all levels. Experience from other health systems indicates that effective professional leadership is essential in achieving the culture change necessary for the achievement of safe and high quality services. There is a need for leaders and patient advocates for safety and quality at all levels in healthcare, including at national level. International experience indicates that patient safety culture should be measured nationally from time to time and that the assessment of patient safety culture and behaviours should be incorporated into continuous quality improvement processes and professional regulation. For example, the Bristol Report (2001) in the UK stated the following:

A culture of safety in which safety is everyone’s concern must be created. Safety requires constant vigilance. Given that errors happen, they must be analysed with a view to anticipating and avoiding them.
A culture of safety crucially requires the creation of an open, free, non-punitive environment in which healthcare professionals can feel safe to report adverse events and near-misses.

There should be an independent agency to which certain sentinel events are reported so as to be analysed with a view to disseminating lessons throughout the health system.

The culture of blame is a major barrier to the openness required if sentinel events are to be reported, lessons learned and safety improved. The system of clinical negligence is part of this culture of blame. It should be abolished. It should be replaced by effective systems for identifying, analysing, learning from and preventing errors and other sentinel events. An expert group should consider alternatives to clinical negligence, including an alternative administrative system of compensating those who suffer harm arising from medical care.

Incentives for reporting sentinel events should be introduced, whereby healthcare professionals’ contracts would provide that they would be immune from disciplinary action from their employer or professional regulatory body if they were to report a sentinel event within 48 hours. Confidential reporting should be provided for. Failure to report would attract possible disciplinary action.

An approach to safety based on designing safer systems and equipment should be encouraged. Interested parties should collaborate to tackle some of the more persistent causes of unsafe practices.

At trust board level, an executive director should be responsible for putting into operation the trust’s strategy and policy on safety and a non-executive director should provide leadership to promote a culture of safety.

Again, it is acknowledged that some of the specific recommendations in the Bristol Report are particular to the UK healthcare system. However, the general principles underpinning these recommendations should be taken into account in this jurisdiction also. The recommendations of the Lourdes Hospital Report are outlined in Section 2.7 of this Report.

5.1.2 Definitions of leadership

Leadership is recognised as being important in setting the direction of an organisation, developing its culture, ensuring delivery and maintaining effective governance. Good leadership is widely recognised as being central to the delivery of effective healthcare. Leaders change things by firstly examining the current situation, looking ahead to future possibilities and recognising the areas for improvement. They then create a new system or change the system from what it is to what it should be. Definitions of leadership include:

‘…a set of processes that creates organisations in the first place or adapts them to significantly changing circumstances. Leadership defines what the future should look like; aligns people with that vision and inspires them to make it happen despite the obstacles.’ (Kotter 1996)

‘Leadership is an action not a position. Most leadership skills are not innate traits, rather they can be learned.’ (Reinertsen 1998)
'There are a number of qualities which are central to leadership at any level. A leader must be able to inspire and be seen to have integrity. These qualities will develop more easily by someone who works in a team, who learns effectively and who communicates and explains policy. A leader who sees quickly to the heart of a problem will be able to position himself or herself and be able to gauge situations correctly.' (Donaldson 2001)

In the NHS, UK, a leadership qualities framework has been developed which provides a blueprint for effective leadership in the NHS. The framework describes the key characteristics, attitudes and behaviours to which leaders in the NHS should aspire. It has been tested and validated within the NHS and it sets the standard for outstanding leadership in the NHS.

NHS Leadership Quality Framework

(Institute for Innovation and Improvement, NHS, 2003)

Additionally, following the recent critique in the Tooke Report (2007) of failed leadership in postgraduate training in the UK, the Royal College of Physicians recognised the urgent need for educating potential leaders within the healthcare system. It pioneered a highly innovative Masters programme, in collaboration with Birkbeck College, in Medical Leadership, in order to respond to the systemic leadership deficits within the NHS.
5.1.3 International experience

National leadership

Internationally, most systems that have systematically addressed the problem of patient safety and quality improvement have identified an important role for national leadership in the area of patient safety and quality. Key leadership roles at national level for patient safety knowledge, development and learning and promotion of good practice have been assigned, either in a single national agency or a council or forum of existing agencies and offices. For example, in the United Kingdom the National Patient Safety Agency fulfils this function, while in Australia the Australian Commission on Safety and Quality in Healthcare has a similar remit.

The Australian Commission on Safety and Quality in Healthcare was established in 2006 and succeeded the Australian Council on Safety and Quality in Healthcare. The functions of the Australian Commission are to:

- lead and coordinate improvements in safety and quality in healthcare in Australia by identifying issues and policy directions, and recommending priorities for action
- disseminate knowledge and advocate for safety and quality
- report publicly on the state of safety and quality including performance against national standards
- recommend national data sets for safety and quality, working within current multilateral governmental arrangements for data development, standards, collection and reporting
- provide strategic advice to Health Ministers on best practice thinking to drive quality improvement, including implementation of strategies
- recommend nationally agreed standards for safety and quality improvement.

Both of these organisations in the UK and Australia have affiliations with the WHO’s World Alliance for Patient Safety which provides leadership and raises awareness and political commitment to improve the safety of care and facilitates the development of safety policy and practice in all WHO member states.

In the United Kingdom, the Chief Medical Officer and the Chief Nursing Officer have had very high profile leadership roles in the promotion and development of the safety and quality agenda, with the Chief Medical Officer also having an international profile as chair of the WHO Alliance for Patient Safety.

Leadership within the healthcare organisation

In the UK a number of inquiries and reports into some high profile cases and allegations of serious failings in healthcare have been carried out over the last decade. Although there have been significant variations in the particular circumstances surrounding each inquiry, the same explanations for failure are reported time and time again. One of the recurrent
deficiencies is that of inadequate leadership by managers or clinicians, characterised by a lack of vision, an inability to develop shared or common objectives, a management style which can be weak or bullying and a reluctance to tackle known problems even in the face of extensive evidence. Leadership at all levels within the healthcare structure is clearly important in setting the direction of an organisation, developing its culture, ensuring delivery and maintaining effective governance.

Professional leaders within healthcare delivery systems need to ensure safety and quality, lead the professional change in attitudes and behaviours required and ensure dissemination of knowledge and adoption of best practice.

5.1.4 Conclusions and Recommendations

Leadership is critical to achieving the kind of changes that are required in order to improve the whole landscape on patient safety and, for this, certain initiatives in the areas of education, training and research are essential. The Irish health service requires a stream of ambitious, skilled and highly motivated leaders who will contribute to a new dynamism in the health service in the future, with the potential to promote the safety and quality agenda at an accelerated pace.

The Commission recommends the following:

**R5.1** Key leadership roles must be assigned to designated professionals and agencies at national level for the purpose of providing strong clinical leadership to the system in the area of patient safety and quality. This should be achieved by strengthening existing senior professional roles within the system, such as that of the Chief Medical Officer and the Chief Nursing Officer within the Department of Health and Children and/or the creation of new leadership roles within existing agencies such as HIQA and the HSE. Such leadership roles must include advocacy for safety and quality, the development and dissemination of patient safety knowledge and learning and the promotion of good practice.

**R5.2** Universities/Higher Education Institutes, in conjunction with postgraduate training bodies, must design versatile suites of multi-disciplinary education programmes at Diploma, Masters and Doctoral level in Healthcare Leadership.

5.2 Accountability

Individual and system organisational accountability is a key driver for safety and quality. Accountability seeks to identify account-giving behaviour i.e. to whom is someone responsible and for what is he/she responsible? One of the key principles of governance is that there must be clear lines of accountability. Accountability is multifaceted and complex within the health system. There is accountability and ownership at individual, team and system levels and there is accountability to employers, to professional bodies,
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to patients and the public and to the political system. For example, individual clinicians are accountable to their patients, to their professional regulatory bodies and to the healthcare organisations in which they work.

Accountability needs to be clear, concise and cohesive. The overall accountability for any patient’s care is a combination of the:

- professional accountability of clinicians providing the care
- clinical and managerial accountability for ensuring that the systems and processes, and the environment within which the care is provided, are effective and robust
- policy-makers’ accountability for ensuring that the future development of care is evidence-based and meets the needs of the population.

However, it is imperative that clinicians and managers work together seamlessly and effectively to ensure that all of these aspects of accountability are discharged in a complementary way so that the overall patient experience is of safe high quality care.

The Prospectus Report (Department of Health and Children 2003) stated:

To date in Ireland the mechanisms that are central to effective clinical governance have generally been patchy in their development.

There have been a number of reviews internationally of health system safety and quality failures, e.g. the Bristol Inquiry (2001) in the UK, with a common finding that there existed weak systems of leadership, governance and accountability in healthcare (‘no-one was in charge’), with confused lines of responsibility and accountability between professional and managerial staff, and often with parallel lines of responsibility for different professional groups within the one organisation. These inquiries found that there was a lack of clarity of responsibility for patient safety and healthcare quality.

As care becomes more complex and the cross-referral of cases more frequent, care involving multiple clinicians is likely to become more common. This raises concerns in relation to the clarification of roles and responsibilities between different clinicians and teams involved in the care of the patient. It is of crucial importance to the safety of the patient that there is one clinician identified as the clinician responsible for the patient at all times. Patients and their families should be kept informed and able to discuss their care with that clinician. When the care of the patient is transferred from one clinician or team to another, there must be clear identification and documentation of who is responsible for the patient during and after that transition.

Similar findings of weak accountability structures, i.e. a lack of clarity about accountability for safety and quality, have been made in reviews in Ireland e.g. the Lourdes Hospital Report, the report of the Comptroller and Auditor General into the Consultants’ Contract, the HIQA Hospital Hygiene Audit and other recent reviews. All of these reports propose new organisational arrangements to improve clinical quality which incorporate a number of elements including accountability of senior clinicians, management and the institutions.
5.2.1 International experience

Accountability at national level

A common theme in the strategies that have been developed in other health systems to address the question of safety and quality in healthcare is the central importance of a clear system of governance and accountability for safety and quality, resulting in the types of organisational change that are required. A variety of methods to give effect to this prioritisation of patient safety and quality have been employed in other international healthcare systems. These methods include the enactment of legislation to support patient safety and quality of care and the clear identification of those who are accountable for the delivery of safe and high quality healthcare.

The methods include:

- legislation specifying patients’ rights to safety and quality in healthcare
- legislation specifying professional obligations to report adverse events
- legislation placing a duty of quality on healthcare organisations in the UK
- professional regulatory codes of conduct in many countries, including the UK and Ireland
- organisational codes of governance which clearly identify safety and quality as a core objective and which specify the processes by which these objectives will be achieved and how organisational performance in these areas is to be monitored
- the inclusion of safety and quality assurance requirements as part of individual and service level contractual agreements
- nationally agreed standards of governance (as part of licensing or accreditation systems)
- the specific inclusion of safety and quality issues as part of normal business processes (for example, through the setting of organisational performance indicators and targets in the area of safety and quality and the requirement for regular reports via internal and external accountability mechanisms on organisational safety and quality performance).

Accountability within the healthcare organisation

International experience supports the concept that to achieve a clear system of leadership and accountability every individual working in the system should be aware of his/her role and responsibility and there should be a collective focus on the achievement of safe, high quality care. There needs to be modern management capability with the required authority and accountability that achieves sound decision-making at senior management level, allowing for delegated decision-making as close as possible to the level of care delivery and that involves clinicians centrally in the process.

Two distinct issues have to be addressed in this context:

- the responsibility of health service managers to ensure the safety and quality of the systems they manage
- the responsibility and accountability of clinical leaders within the overall management system.
Accountability of health service managers

Descriptions of good governance systems describe paths of accountability that are accessible and robust, with clearly identified roles, responsibilities and reporting relationships, from junior staff through to the chief executive or equivalent. The international literature supports the proposition that boards and chief executives should be accountable for the safety and quality of the service delivered and that therefore they should be actively involved and supportive, and show leadership in the development of governance structures in their organisations. For example, in the NHS chief executive officers and the NHS boards are accountable for the safety and quality of their services. The Health Act 1999 provides that it is the duty of each health authority, primary care trust and NHS trust ‘to put and keep in place arrangements for the purpose of monitoring and improving the quality of healthcare which it provides to individuals’.

In the UK the National Patient Safety Agency recommends that in order to establish and support a clear and strong focus on patient safety in an organisation, there should be an executive board member with responsibility for patient safety, there should be identified patient safety advocates in each directorate, division or department and patient safety should be high on the agenda of board or management team meetings. All staff should participate in developing quality strategies and look critically at processes of care and improve them.

The international experience supports the view that in each organisation someone clearly responsible for safety and quality matters should be nominated at board or senior management level and accountable ultimately to the chief executive officer. The chief executive officer of a healthcare organisation should have the ultimate authority, responsibility and accountability for patient safety and quality of care.

Accountability of clinical leaders

Traditionally, the accountability of professionals was defined in professional terms as accountability to the individual patient and accountability to a professional code of ethics and standards, rather than accountability in system terms. However, this traditional view has been recognised to be inadequate for the requirements of a modern, open health system.

In the UK, in part to support the involvement of clinicians in the management of services, clinical directorates were introduced from 1990 and are now universal across secondary care organisations (Kirkpatrick et al 2007). The response of doctors to these posts has been mixed although there has been a growing willingness on the part of the British Medical Association and the Royal College of Physicians to accept the principle of clinical directorates. Within hospitals, large numbers of doctors took on clinical director roles, leading to the emergence of a new generation of hybrid professional managers. Some research suggests that a minority of doctors have actively engaged with these roles and that this, in turn, helped to enable cost consciousness, performance review, standardisation and evidence-based practice in UK hospitals.
However, most doctors did not and still do not rush to become clinical directors. In some cases existing heads of specialties were simply re-labelled as clinical directors, while in other situations clinical directors emerged reluctantly or were even coerced (Kirkpatrick et al 2007). Recent studies largely confirm this uneven and lukewarm commitment amongst doctors to serve as managers within hospitals in the NHS, and they also point to marked deficiencies in education and training. While there has been some interest in acquiring management skills, including getting to grips with financial and performance management requirements, it has up to now not figured prominently in the education of young doctors. However, in the UK this situation may well change with medical education and training from general undergraduate level to postgraduate level changing to a ‘competency-based’ approach that will, in principle at least, be much more closely aligned to the ‘scientific-bureaucratic’ model of evidence-based medicine, care pathways and clinical guidelines.

In Ireland, the requirement to have senior clinicians involved in management has been recognised in several recent strategy documents including the Prospectus report, the Buttimer report and in the Comptroller and Auditor General’s report on the Consultants’ contract. The Comptroller and Auditor General in his report on the extent to which clinicians have been involved in management to date noted that participation was variable, there was a lack of training and opportunity and there were weaknesses in organisational structure, with no career structure for clinical managers.

Professionals should be accountable for their performance not only to their professional organisations, but also to the organisation in which they work and ultimately to the patients and community which they serve. Contractual and organisational arrangements need to be put in place to give effect to this. The consultant contract negotiations which are ongoing at the time of writing this Report envisage the establishment of a system of clinical directorships within the public hospital system.

5.2.2 Conclusions and Recommendations

The development of a clear system of governance and accountability for safety and quality is of central importance in achieving the culture and organisational changes required for the achievement of a safe, high-performing health system. Ensuring the health system-wide (public and private) development of such a system of governance and accountability requires two areas of policy development. Firstly, national policy direction to the effect that patient safety and quality are identified as core principles of healthcare delivery across all sectors is required. Secondly, over-arching principles which underpin the development of systems of governance and accountability within all healthcare organisations, public and private, should be developed which clearly identify the role and responsibility of all working within that organisation in respect of safety and quality.
The Commission is of the view that patient safety and quality of care must become core principles in healthcare and recommends the following:

**R5.3** Nationally agreed standards of governance must be developed as part of a licensing system. All healthcare organisations must have in place a governance framework which clearly describes responsibilities, delegated levels of authority, reporting relationships and accountability within the organisation. In particular, there must be clear assignment and documentation of responsibility within and between clinical teams involved in the care of individual patients. The governance framework should also include a code of conduct and behaviour for all healthcare workers which should be published and publicly made known to service-users in healthcare facilities through awareness measures such as notice boards, posters, etc.

**R5.4** Professional regulatory codes of conduct (clinical and managerial) must prioritise patient safety as the primary duty of all healthcare professionals.

**R5.5** Organisational codes of governance must be implemented which clearly identify safety and quality as a core objective and which specify the processes by which these objectives will be achieved. Organisational performance in these areas should be monitored, through, for example, the setting of specific organisational performance indicators and targets in the area of safety and quality and the requirement for regular reports via internal and external accountability mechanisms on delivery against those targets. Patients should be provided with an accessible opportunity to contribute to such accountability mechanisms.

**R5.6** There should be a clear system of accountability throughout each healthcare organisation which connects all those with responsibility for patient safety at each level in the organisation through to the Chief Executive of each facility. This reporting relationship should, where appropriate, continue through regional and national levels to the main Board of the organisation.

**R5.7** The Chief Executive within each defined healthcare organisation must be ultimately responsible and accountable for patient safety and quality within that organisation.

**R5.8** A system of clinical directorates must be implemented within all healthcare organisations which should ensure that the clinical director, appointed on a competency basis, would lead and be accountable for all aspects of patient safety and quality of care within the directorate.
At all times during an episode of care, it should be clearly identified and documented who is the responsible clinician accountable for the patient. The patient, and the patient’s relatives or carers, should be informed and be able to discuss his/her care with that clinician. Where a patient moves into a different clinical environment, and the responsible clinician changes for a period of his/her care, there should be a formal handover of information and accountability for the overall care of that patient. This change should be made explicit and be documented, and the patient, along with his/her relatives or carer, should be informed.

Safety and quality assurance requirements must be integrated as part of individual and service level contractual agreements.

5.3 Management and reporting structures

A detailed audit of current governance structures and mechanisms in the Irish health system was not undertaken by the Commission. However, it is nonetheless clear that there is currently considerable variation in the management structures and mechanisms by which governance is exercised in different parts of the health system. The Commission felt that this variation poses particular challenges for the future achievement of effective governance.

5.3.1 Current healthcare delivery structures in Ireland for healthcare governance

The structural issues identified within the current health system which present challenges for the development of sound governance structures include:

- heterogeneity of management and oversight structures
- span of management control between Board oversight and frontline services in certain HSE areas
- need for defined governance structures in primary and continuing care services
- lack of integration structures across the boundaries of care between public and private healthcare, hospital, community, voluntary and primary care services.
Heterogeneity of management and oversight structures

The different mechanisms and management structures for governance in the health system include:

- publicly funded hospitals
- voluntary hospitals with independent Board governance structures
- HSE hospitals (previously health board) under central HSE Board governance with management teams and management processes of varying levels of size and complexity
- HSE primary continuing community care services under central HSE Board governance
- primary care services provided on contract by independent medical practitioners
- other community services funded by the HSE and provided by voluntary agencies through service agreements
- private independent general practice services
- private hospital services
- the governance role of the Department of Health and Children
- the governance role of the healthcare regulatory agencies (e.g. HIQA).

Span of management control between Board oversight and frontline services in certain HSE areas

There is a tension between the requirement for a strong, centralised decision-making structure to ensure national standardisation and consistency of service delivery and the need for appropriate delegation of authority and accountability to frontline services to ensure empowered decision-making and patient responsiveness at local level. As noted in the Prospectus Report (Department of Health and Children 2003), there is a need to ‘balance the tensions between local and national needs, between specialist knowledge and external oversight, between political and managerial imperatives’.

To address this, the Prospectus Report recommended that:

‘to assist coordination of activities there is a need to develop local structures, close enough to the customer so as to provide a responsive, patient-centred service which is supported by strong policy guidance and executive oversight functions. The ability of local care teams and services to respond quickly and well to the needs of patients is directly related to the efficiency and quality of support they get from the system as a whole.’

In respect of the former Health Board hospitals, the Prospectus Report envisaged that:

‘...existing major health board hospitals be brought under the remit of the National Hospitals Office (NHO), with their own legal identity and governance structures. The objective will be to ensure an integrated management structure for the hospital sector and clear governance arrangements between the NHO and the hospitals.’
The HSE structure as currently configured does not include these structural features. This gives rise to a situation where there is a very long span of governance and management control within certain HSE services. As a consequence, individuals in managerial roles have accountability without necessarily the authority to make decisions.

**Need for defined governance structures in primary and continuing care services**

Although the focus on governance is often on the acute hospital sector, in fact most healthcare is actually delivered in the community and primary care setting and there is clearly at least an equal need to develop appropriate governance mechanisms for these care settings. However, there are obvious difficulties in the Irish system because much of the care is delivered by individual practitioners or small group practices, through local community care offices and through service agreements with independent providers, rather than through easily defined ‘healthcare organisations’.

**Lack of integration structures across the boundaries of care between public and private healthcare, hospital, community, voluntary and primary care services**

A great deal of modern healthcare is multi-disciplinary in nature and patients frequently have to move between different healthcare providers in accessing care. Providing patient-centred, seamless care requires robust integration mechanisms and strong governance arrangements which ensure that patients receive safe and high quality care where different aspects of their care are provided across different providers.

Consequently, it is fundamental that the governance arrangements across the system enable a connected and integrated approach at local, regional and national levels which ensures that good governance is in place and that learning occurs and is disseminated effectively. It should be the responsibility of all healthcare organisations to ensure that their governance arrangements specifically address this aspect of service provision.

**5.3.2 International experience**

The international literature about investigations of health system failures and safety and quality in healthcare relates predominantly to care in the hospital settings, with some notable exceptions such as the Shipman Inquiry in the UK, and many of the concepts concerning governance already described are most easily applied to this setting. However, in the UK, for example, governance structures for primary care have been established under the primary care trusts which like the acute and specialist trusts, have a responsibility and duty for patient safety and quality of care.

The international patient safety literature clearly identifies that many healthcare errors arise when patient care crosses boundaries of care, such as between hospital and primary care services or between two different disciplinary providers of care. Such errors typically arise because of failures in communication, lack of protocols for care handover, differing systems of care provision between providers and lack of clarity about where responsibility and accountability for patient care lies in such situations.
5.3.3 Conclusions and Recommendations

The governance arrangements across the system should enable a connected and integrated approach at local, regional and national levels which ensures that good governance is in place and that learning occurs and is disseminated effectively. It should be the responsibility of all healthcare organisations to ensure that their governance arrangements specifically address this aspect of service provision.

The Commission recognises that the governance structures which will be required of hospitals and other healthcare facilities, to fulfil the licensing requirements proposed in Chapter Six of this Report, may vary depending on the nature and extent of the services being provided. As a minimum the Commission recommends the following:

R5.11 A Board of Management should be established close to the point of delivery of service to govern the activities of a facility or a networked group of facilities. It should have a code of governance which sets out its role and responsibilities including an oversight role in respect of the safety and quality of health services provided at the facility.

R5.12 The Board of Management of each facility must include representatives of the medical, nursing and other professions involved in the provision of services at the facility and lay people who would represent the interests of patients, carers and the public.

R5.13 The Chief Executive, or equivalent, of an organisation must report to the Board of Management on patient safety and quality of care. Where the organisation is part of the HSE, its Chief Executive will also report to the Chief Executive of the HSE.

R5.14 A senior Clinical Leader at Clinical Director level, or equivalent, should be formally appointed and have delegated responsibility and accountability for patient safety and quality throughout the organisation. He/she must report to the Board on all aspects of safety and quality including the facility’s compliance with mandatory standards on medical and nursing services, infection prevention and control, medication safety and systems of audit including clinical audit.

R5.15 The Board of Management of a facility should meet at least once a month and at any other time when called upon by a majority of its members or the licensing authority to meet and deal with any significant issue of patient safety arising at the facility.
R5.16 The Board must review, on a regular basis, the systems of governance, including risk management and audit, relating to healthcare safety, quality and performance. This should include:

- the delivery of clinical services including clinical audit activities
- mandatory standards and key performance indicators applicable to the services provided by the facility including hygiene and infection prevention and control
- policies, procedures and behaviours relating to communications with patients and their families
- adverse events, complaints, claims and near-misses
- information on waiting times across key service areas
- financial and budgetary management aligned to the provision of safe, high quality care.

The patient experience of the quality of care provided has to be ascertained as part of this review process.

R5.17 As part of the licensing framework, a clear legal duty should be imposed on the Board of Management of each facility or group of facilities to put and keep in place arrangements for the purpose of monitoring and improving the safety and quality of healthcare. A similar statutory duty should be placed on the Chief Executive and Board of the HSE to ensure that all the Boards under its remit are complying with these requirements.

5.4 Education, training and research on patient safety

The interaction between patients and healthcare professionals is at the core of health service delivery. Clearly the safety and quality of healthcare is dependent on the knowledge and competence of the people delivering it. The effective training, recruitment, retention and professional development of healthcare professionals are key elements of a safe, high quality healthcare system. An evidence base is essential for improvements in patient safety, but there is a dearth of research on patient safety issues in Ireland.

Modern healthcare is extremely complex and is delivered in a dynamically changing environment. This presents challenges at every level within the system to ensure that there is a modern, competent health workforce which is fit for purpose and provides the patient with appropriate care, delivered by the ‘right’ person in the ‘right’ environment. International experience emphasises the importance of education, training and professional development in achieving culture change and the contribution good research can make. In the past, the problems of patient safety and quality assurance have received little attention in professional training at undergraduate and postgraduate levels. Furthermore the nature of healthcare is changing with the huge increase in medical knowledge and with the introduction of new types of work, new types of organisations and settings, new multi-
disciplinary teams and new relationships between patients and clinicians. This poses a number of significant challenges for professional education and training at undergraduate and postgraduate levels as well as pointing up the need for much dedicated research in the area of patient safety.

Higher Education Institutions need to develop agreed national core curricula at undergraduate and postgraduate levels in patient safety. Suites of generic modules, diploma, masters and doctoral level courses need to be designed to provide the appropriate level of knowledge, skills and attitudes that healthcare students and practitioners require for safe, effective practice that will ensure patient safety and protection. Furthermore, because of the paucity of evidence-based research on patient safety issues in Ireland, the Health Research Board (HRB) should prioritise in its research strategy the promotion of high quality research into key topics related to patient safety, in alignment with government decisions that regard this issue as one of crucial national importance.

It is clear that a health professional can no longer be regarded as ‘trained for life’ upon qualification. Instead what is required are systems of lifelong learning and professional development, with regular competence assurance to ensure that there is a workforce of skilled professionals who are fit for purpose, competent in managing patients’ needs, aware of the limits of their own competency and adaptable and capable of responding to changing needs. Continuing professional development (CPD) is a key responsibility of individual practitioners, a core function of training bodies and a crucial component of the professional regulatory reforms e.g. the Medical Council’s Competence Assurance Scheme.

It is also a key issue for employers which should have systems in place to ensure that all professional staff participate in CPD and are provided with adequate time and resources to do so. CPD involves not only the continuous upgrading of clinical skills but also the development of the necessary skills of accessing and appraising evidence, clinical audit and reflective practice, the application of standards and the monitoring of performance against standards.

Patient safety training modules have been developed by a number of organisations and these may be tailored to suit the needs and context in which healthcare professionals are being educated and trained. However, there appears to be little consensus to date on the elements of a core curriculum in this field. One example of a movement towards reaching such consensus is the Patient Safety Education Project (PSEP). This was established in 2006 by international leaders in patient safety to build a core curriculum that can be disseminated throughout all healthcare organisations and evaluated using accepted health services research and education research design and methods. PSEP uses Australia’s National Patient Safety Framework to guide the scope and content of the core curriculum. This framework identifies skills, knowledge and behaviours/attitudes to guide patient safety education for healthcare workers at all levels. The plan is to teach teams of doctors, nurses and administrators to become trainers who will then go back to their institutions and teach patient safety, using the core curriculum and adapting the material to suit their particular organisation’s work culture.
The main features of the core curriculum suggested by PSEP are as follows:

- the case for patient safety – the magnitude of the problem; the role of progress in increasing complexity and risk; the challenge of changing culture
- law and other external influences including government, media, insurers, educators and consumers
- conceptual framework of patient safety – limiting blame; systems thinking; transparency and learning; culture and professionalism; accountability; team work; trustworthiness; high reliability design; safety sciences
- how to teach and implement patient safety
- applying human factors design to patient safety
- communicating effectively with patients and carers – consent; communication of risk; cultural awareness and respect
- understanding teamwork and resolving conflicts
- organisation and culture
- impact of technology on patient safety
- effectively engaging patients and families as partners in care
- leadership for safety
- methods for improving safety; root cause analysis; quality improvement methods
- rapid response teams to recognise and treat potentially unstable patients
- particular issues in intensive care units; emergency departments; palliative care
- specific risks, including pressure ulcers; falls; surgery; infection control; medication safety.

5.4.1 Conclusions and Recommendations

The Commission strongly emphasises the need for enhanced education and training on patient safety at all levels of healthcare: undergraduate teaching, postgraduate training, continuing medication education and professional development, and effective safety induction for all healthcare workers. The Commission supports the introduction of competence assurance schemes for all healthcare professionals. Such an innovation recognises the necessity for lifelong commitment to ongoing education and training, peer review and clinical audit.

Training at undergraduate and postgraduate levels must allow for a much broader definition of professional competence, with far greater priority accorded to training in the non-clinical aspects of care: communication skills, multi-disciplinary team skills, education about the
principles and values underpinning the organisation in which professionals work, how care is managed and the skills required for management; and the curricula should be reviewed accordingly by the bodies responsible.

The Commission recommends the following:

**R5.18** All healthcare facilities must provide pre-employment mandatory induction training for all healthcare workers that specifically includes patient safety modules (including the reporting of adverse events). Refresher patient safety training should be provided on a regular basis.

**R5.19** There should be a strong emphasis on safety and quality in the training and education of healthcare professionals. All bodies responsible for the training and continuing development of healthcare professionals should review their curricula to ensure that patient safety and quality, including technical and human factors, is incorporated into the modules.

**R5.20** There should be an active research programme on patient safety and quality issues in healthcare for Ireland.

**R5.21** Education and training suites and modules on patient safety should be developed and implemented in collaboration with the professional regulatory and training bodies and relevant stakeholders at undergraduate and postgraduate levels for all healthcare workers.

**R5.22** The development and implementation of Competence Assurance Schemes by professional regulatory and training bodies should integrate patient safety education and training modules as part of their core elements.

**R5.23** Consideration should be given by the professional regulatory bodies to the development of a means by which patients may be enabled to access information relating to the maintenance of professional competencies by healthcare professionals.
5.5 Skilled professionals in management

Patient safety, quality and the provision of patient-centred services should be at the core of health service delivery and this applies to organisational management processes as well as to clinical services. This has clear implications for the professional ethos, knowledge base, skills and competencies required of modern health service management. The professional nature of health service management has been formally recognised in other systems such as the NHS and in Australia.

International evidence has shown that professionals should be accountable for their performance not only to their professional bodies but also to the organisation in which they work and ultimately to the patients and community which they serve. Clinicians need to be integrated into senior management levels as this supports the desired culture change in healthcare. Contractual and organisational arrangements can be put in place to give effect to this through the introduction of a system of clinical directorates with clearly defined accountability and reporting relationships.

It is important that the managerial skills, change management skills and competencies required of clinicians with managerial responsibilities are specifically recognised and the appropriate training, coaching and mentoring supports provided.

5.5.1 Human resources management

Modern and effective human resource management strategies are required to ensure the recruitment, retention and development of managerially and professionally talented people who are committed to and capable of delivering on the quality agenda, able to embrace change and able to work individually or in teams towards agreed organisational objectives. Human resource strategies for the healthcare workforce should be developed to address the issue of workforce capacity in terms of workforce planning, recruitment and retention and training and development needs, assessment of need and horizon scanning, supervision and training of junior staff and the quality of working life for those involved in the health services.

5.5.2 Conclusions and Recommendations

The Commission concluded that creating a healthcare system that functions with a high level of governance and professionalism and that supports safety and quality of care will require strong management capability at all levels.

The Commission recommends the following:

R5.24 A specific vocational management training programme should be developed which is aimed not only at producing high quality managers but also at enhancing the management capability of healthcare professionals at all levels of the health system; this programme should also include specific modules on patient safety and quality of care.
R5.25 The competencies required for health service management should be clearly identified and the management team, up to and including the Chief Executive, should demonstrate competence-based training and be subject to ethical and disciplinary codes similar to other healthcare professionals.

R5.26 Appropriate training, coaching and mentoring supports must be provided to develop the managerial skills, change management skills and competencies required for clinicians with managerial responsibilities.

R5.27 Healthcare organisations should put in place human resource processes and strategies which ensure that all professionals employed in the organisation are fully compliant with continuing professional development requirements.
CHAPTER SIX

Organisational and Professional Regulatory Framework

6.1 Definitions and principles of regulation

Regulation may be defined as sustained and focused control exercised by a public agency over activities that are valued by a community, and in healthcare specifically as any set of influences or rules exterior to the practice or administration of medical care that imposes rules of behaviour. It is designed to serve three purposes:

- to improve performance and quality
- to provide assurance that core standards are achieved
- to provide accountability both for levels of performance and value for money.

(Sutherland and Leatherman 2006b)

Regulation is commonly based on three activities:

- direction: communication of expectations and requirements
- surveillance: assessment of performance and compliance with standards, targets and rules
- enforcement: use of positive or negative powers to bring about change.

While regulatory interventions can potentially drive improvements in the performance of those who are the subject of regulation, it has also been argued that it can have dysfunctional consequences by leading to temporary improvements to coincide with inspection and a focus on core standards rather than an aspiration for true excellence. Regulation can also be costly and overly driven by central demands rather than local needs.

Effective regulators should be responsive to the diversity of organisations regulated, should have a wide range of incentives and sanctions at their disposal which are used appropriately, should work with and through other stakeholders in the organisations they regulate, and should require a balance between independence and accountability. The principles of good regulation include the following:

- **Necessity** – Is the regulation necessary? Can unnecessary bureaucracy be reduced? Are the rules and the structures that govern this area still valid?
- **Effectiveness** – Is the regulation properly targeted? Is it going to be properly complied with and enforced?
- **Proportionality** – Do the advantages outweigh the disadvantages of the regulation? Is there a smarter way of achieving the same goal?
- **Transparency** – Have stakeholders been consulted prior to regulating? Is the regulation in this area clear and accessible to all? Is there good back-up explanatory material?
6.2 Standards and licensing

Licensing/licensure
Licensure in healthcare is usually a mandatory process by which a governmental authority grants permission to an individual practitioner or healthcare organisation to operate or to engage in an occupation or profession. Licensure regulations are generally established to ensure that an organisation or individual meets minimum standards to protect public health and safety.

Licensure of individuals is usually granted after some form of examination or proof of education and may be renewed periodically through payment of a fee and/or proof of continuing education or professional competence. Organisational licensure is usually granted following an on-site inspection and evaluation process to determine if minimum health and safety standards have been met.

Maintenance of licensure is an ongoing requirement for the healthcare organisation to continue to operate and care for patients. It usually includes meeting minimum standards in relation to governance. Issues of building and fire safety, including hazardous waste handling, are frequently considered in health facility licensing standards. Continued licensure may be automatically renewed with a payment of a specified fee, assuming no problems have been identified or reported, or the renewal may require periodic inspections and/or submission of documentation.

Accreditation
Accreditation is a formal process by which a recognised body, usually a non-governmental organisation (NGO), assesses and recognises that a healthcare organisation meets applicable pre-determined and published standards. Accreditation is often a voluntary process in which organisations choose to participate, rather than one required by law and regulation.

Accreditation standards are usually regarded as optimal and achievable, and are designed to encourage continuous improvement efforts within accredited organisations. An accreditation decision about a specific healthcare organisation is made following a periodic on-site evaluation by a team of peer reviewers, typically conducted every two to three years.
Accreditation usually involves four distinct components:

- preparation and self-assessment undertaken by the organisation
- accreditation survey undertaken by a team of peers/service-users to validate the self-assessment
- provision of an outcome report and determination of an accreditation award
- continuous assessment.

Certification

Certification is a process by which an authorised body, either a governmental or non-governmental organisation, evaluates and recognises either an individual or an organisation as meeting pre-determined requirements or criteria. Although the terms ‘accreditation’ and ‘certification’ are often used interchangeably, accreditation usually applies only to organisations, while certification may apply to individuals, as well as to organisations.

When applied to individual practitioners, certification usually implies that the individual has received additional education and training, and has demonstrated competence in a specialty area beyond the minimum requirements set for licensure. An example of such a certification process is a medical practitioner who receives certification by a professional training body in the practice of obstetrics. When applied to an organisation, or part of an organisation, certification usually implies that the organisation has additional services, technology or capacity beyond those found in similar organisations.

Inspection

Inspection is a mechanism of ‘external oversight’ where teams of experts make periodic visits to a regulated organisation in order to assess its performance and accreditation status. Many countries have a range of specialised inspectorates for issues such as health and safety, fire, hygiene, etc. Satisfactory inspections often result in certification or registration.

6.2.1 Background to accreditation and licensing

Accreditation programmes have their roots in independent, voluntary initiatives which assessed structural elements of hospital-based care. However, in recent years they have developed into multi-disciplinary assessments of healthcare processes, functions, organisations and networks. The concept of accreditation is generally regarded to have been introduced in the United States in 1917 when the American College of Surgeons established a set of minimum standards for training posts in surgery (Sutherland and Leatherman 2006b). Accreditation is the most commonly used external mechanism for standards-based quality improvement in healthcare.

On the other hand, licensure is usually a mandatory process with minimum standards that must be met so as to prove fitness to provide healthcare services. This distinction...
between accreditation and licensing has eroded over time and some healthcare systems now use the accreditation process as a tool for regulation or as a substitute for licensing (e.g. some states in the US). Even in settings where accreditation remains voluntary, non-participation often results in substantial financial and organisational consequences and is considered to be a competitive necessity.

Licensing of healthcare services in some countries applies only to private healthcare facilities; or the regulations and standards are different for private and public healthcare services – for example, currently in the UK there are different specified standards for public and independent healthcare providers.

6.2.2 Standard setting

Standards communicate the levels of performance that are expected from regulated organisations. Standards help to ensure that regulatory processes are transparent and fair by explicitly describing the criteria on which organisations will be judged. Once knowledge and evidence about ‘best practice’ are translated into standards, assessments are easier to make and are less contestable.

Standards are used widely, often in tandem with other interventions. In various applications they can:

- translate evidence from clinical research into models of ‘best practice’ e.g. guidelines to inform clinical practitioners and patients
- define minimum levels of throughput or ‘volumes’ based on research, regarding the minimum numbers of procedures needed by a unit or individual to maintain expertise and quality of care
- underpin other regulatory interventions, such as accreditation, where inspectors measure performance against pre-defined standards, particularly for organisational structures and processes
- translate policy and strategy into explicit expectations for organisational outcomes
- advise on appropriate adoption of new technologies.

If standards are set in a context of licensing, inspection of the facilities in the organisation applying for a licence is necessary. This inspection does not have to be carried out by the licensing authority but could be done by a different organisation which may be setting the standards accepted as appropriate by the licensing authority.

6.2.3 Current regulation in Ireland

In Ireland there is no licensing system for healthcare facilities or services. However, the establishment of HIQA has further developed the Social Services Inspectorate (SSI) function across Ireland. When fully commenced, this will result in the inspection and registration of designated residential care centres for older people, children and people with disabilities. It will represent a licensing regulatory framework for residential care services across social care, with legal sanctions and powers of enforcement.
In the current Irish context, private insurance companies can also be seen as significant drivers of improvement in patient safety and quality assurance by linking payment for healthcare services to compliance with standards set by independent accreditation bodies, assessing new health technology and assessing the clinical outcomes of services delivered to their members.

Individual practitioners are required to be registered with the Medical Council and certain institutions are required by law to be registered e.g. maternity homes, nursing homes, mental health hospitals/inpatient facilities and child care facilities. A voluntary accreditation scheme has been in operation in recent years, overseen initially by the Irish Health Services Accreditation Board which developed a framework for accreditation of acute care services in Ireland in 2005. This framework detailed the standards required for accreditation and also highlighted what the Board considered to be core/minimum standards for acute services. Since 2007 these functions have been integrated into the functions of HIQA.

Registration of Maternity Homes Act 1934: This Act requires all maternity homes (premises used for the reception of pregnant women) to be registered with the local authority. An application may be refused or a registration may be cancelled if there are concerns about the applicant or the premises. The superintendent nurse must be a qualified nurse or certified midwife. It is prohibited for a person to carry on a maternity home in unregistered premises.

Health (Nursing Homes) Act 1990: Nursing homes must be registered with the health board. An application to register a facility can be refused or an existing registration can be cancelled if there are concerns about the premises, the applicant or the ability to comply with regulations. The registration is for a term of three years.

Child Care Act 1991: All children’s residential centres for children in the care of the health board must be registered with the health board. The health board can refuse to register a centre or can cancel an existing registration if unsatisfied with the applicant because of past convictions or the compliance of the premises with regulations.

Mental Health Act 2001: The Mental Health Commission is an independent statutory body set up by the Mental Health Act 2001. It has two important functions (1) to make sure that mental health services maintain the high standards and good practices set out in the law, and (2) to protect the interests of people using mental health services.

The Mental Health Commission maintains a register of all the centres that it has approved. The term ‘centre’ in this context means a hospital or other in-patient facility for the care and treatment of persons suffering from mental illness or mental disorder. The Mental Health Commission appoints the Inspector of Mental Health Services. The Inspector visits approved centres and makes sure that mental health services are providing quality mental healthcare in line with the law.

Health Act 2007: This Act provided the legislation to establish HIQA, the Social Services Inspectorate (SSI) and the regulation of designated centres. HIQA has incorporated the
Irish Health Services Accreditation Board. The Act deals mainly with the establishment of HIQA, but it also integrates some of the provisions of the Health (Nursing Homes) Act 1990 and the Child Care Act 1991.

In this Act, the term ‘designated centre’ means an institution at which residential services are provided by the HSE, a service provider or a voluntary body. Designated centres include children’s residential centres, nursing homes and centres for persons with disabilities. But in this Act a ‘designated centre’ does not include:

- a centre registered by the Mental Health Commission
- an institution managed by or on behalf of a Minister of the government
- that part of an institution in which the majority of persons being cared for and maintained are being treated for acute illness or provided with palliative care
- an institution primarily used for the provision of educational, cultural, recreational, leisure, social or physical activities
- a special care unit
- a children detention school as defined in Section 3 of the Children Act 2001.

HIQA is responsible for setting standards in health and social services and monitoring healthcare quality. This work covers the health and social services system with the exception of the mental health services. The Authority may undertake an investigation as to the safety, quality and standards of the health services if the Authority believes on reasonable grounds that there is a serious risk to the health or welfare of a person receiving those services.

The Health Act 2007 places the Social Services Inspectorate (SSI) within the Health Information and Quality Authority on a statutory basis as the Office of the Chief Inspector of Social Services, with specific statutory functions. The work of the Inspectorate has been focused on children in care and primarily on inspection of residential care. Within the Authority, its role has been expanded to include the inspection and registration of residential services in the public, private and voluntary sectors for older people and people with a disability.

6.2.4 Regulation of healthcare in other jurisdictions

The United Kingdom

In the UK the regulatory framework for health and adult social care has been fragmented, with different procedures and standards for NHS providers and independent sector providers. The system in place involves a number of regulatory and standard-setting bodies, including the following:

The Healthcare Commission assesses and inspects all registered healthcare services annually to ensure that they are meeting national minimum standards; analyses the efficiency of healthcare spending; provides an independent complaints handling service;
investigates failures in healthcare services and publishes ratings on NHS hospitals and trusts and an annual report on healthcare in England and Wales. The Healthcare Commission also has responsibility for regulating and inspecting the independent healthcare sector. The term ‘independent healthcare’ refers to any private, voluntary, not-for-profit or independent healthcare establishment under the regulatory remit of the Healthcare Commission. These establishments include private acute and mental health hospitals, independent clinics and other establishments providing prescribed treatments such as medical or dental treatment under anaesthesia or sedation, obstetric services and cosmetic surgery.

The Mental Health Act Commission (MHAC) keeps under review the use of the Mental Health Act powers in relation to detained patients and appoints doctors and others where required by legislation for the authorising of treatment.

The Commission for Social Care Inspection (CSCI) currently regulates adult social care services.

The Audit Commission ensures that public money is spent economically, efficiently and effectively across many public services.

Monitor is the independent regulator of NHS Foundation Trusts.

The National Institute for Health and Clinical Excellence provides patients, health professionals and the public with authoritative, robust and reliable guidance on current ‘best practice’, using teams of experts to review health interventions and technologies.

Standards setting in the UK healthcare services
The Department of Health, UK, sets national standards through ‘Standards for Better Health’ and the National Service Frameworks. ‘Standards for Better Health’ (2004), sets core and developmental standards for all organisations providing services to or for the NHS.

The National Service Frameworks (NSFs) are long-term strategies for improving care for identified conditions such as coronary heart disease and diabetes. An external reference group brings together professionals, service-users and carers, health service managers and partner agencies to develop the frameworks.

Developments in the UK regulatory process
The UK government is now proposing a new system of regulation for health and social care involving the establishment of a new regulatory body, the Care Quality Commission which will build on the models developed by the existing regulators (Department of Health UK 2007a).

It is anticipated that, following consultation, service providers currently regulated by the Healthcare Commission or the Commission for Social Care Inspection will be required to be registered, including NHS trusts, NHS foundation trusts and primary care trusts, as
well as independent sector healthcare providers and providers of adult social care. NHS primary care is not currently regulated by the Healthcare Commission. A consultation process is expected to review this position.

Canada

In the Federal State of Canada, the Constitution Act 1867 states that provinces are responsible for the ‘establishment, maintenance and management of hospitals’. This responsibility extends to other types of health facilities such as long-term care facilities. The phrase ‘maintenance and management’ includes responsibility for regulating the quality and thus the safety of the health services, whether these services are funded by the government or not.

However, the regulation of hospitals is not uniform across Canada. Most provinces do not require that public hospitals are licensed, with some provinces only requiring that private hospitals are licensed. Private hospitals generally, although not exclusively, provide health services that are not covered by Medicare e.g. cosmetic surgery. Some provinces use law to regulate facilities (for example, British Columbia regulates private hospitals), whereas other provinces (e.g. Alberta) regulate types of services i.e. surgical facilities, private or public.

The licensing procedure, for example in British Colombia, is usually based on structural criteria and the character and fitness of the applicant and licences are usually granted for one year and can be revoked for cause. Provincial governments can also make regulations that ensure basic minimum standards. For example, in Alberta, this has been legislated for in the Health Facilities Review Committee Act which stipulates that the committee must inspect all approved acute care and ancillary care hospitals, nursing homes, mental health hospitals and special care centres. If a major concern is identified the committee will bring it to the attention of the provincial minister of health and welfare.

Some provinces require that the facilities be accredited. For example, in Quebec every institution must have the health and social services it provides accredited by a recognised accreditation body and should create a risk and quality management committee.

Australia

In Australia, a federal state, regulation of institutions is generally a function of the states and territories, with the exception of residential care for the aged which is primarily financed and regulated by the federal government. The management and ownership of public hospitals is the responsibility of individual states, while major public health and primary care issues are led centrally. In regulatory terms, Australia relies upon professional self-regulation and state health departments to ensure quality; there is no independent quality regulator per se.
The primary mechanism through which states secure quality is licensing. Hospital licensing of public and private hospitals is done by the states under their legislative arrangements. Private hospitals and day procedure centres are licensed throughout Australia. The Private Health Facilities Act 2007 will see a continuation of the licensing and regulatory framework but with the removal of the licensing distinction between private hospitals and day procedure centres. The licensing standards will be provided for by way of regulation rather than by third party accreditation and there is to be consultation with stakeholders regarding the standards.

The Director-General of Health may suspend a facility’s licence if, as a consequence of a breach of a licensing standard, there is a substantial risk to patient safety. Authorised officers will be permitted to enter and inspect any premises for the purposes of determining whether there has been a contravention of the Act, the regulations or a licence condition. Under the current Act, officers may only enter licensed premises or premises that are the subject of an application, that is, there is no right to enter premises which officers reasonably believed were operating as an unlicensed private hospital or day procedure centre.

Authorised officers may issue ‘improvement notices’ which require the licensee to take the action specified in the notice within a specified period for the purpose of ensuring that the licensee complies with this Act, the regulations or a licence condition. Individual directors or managers may be prosecuted for an offence under the Act if individual directors and/or managers knowingly permitted the breach to occur.

**New Zealand**

The regulation of institutions in New Zealand is legislated for by the Health and Disability (Safety) Act 2001. This applies to institutions that provide hospital, rest-home (long-term care), and residential disability services. Healthcare providers cannot operate without certification (licensing) under this Act. In order to obtain certification, a provider must comply with the requirements of this Act and to the subsidiary standards set out in the Health and Disability Sector Standards 2001. The standards set minimum safety levels and encourage continuous quality improvement in six areas: consumer rights, service delivery, managing service delivery, organisational management, pre-entry and entry to services, and safe and appropriate environments. There are additional standards for infection control, restraint minimisation and mental health.

The Director General of Health designates an independent auditor who carries out a certification audit on the facility. The facility will normally receive certification for three years, but it may be for a lesser period if there are concerns or for a maximum five-year period if the facility has shown continual improvement.
**Netherlands**

Dutch law clearly defines the responsibility of healthcare organisations for the quality of organisational aspects and the responsibility of healthcare professionals for the quality of the care they provide. The legislation applies to all healthcare ‘facilities’, which includes not only ‘institutions’ but every ‘collaborative of healthcare professionals working together to deliver care’ i.e. to hospital-based specialist groups and to GP group practices.

The Netherlands Healthcare Inspectorate is an independent regulator which regulates providers to ensure quality, and has powers to take appropriate remedial action. It can report on request and at its own initiative to the Minister of Health, Welfare and Sport. If there is concern about the poor quality of care delivered by a collaborative medical group (or facility), the Minister of Health may send a written enactment to the medical practice stating what action should be taken or, in a serious case, the Inspectorate may send an order to cease practice with immediate effect.

The independent regulators are supported by a licensing regimen operated by the Ministry of Health, Welfare and Sport, which sets minimum standards. Licensees must demonstrate governance procedures and appropriate access to emergency care. In addition, the legislation requires institutions to have in place systems to collect data so as to measure and improve the quality of patient care, and they should involve patients in this process. Institutions must report annually to the Ministry of Health, the Healthcare Inspectorate and the regional representative organisation of patients on their quality management activities.

The purpose of the legislation is to promote and monitor quality in the field of healthcare and to protect patients against the possibility of incompetent or negligent professional care. It also offers the protection of a range of professional titles, e.g. medical doctors, dentists and pharmacists, and lists ‘reserved procedures’ which can only be performed by entitled and competent professionals. All reserved procedures are medical procedures e.g. surgical and obstetric procedures, anaesthesia and artificial insemination.

**The United States of America**

Licensing and the imposition of standards varies across the United States and the Commission studied a number of states. New Jersey is highlighted here by way of illustration.

**New Jersey State**

In New Jersey the Division of Health Facilities Evaluation and Licensing ensures that the citizens receive quality healthcare at the appropriate level of care in regulated facilities.
To accomplish this, the division:

- regulates a wide range of healthcare settings for quality of care, such as hospitals, nursing homes, assisted living residences, ambulatory care centres, home healthcare, medical day care and others
- licenses nursing homes and certifies assisted living administrators
- certifies nurse aides, including performing background checks
- provides consumer information in the form of report cards and other performance information.

In New Jersey, as part of the regulatory process, a certificate of approval must be granted by the authorised state agency to a healthcare provider (where state law warrants such pre-approval), stating that the need for a particular facility or service in the proposed location is deemed by the state to be warranted and that the proposed facility meets the needs of those for whom it is intended.

An application for a licence or change in service may be denied if the applicant cannot demonstrate that the premises, equipment, personnel, including principals and management, finances, rules and bylaws, and standards of healthcare are fit and adequate and that there is reasonable assurance that the healthcare facility will be operated in accordance with the standards required by these rules. The Department of Health shall consider an applicant’s prior history in operating a healthcare facility either in New Jersey or in other states and any evidence of licensure violations as well as any record of criminal convictions representing a risk of harm to the safety or welfare of patients in making this determination.

The New Jersey State Department of Health may impose a fine, cease admissions to a facility, order removal of patients from a facility, revoke or suspend a licence, order closure of a service or unit within the hospital and/or impose other lawful remedies. Individual licences shall not be required for separate hospital buildings and services located on the same or adjoining grounds, if these are operated under one management. All off-site ambulatory care service facilities (including mobile units) must be licensed to operate. All general hospitals applying for licensure have to provide specified professional departments, services and facilities e.g. Emergency Department, Infection Control and Sanitation, Medical Staff, Nursing Service, Pharmacy Department, Quality Assurance.

A summary of licensing arrangements in other jurisdictions is presented in table format on the next page:
**Table: International Examples of Licensing of Healthcare**

<table>
<thead>
<tr>
<th>Licensing/Registration system for Healthcare Organisations</th>
<th>United Kingdom</th>
<th>Canada</th>
<th>Australia</th>
<th>New Zealand</th>
<th>Netherlands</th>
<th>United States of America (New Jersey State)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes New system of registration currently being introduced</td>
<td>Yes</td>
<td>Not consistently required across the Provinces – more commonly required in the private sector but also required in some public hospitals</td>
<td>Yes Licensing of hospitals at State level</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes No consistent requirement for licensing across States</td>
</tr>
<tr>
<td>Sectors requiring Licensing/Registration</td>
<td>Registration will apply to both public and private/ independent sector</td>
<td>Public and private sectors but not in all Provinces</td>
<td>Public and private sectors</td>
<td>Public</td>
<td>Public and private sectors</td>
<td>Public and private sectors</td>
</tr>
<tr>
<td>Licensing/Registration of Healthcare Providers</td>
<td>United Kingdom</td>
<td>Canada</td>
<td>Australia</td>
<td>New Zealand</td>
<td>Netherlands</td>
<td>United States of America (New Jersey State)</td>
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<tr>
<td>NHS Trusts, Foundation Trusts and independent providers</td>
<td></td>
<td>If required hospitals and long-term care and residential care facilities</td>
<td>Private and public hospitals and day care centres</td>
<td>Hospitals, long-term care and residential disability services</td>
<td>All healthcare organisations/facilities. Facilities includes all institutions and collaboratives of healthcare professionals working together e.g. groups of GPs</td>
<td>Hospitals – acute and long-term care/rehab residential healthcare facilities, nursing homes, ambulatory care facilities</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Licensing/Registration of Acute Hospitals</th>
<th>Yes</th>
<th>Yes</th>
<th>Yes</th>
<th>Yes</th>
<th>Yes</th>
<th>Yes</th>
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</thead>
<tbody>
<tr>
<td>In some provinces</td>
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</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Licensing/Registration of Residential/Long-stay Healthcare Institutions</th>
<th>Yes</th>
<th>Yes</th>
<th>Yes</th>
<th>Yes</th>
<th>Yes</th>
<th>Yes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Licensing more widespread but still not in all Provinces</td>
<td></td>
<td></td>
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<tr>
<td>Yes Must meet Commonwealth Quality of Care Principles (Standards)</td>
<td></td>
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<td></td>
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<tr>
<td>Licensing/Registration of Primary Care</td>
<td>United Kingdom</td>
<td>Canada</td>
<td>Australia</td>
<td>New Zealand</td>
<td>Netherlands</td>
<td>United States of America (New Jersey State)</td>
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<tr>
<td>Registration to be introduced – currently undergoing consultation process</td>
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<td></td>
<td>Yes</td>
<td>GP group practices</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Compliance Criteria – Minimum/Core Standards</th>
<th>United Kingdom</th>
<th>Canada</th>
<th>Australia</th>
<th>New Zealand</th>
<th>Netherlands</th>
<th>United States of America (New Jersey State)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes New standards to be developed (based on ‘Standards for Better Health’)</td>
<td>Yes Hospitals – structural criteria and fitness of applicant. Some Provinces require hospitals to be accredited. Residential care – structural criteria include number of patients, some standards for hygiene and safety</td>
<td>Yes Private hospitals must meet standards. Aged care institutions must meet Commonwealth Quality of Care Principles (Standards)</td>
<td>Yes Standards Set minimum safety levels and encourage continuous quality improvement</td>
<td>Yes Minimum standards including demonstrating governance procedures and appropriate access to emergency care</td>
<td>Yes Vary by state but in New Jersey minimum standards</td>
<td></td>
</tr>
<tr>
<td>Compliance Criteria - Developmental Standards</td>
<td>United Kingdom</td>
<td>Canada</td>
<td>Australia</td>
<td>New Zealand</td>
<td>Netherlands</td>
<td>United States of America (New Jersey State)</td>
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</tr>
<tr>
<td>New standards to be developed</td>
<td>Yes</td>
<td></td>
<td>Yes</td>
<td>Continuous Quality Improvement in six areas: – consumer rights – service delivery – managing service delivery – organisational management – pre-entry and entry to services – safe and appropriate environments</td>
<td>Yes Healthcare organisations should monitor and improve the quality of care</td>
<td>Yes Vary by State but funding for facility can be deemed approved if facility accredited</td>
</tr>
</tbody>
</table>

| Evaluation Process - Self assessment | Yes | Yes | Yes | Yes | Yes | Yes |

| Evaluation Process - Inspection | Yes | Yes | Yes | Yes | Yes | Yes |

6.2.5 Conclusions

Licensing is usually a mandatory process by which a governmental authority grants permission to a healthcare organisation to operate or to engage in an occupation or profession. Different terms e.g. ‘licensing’, ‘registration’ are used in different countries to identify the same process of mandatory registration, with minimum standards allowing a provider to operate, and this can cause confusion. In this Report, the regulatory process including any licensing/registration and accreditation is described for each of the selected countries.

Although regulation has been in place for decades in the United States, studies of the effectiveness of regulation on the quality of healthcare are of low quality. As regulation in its different forms is widespread it is difficult to have control situations, i.e. where regulation is not in place, or to identify which regulatory interventions are effective. However, in general other jurisdictions seem to be moving in the direction of more regulation in healthcare, both at an individual level and at institution level. In the United States, Medicare and Medicaid deem accreditation as meeting their conditions for participation and therefore release of funds. This, in effect, means that through accreditation the services are licensed.

Australia also has a federal structure, with different states determining their regulation of healthcare facilities. Many states, for example New South Wales, have a system of regulation that involves regulation of private healthcare facilities and long-term care services. Again, accreditation is common in Australia. In Canada the provinces are responsible for the establishment, maintenance and management of hospitals and long-term care, but the regulation of these facilities varies. Some provinces require their hospitals to have licences. Some only require private hospitals to have licences. For example, British Colombia and some provinces require their facilities to be accredited.

Currently in the UK the Department of Health’s Standards for Better Health (2004) are used by the Healthcare Commission in its Annual Health Check for healthcare services. These standards are made up of core and developmental standards. Meeting the core standards is not optional and healthcare organisations must comply with them. The Healthcare Commission also monitors the private/independent healthcare sector, using a separate set of standards under the Care Standards Act 2000. However, the UK is currently undergoing reform in relation to its regulatory functions in healthcare. A new regulatory body that will encompass social and health regulation – the independent Care Quality Commission – is being created. It is proposed that this new body will be established in 2008 and will take over the regulatory functions in early 2009. In the health and social care sector, assurance will be strengthened by using a common system of registration, compliance and enforcement that will apply equally to NHS and independent sector providers. For the first time the new regulator will be able to close NHS services, as well as those provided by the independent sector and adult social care, if they are a threat to the safety of patients or service-users.

The research evidence about the impact of regulatory interventions, including licensing and accreditation, on the quality of healthcare is drawn primarily from observational
Building a Culture of Patient Safety

studies i.e. case control and cohort studies. The evidence of the effect of regulation on healthcare is sparse, with no robust evidence of the effectiveness of licensing of healthcare on the quality of the healthcare. However, although there is no available evidence on the effectiveness of licensing on the quality of care, the absence of evidence does not imply the absence of effect. Internationally while there is diversity in methods of regulation, the trend is towards more regulation driven by, amongst other things, the increase in the expansion of private healthcare.

In the view of the Commission, licensing as part of a safety and quality framework will improve patient safety and quality of care. The Commission considers that while licensing itself will be based on core standards, the licence process could be seen to be limited unless quality improvement is embedded in the form of achieving standards higher than the core licensing levels. To obtain the licence, therefore, a health facility will be required to show that it is engaged in a continuous quality improvement process e.g. accreditation.

6.2.6 Recommendations
The Commission was asked to make recommendations in relation to a statutory system of licensing for public and private healthcare providers and services. Having given detailed consideration to the research outlined above in relation to the experience of other jurisdictions, the submissions received and the meetings and presentations from a number of stakeholders, the Commission recommends the following:

R6.1 There should be a mandatory licensing system in Ireland to cover both public and private healthcare providers. It must be an equitable and transparent system, with a review of the licences every three years. It will apply to existing and new bodies, with time being given for compliance.

R6.2 The Mental Health Commission which currently undertakes mandatory inspection of public and private mental health facilities should continue to operate this registration system until the licensing framework has commenced, at which time consideration should be given to whether and how both systems might be appropriately integrated.

R6.3 There should be a licence for hospitals/hospital groups/other healthcare facilities and also service-specific licences within the hospital or facility e.g. radiotherapy, intensive care.
Building a Culture of Patient Safety

R6.4 The licensing system should commence with application to the acute hospitals and other facilities based on analysis of potential risk to patient safety. This list should include facilities where the following treatments are provided:

- medical treatment under anaesthesia or sedation
- dental treatment under general anaesthesia
- obstetric services
- cosmetic surgery
- techniques and technologies such as laser and intense pulse light therapy, hyperbaric oxygen chambers, private dialysis, In Vitro Fertilisation and endoscopies and any others to be prescribed by the Minister for Health and Children.

R6.5 Following the introduction of the licensing framework in the sectors listed above, the licensing system should subsequently be rolled out to other facilities such as primary community and continuing care, following comprehensive consultation with relevant stakeholders in those sectors.

R6.6 Licensing should be linked to compliance with stated standards, enforceable through inspection and imposition of sanctions if necessary. The sanctions should range from warnings, with time limits for compliance, up to withdrawal of licence either for a specific service within the hospital or the hospital itself if required.

R6.7 The licensing system should be self-financing, with a licence fee to be paid according to the size of the facility/number of beds etc.

R6.8 The licensing function should be assigned to HIQA with a provision in legislation requiring it to carry out this function in a manner independent from its other functions so that those responsible for deciding on licence applications do not have any role in the setting or monitoring of healthcare standards to apply to such licences.

R6.9 In advance of the introduction of legislation providing for licensing, HIQA should progress urgently the development of standards on safety and quality to be applied to hospitals and all future licensed healthcare facilities. HIQA should also be asked to commence work immediately on standards in respect of any area where a high and immediate risk to the health and/or welfare of patients or the public is identified. Subject to current legal provisions, arrangements should be put in place by which private healthcare providers would voluntarily adhere to such standards, agree to be monitored and the resulting reports published. Private health insurers should require all private healthcare facilities to adhere to the standards set by HIQA where such standards exist.
R6.10 The licensing authority should work with other regulators across health and social care to ensure that, when other regulators are licensing a service within the same facility, the licensing authority and respective regulator(s) work together to co-ordinate the most effective system to reduce the burden of inspection on the provider and to enhance safety and quality for the users of the service.

R6.11 The regulations that determine the criteria for obtaining a licence should include the following (not an exhaustive list):

- effective governance and management arrangements
- protocols for the transfer of patients to and from other healthcare providers so as to ensure a safe and seamless patient journey
- risk management systems in place
- participation in audit and adverse event reporting systems
- participation in recognised systems of continuous quality improvement e.g. accreditation
- appropriately trained and competent staff
- implementation of evidence-based practice
- participation in continuing medical education (CME) and competency re-validation programmes
- mechanisms for patient participation and feedback
- information management
- meeting health and safety standards
- appropriate structure, equipment and service design.

R6.12 Applications for a licence must demonstrate compliance with specified core standards in order to be given approval in principle. This will be followed by an assessment (including inspection) by the licensing body which in turn will lead to the granting of a licence.

R6.13 The operation of the licensing process should be reviewed through quantitative and qualitative methodology after three years.

R6.14 The impact of licensing on patient safety and quality in healthcare in Ireland should be reviewed through quantitative and qualitative methodology after three years of operation.

6.3 Regulation of healthcare professionals

The common feature shared by professions is that they are special kinds of knowledge-based occupations. The type of knowledge, the social and cultural value attributed to it and the way in which each occupation handles that knowledge are seen as central to both the process of professionalisation and maintaining/extending professional positions.
Another factor that commonly distinguishes health professional groups in particular is the requirement to obtain a licence to practise from the state. In this way health professionals draw a boundary around their knowledge which excludes outsiders. This boundary is usually underpinned by legislation which brings about market control for health professionals in the supply of healthcare.

Self-regulation has traditionally been a typical feature of professional groups, in particular health professions, in most jurisdictions. In this model a governing body is comprised of members elected by the profession as well as a number of members appointed by the government. The governing body carries out a number of functions for which it is accountable to the government. Proponents of self-regulation argue that:

- it offers advantages of bringing insider knowledge to bear on a problem
- self-regulatory regimens are more acceptable to those being regulated, thus promoting compliance
- it is generally of lower cost as it requires less monitoring than direct regulation
- it is more responsive; it allows self-regulatory bodies to act quickly in response to new demands since they do not have to wait for the passing of additional legislation.

However, critics counter that bodies based on self-regulation lack legitimacy, given that they are open to the accusation of protecting self-interest; public accountability can be weak; and finally self-regulation relies on the acceptability of measures to its members, which can mitigate their strength.

Internationally, the role of the health professions in society and their self-regulatory status is changing. This change is driven by a number of trends (Allsop and Saks 2002):

- Public trust in health professions has declined.
- Governments have changed regulatory structures for nursing, pharmacy and allied health professionals, and this in turn has put pressure on the professions of medicine and dentistry which have more established regulatory structures.
- Traditional hierarchies between health professional groupings are being challenged by developments in human resources for healthcare such as multi-disciplinary care and more flexible working arrangements.
- Globalisation of the healthcare workforce, with increased mobility, has challenged the traditional regulatory structures of health professions.

For these reasons, reform of the regulation of health professionals has been an important feature of the policy response to patient safety and quality assurance internationally.

There are a number of objectives in relation to professional regulatory interventions:

- to improve the quality of patient care
- to set standards of clinical competence for practice
- to foster continuing education and development required for excellence over a lifetime of practice
Building a Culture of Patient Safety

- to identify the competence of the individual practitioner
- to reassure patients and the public about the competence of those belonging to the healthcare professions.

(Sutherland and Leatherman 2006b)

Four professional regulatory interventions may be considered:

**Licensure and registration:** Licensure refers to the granting of legal permits to practise to those who can demonstrate appropriate levels of knowledge, skills and competence. Registration refers to the compilation of a list of individuals who satisfy the relevant authority of their qualification to practise. Licensure is the most widely used professional regulatory intervention; almost all countries maintain a register of medical practitioners.

**Certification and recertification:** Certification is an acknowledgement of a level of achievement or performance, recognising achievement that exceeds minimum acceptable standards. Recertification or revalidation is a process that requires the practitioner to maintain/collect evidence that confirms the standard of the practice and to demonstrate continuing competence. Recertification is becoming increasingly popular owing to concerns that the level of performance at certification (often required for licensure) may erode over time. The strengths of certification lie in the way it encompasses objective, summative measures of knowledge, subjective ratings of approval and respect from peers, requirements for ongoing learning, methods for self-auditing of clinical practice and improvement, and information on the competence of individual doctors that is comprehensible to patients.

**Credentialing:** This refers to the systematic collection, review and verification of a practitioner's professional qualifications; it often includes the use of patient-level data to validate clinical activity. It is usually carried out by institutional providers or purchasers of healthcare to select and retain medical professionals of assured quality.

**Privileging:** This is a system that is often used in conjunction with credentialing. It allows medical professionals to undertake certain clinical activities, usually invasive procedures with higher risk. The professional's competence and qualifications to undertake certain procedures is assessed by an expert committee using the data contained in a credentialing system.

(Sutherland and Leatherman 2006b)

6.3.1 Professional regulatory bodies in Ireland

**The Medical Council:** The Medical Council was established by the Medical Practitioners Act 1978 and came into operation in 1979. Its roles include:

- assuring the quality of undergraduate education of doctors
- assuring the quality of postgraduate training of specialists
- registration of doctors
- disciplinary procedures
- providing guidance on professional standards/ethical conduct.
The Council currently maintains two registers:

- The General Register of Medical Practitioners: all doctors who practise medicine in Ireland must be registered.
- The Register of Medical Specialists: this is a voluntary register of medical practitioners in approved specialty divisions who have completed training and require no further training or supervision to practise independently a given discipline. There are a number of routes for inclusion on the specialty register.

In 2006 the Medical Council published a consensus statement entitled *Performance in Practice, Maintenance of Professional Standards*, which sets out three strands to competence assurance:

**Continuing Quality Assurance (CQA)**

- All doctors will be asked to participate in a CQA programme (50 hours per year) and should align themselves with a Post Graduate Training Body (PGTB) where possible.
- Council will monitor doctors who cannot align themselves with a PGTB.
- Doctors should submit evidence of participation in educational activities to their monitoring body.
- Doctors will be encouraged to participate in clinical audit and peer review activities as part of their ongoing education (up to 50% of their annual hourly total).
- Council will formally accredit the PGTB programmes on an ongoing basis.

**Professional practice review**

- A multi-source feedback questionnaire will be used as a quality improvement tool.
- The doctor will nominate medical, non-medical peers and patients to fill out questionnaires.
- A confidential summary of the results will be sent to the doctor.
- The Council will receive a collective statistical report and a confidential copy of the lowest five percentile.

**Performance assessment**

- If concerns are expressed about a doctor, he/she may be asked to have his/her performance assessed.
- The processes, standards, measurement tools and reports are currently being assessed as part of a pilot study.
- A structured assessment will be carried out by two trained peer assessors and one lay assessor.
- Recommendations will be made for individual doctors accordingly.

The Medical Council’s function on disciplinary matters is carried out by its Fitness to Practise Committee. It considers complaints made by the Council or any person into the conduct of a registered medical practitioner on the grounds of alleged professional
misconduct and/or fitness to engage in the practice of medicine by reason of physical or mental disability. Recent reform of the role of the Medical Council set out in the Medical Practitioners Act 2007 is considered in Section 6.3.2.

The Dental Council: This Council regulates dental practitioners under the Dental Act 1985 and has the following roles:

- to establish, maintain and publish a Register of Dentists and a Register of Dental Specialists and to provide for the registration and the retention of dentists’ names in these registers
- to satisfy itself as to the adequacy and suitability of the dental education and training provided in the State’s dental schools and to the standards required at examinations for primary qualifications
- to inquire into the fitness of a registered dentist to practise dentistry on the grounds of his/her alleged professional misconduct or his/her alleged unfitness to practise by reason of physical or mental disability and to take appropriate action. The Council has power, subject in some instances to confirmation by the High Court, to advise, admonish, censure, suspend, attach conditions to registration or erase a dentist’s name from the Register
- to make, with the consent of the Minister, schemes for the establishment of classes of auxiliary dental workers
- to discharge the duties assigned to the Council pursuant to the provisions of EU Dental Directives
- to advise the dental profession and the public on all matters relating to dental ethics and professional behaviour.

The Nursing Board (An Bord Altranais): The Nursing Board was established by the Nurses Act 1985. The Act assigns functions to the Board under the headings of Education and Training, Registration, Fitness to Practise and Miscellaneous. Its roles are:

- to establish and maintain a register of nurses
- to provide for the education and training of nurses and student nurses
- to inquire into the conduct of a registered nurse on the grounds of alleged professional misconduct or alleged unfitness to engage in such practice by reason of physical or mental disability
- to give guidance to the profession
- to manage the Nursing Careers Centre, which was set up in 1998 to facilitate a centralised system of processing and selection of applicants wishing to enter nursing; promote and market nursing as a career; provide careers information to registered nurses and midwives.

The Pharmaceutical Society of Ireland was dissolved and re-established by the Pharmacy Act 2007 and acts as the regulator of pharmacy in Ireland. It has the following roles:

- protect patients and the public interest
- maintain registers of pharmacists and pharmacies
inspect pharmacy practices and enforce pharmacy legislation
- draw up codes of conduct for pharmacists and pharmacy owners and oversee the quality assurance and application of best practice across the sector
- promote and ensure high standards of education and training, including continuing education in pharmacy
- conduct inquiries to determine ‘fitness to practise’ and ‘fitness to operate’
- process complaints relating to pharmacy practice and operation
- act as the registration authority for pharmacists wishing to practise in Ireland who have obtained their qualification outside of Ireland and the EU
- act as the competent authority for mutual recognition of qualifications from other EU countries.

The Opticians Board was established under the Opticians Acts 1956 and 2003 and regulates optometrists and dispensing opticians. It has roles in the area of registration for these professions as well as overseeing education and training.

6.3.2 Recent regulatory changes

Medical Practitioners Act 2007: The main features of this Act are as follows:

- Reform of the membership of the Medical Council such that the balance between medical and non-medical representation may potentially include a majority of persons who are not nominated by the medical profession.
- In relation to registration, the new Act provides that doctors must be registered to practise medicine, and there is also provision regarding designation of restricted titles.
- There will in future be one register with four divisions, namely: specialists, specialist trainees/interns; general; visiting European Economic Area (EEA) practitioners.
- Maintenance of professional competence on an ongoing basis will be a statutory requirement for medical practitioners, facilitated by the Medical Council, the Health Service Executive and other employers. It will be the duty of the Medical Council to satisfy itself regarding the maintenance of professional competence of registered medical practitioners.
- Fitness to Practise provisions are reformed to provide for a new Preliminary Proceedings Committee (the majority of members of which must be medical practitioners) and Fitness to Practise Committee (the majority of the membership of which must be persons who are not medical practitioners), and which cannot have common membership. Inquiries will normally be held in public.
- The Medical Council and the Health Service Executive will take over many of the responsibilities of the Postgraduate Medical and Dental Board, which will be dissolved.
- The Medical Council will be required to prepare a statement of strategy, develop a business plan and produce an annual report, all of which are to be submitted to the Minister for Health and Children.
The Pharmacy Act 2007: The main features of this Act are:

- a stronger statutory basis for the Pharmaceutical Society of Ireland
- majority non-pharmacist representation on its Council
- updating regulations for the registration of pharmacists, including non-EU/EEA graduates, and introducing registration for pharmacy businesses
- matters concerning the delivery of community pharmaceutical services, such as linguistic and forensic competence and experience for supervisory pharmacists
- the removal of the prohibition on non-Irish graduates being employed as supervising pharmacists in pharmacies less than three years old
- fitness to practise provisions, to ensure the highest standards from pharmacists and to safeguard the safe and effective delivery of pharmaceutical services to all citizens of the State.

Health Act 2007: This Act includes provisions giving statutory protection against penalisation to employees who make protected disclosures in accordance with procedures set out in the legislation and protection from civil liability for any person making a protected disclosure on reasonable grounds to his/her employers, scheduled bodies such as HIQA or the professional regulatory bodies.

Health and Social Care Professionals Act 2005: In 2007 the Health and Social Care Professionals Council was established under the Health and Social Care Professionals Act 2005. This will lead to the statutory registration of twelve health and social care professions, none of whom were previously subject to statutory registration:

1. clinical biochemists
2. dieticians
3. medical scientists
4. occupational therapists
5. orthoptists
6. physiotherapists
7. podiatrists
8. psychologists
9. radiographers
10. social care workers
11. social workers
12. speech and language therapists.

Twelve separate registration boards are established, one for each profession; other professions may be included in the future. The Council’s objective is ‘to protect the public by promoting high standards of professional conduct and professional education, training and competence among registered practitioners’. The functions of the Council, as laid down in the Health and Social Care Professionals Act 2005, are:
to oversee and co-ordinate the activities of registration boards
- to provide administrative support and secretarial assistance to registration boards and their committees
- to receive applications and make decisions concerning the refusal of registration boards to grant or restore registration
- to enforce standards of practice for registrants of the designated professions, including the codes of professional conduct and ethics adopted by their registration boards
- to establish committees of inquiry into complaints against registrants of the designated professions
- to make decisions and give directions relating to the imposition of disciplinary sanctions on registrants of the designated professions
- to advise the Minister, either on its own initiative or at the Minister’s request, on all matters relating to the Council’s functions under the Health and Social Care Professionals Act 2005
- to encourage registration boards to collaborate with each other, where practicable, including in the professional education and training of registrants
- to perform any function that may be assigned by the Minister to the Council relating to the registrants of any designated profession, their education and training and the practice of the profession, and the implementation of any directive or regulation of the Council of the European Union concerning the practice of, and persons engaged in, healthcare or social care.

Legislative reform in the areas of regulation of the dental and nursing professions is also envisaged in the near future.

Nurses and Midwives Bill: A Nurses and Midwives Bill is expected to be proposed in 2008. Its already stated purpose is to modernise the regulatory framework for nurses and midwives and to enhance patient safety and the protection of the public. The provisions of the draft scheme of the Bill are closely aligned to the provisions of the Medical Practitioners Act 2007, the Health and Social Care Professionals Act 2005 and the Pharmacy Act 2007. The results of a recent public consultation process are currently being examined, following which the legislation will be progressed.

6.3.3 Regulation of healthcare professions in other jurisdictions

The United Kingdom
Policy in the area of professional regulation in the United Kingdom has been shaped by high profiles incidents in the UK involving poor performance (e.g. Bristol Report) and criminal behaviour (e.g. Harold Shipman), as well as changing public expectations and the evolution of different perceptions of the role of the state in influencing policy on professional regulation.
There are a number of regulators of the health professions in the UK including:

- General Medical Council (GMC)
- General Chiropractic Council
- General Dental Council
- General Optical Council
- General Osteopathic Council
- Health Professions Council, which regulates Art Therapists, Biomedical Scientists, Chiropodists/Podiatrists, Clinical Scientists, Dieticians, Occupational Therapists, Operating Room Practitioners, Orthoptists, Paramedics, Physiotherapists, Prosthetists and Orthotists, Radiographers and Speech and Language Therapists
- Nursing and Midwifery Council (NMC)
- Pharmaceutical Society of Northern Ireland
- Royal Pharmaceutical Society of Great Britain.

In recognition of the increasingly complex field of regulation of health professionals in the UK, the Council for Healthcare Regulatory Excellence (CHRE) was established in 2003 as a statutory overarching body. CHRE is accountable to Parliament and has the following functions:

- promoting co-operation and consistency across the regulation of all the healthcare professions, in the interests of patients
- promoting the interests of the public and patients in the field of the regulation of health professionals
- promoting best practice in professionally-led regulation
- reporting annually to Parliament on CHRE’s work, with discretion to report on the performance of individual regulatory bodies and to compare their performance of similar functions
- developing principles of good regulation
- advising Ministers across the UK on professional regulation issues in healthcare.

CHRE reviews all final Fitness to Practise decisions in relation to competence and conduct and provides regulators with feedback to improve the quality of their decision-making process. It may also refer a regulator’s decision on a fitness to practise case to the court where it is of the opinion that the decision was unduly lenient. The number of cases in which this power has been exercised has decreased in recent years.

CHRE has a number of statutory powers which allow it to monitor how regulators operate by investigating and reporting on how they function, comparing their performance and recommending changes in how they carry out their work. It is currently moving towards a standards-based approach covering five regulatory functions – standards and guidance; registration; fitness to practise; education; governance and external relations.

Regulation of non-medical health professionals was reviewed in the UK (Department of Health 2006c). A key theme in the recommendations made in this review was for better consistency, integration and coordination of regulation and common standards across the
professional groups, between regulators and employers, and across the health service. It proposed registration and re-validation for non-medical health professions. It also recommended a single point of contact for members of the public who wish to express concerns and that the CHRE should organise agreed local investigation protocols as well as auditing a sample of decisions made.

The Health and Social Care Bill 2007 currently progressing through the UK Parliament will, if passed in its current form, make a number of changes to CHRE:

- The CHRE Council will in future be appointed rather than nominated by the regulatory bodies.
- Powers of audit will extend to the preliminary stages of Fitness to Practise (FTP) investigations.
- A new body called the Office of Health Professionals Adjudicator (OHPA) will be established to undertake independent adjudication of disciplinary matters.
- Fitness to Practise panels will no longer make final determinations regarding a professional’s registration; panels will be comprised of lay persons and persons with relevant professional qualifications aided by legal assessors and clinical and specialist advisors where appropriate.
- Regulators will prosecute cases before the independent adjudicator; annual fees will be payable to the OHPA by the regulatory bodies.
- Regulators can appeal cases of undue leniency. The use of this power will be monitored by CHRE to ensure that regulators act in the public interest.
- CHRE will lose its power to appeal cases of leniency.

The United States

In the United States, health professionals are regulated at both state and federal level. Licensing of medical professionals is a state-level responsibility carried by the State Medical Board. To prevent ‘state-hopping’ there are federal-level initiatives including the following:

The National Board of Medical Examiners: The Board sets national standards for the level of knowledge and competency that medical students should reach in order to graduate in medicine.

The Federation of State Medical Boards: Its roles include:

- co-sponsoring the United States Medical Licensing Examination
- maintaining a comprehensive databank of disciplinary actions taken against physicians by state medical boards and other agencies
- developing policies that promote best practices in medical regulation and encourage uniformity in how states license and discipline physicians
- verifying physicians medical credentials for state medical boards
- providing educational programmes for members and staff of state medical boards.
The National Practitioner Data Bank (NPDB) and the Healthcare Integrity and Protection Data Bank are databases administered by the US Department of Health and Human Services, in partnership with other organisations, to facilitate various stakeholders in the health system to obtain information relevant to the competence and conduct of healthcare professionals.

Medical professionals in the US undergo a process of certification and re-certification, overseen by the American Board of Medical Specialties, (ABMS), if they intend to practise as specialists.

Canada

Canada is similar to the United States in terms of its structures for health professional regulation in that most power with regard to licensing and regulation lies at the provincial and territorial government level. The Provinces and Territories usually delegate control over medical practitioners to professional colleges whose primary duty is to set standards, license practitioners and deal with complaints. In some Provinces and Territories, the role of the professional colleges is supported by Health Professional Regulatory Advisory Councils which determine the professions to be regulated and oversee the regulatory activities of the colleges.

Australia

In common with the US and Canada, the system of healthcare in Australia shares responsibility between the state and federal level. Regulation of doctors is a matter for individual states and is a function undertaken by a state-level Medical Board. A state-level healthcare complaints commission may also take a role in managing a complaint about professional conduct. Continuing assessment of medical professionals is not yet fully developed; while some states require demonstration of continuing fitness to practise, this is not linked to licensing or registration. There are moves to try to improve harmonisation in the regulation process.

The Australian Medical Council is an overarching body which:

- accredits Australian and New Zealand medical schools and medical courses
- accredits Australian/Australasian programmes of specialist medical training
- advises on the recognition of medical specialties and sub-specialties
- assesses overseas trained medical doctors who wish to practise medicine in Australia
- advises State and Territory Medical Boards on uniform approaches to the registration of medical practitioners and maintains a national network of State and Territory medical registers
- advises the Australian Health Ministers’ Advisory Council on the registration of doctors.
New Zealand

Relevant legislation in New Zealand includes the Health and Disability Commissioner (HDC) Act 1994, the Health Practitioners Competence Assurance Act 2001 and the Health and Disability Services (Safety) Act 2001. The aim of the HDC is ‘to promote and protect the rights of health consumers and disability consumers, and, in particular, to secure the fair, speedy and efficient resolution of complaints relating to infringements of those rights’. These aims are pursued through the implementation of a code of rights, the establishment of a complaints process to ensure enforcement and ongoing provider and consumer education.

Patients may also complain to the Health and Disability Commissioner (HDC) which may: take no action, recommend an educational approach, seek an apology, make a formal referral to mediation, commence an investigation or take other stated measures. The HDC liaises with the Ministry for Health, professional regulators, the Accident Compensation Scheme and the coroner as required. There is an obligation to refer the complaint to the appropriate authority when the practice of a healthcare provider poses a risk to patient safety. Disciplinary proceedings may be instituted by the Director of Proceedings who may bring the matter before the Health Practitioners Disciplinary Tribunal and/or the Human Rights Review Tribunal.

6.3.4 Conclusions

Accumulating evidence to prove what works in policy reform is challenging. However, based on research carried out in other jurisdictions there is evidence to support extension of licensing and registration to non-medical professionals. Certification and re-certification to assure maintenance of competence is also supported by evidence as an effective intervention. Credentialing is a popular intervention in the US; however, an evidence base regarding its impact has yet to accumulate.

Many systems are moving away from a traditional model of self-regulation for health professions to one where there is greater lay involvement. Appointment is being increasingly used for membership rather than election by peers to address concerns regarding self-interest. In some jurisdictions there is also a trend to ensure that designated lay members are not active in other health professions. Some systems have established bodies to improve integration of regulation across professional groups. The Commission for Healthcare Regulatory Excellence in the UK is the most obvious model in this regard. All systems are active in responding to complaints arising from concerns that standards of practice have not been met. In addition, most systems are interested in processes to assure maintenance of competence to meet standards, especially on behalf of the medical profession.

In Ireland regulation of health professions is already changing. This is a legitimate response to public and political concerns about the strength of this component of the health system arising from high profile incidents exposing failures in care and potential weakness in professional regulation. Recent policy reform has made significant changes to the medical
and pharmacy professions. Other health and social care professionals have recently been included in the system of health professional regulation in Ireland. Legislative reform of other professions including nursing and dentistry is expected shortly.

Regulatory bodies are moving towards a common stated objective of protecting the public; this is more evident in the bodies that have been the subject of recent reform and is one of the stated objectives of the recently established Health and Social Care Regulatory Forum. Governance of professional regulation is moving towards a model where bodies have a lay majority and where members are appointed rather than elected by peers. This addresses concerns about the tension that can arise in governance of these bodies between protecting self-interest and promoting public accountability. In addition, there is also a trend towards strengthening accountability to Government; this is clearest in the recent reform of the Medical Council and the Pharmaceutical Society of Ireland where exact requirements have been set down requiring these bodies to prepare a statement of strategy, develop a business plan and produce an annual report, all of which are to be submitted to the Minister for Health and Children.

This common public interest objective is transacted by the regulatory bodies through similar mechanisms. However, some differences in regulatory interventions remain, and opportunities for harmonisation and coordination are evident.

- The regulatory bodies are concerned with standards with regard to practice. However, while some of these standards are generic across different health professionals groups, a common vision in this regard has not been articulated.
- The regulatory bodies are responsible for registration and have a role in supporting education and training requirements to meet standards in this regard. However, professional roles are changing and multi-disciplinary working is becoming central to the provision of healthcare. There is an opportunity for the bodies to work together on elements of education and training which support these new ways of working in the health sector.
- The regulatory bodies investigate concerns that professionals may fail to meet the required standards. Opportunities for harmonisation and coordination arise with regard to handling concerns. A common framework for investigation and management of complaints could be developed along with a system to evaluate this process across professions. In addition, as the number of regulatory bodies increase, a ‘first point of call’ for members of the public who have a complaint regarding a health professional could make this part of the system more user-friendly.
- The regulatory bodies also support professionals in maintaining standards. However, there is divergence in this regard. Currently the Medical Practitioners Act 2007 provides the Medical Council with the strongest powers in this area, making maintenance of professional competence a statutory requirement for medical professionals. There is an opportunity to consider whether maintenance of standards needs to be strengthened across professional groups, and whether this approach can be harmonised and coordinated.
In considering the functions and governance of the professional regulatory bodies in healthcare, the Commission considered in particular the disciplinary functions exercised by those bodies. It took note of the Fifth Shipman Report by Dame Janet Smith in the United Kingdom which analysed the disciplinary functions of the General Medical Council. These functions are broadly comparable to those exercised by the Medical Council in Ireland though some differences do exist between the two regimes. In reaching its recommendations in relation to the exercise of disciplinary functions in the Shipman Report, the report pointed to the provisions of the Human Rights Act 1998 which entitle a person to ‘a fair and public hearing ... by an independent and impartial tribunal’ in the determination of his/her civil rights and obligations.

The fundamental purpose of Fitness to Practise (FTP) inquiries is to promote and safeguard the public interest, which involves individual patient protection, the maintenance of public confidence in the profession and declaring and upholding proper standards of conduct. If that fundamental purpose is to be met, there are some basic principles that should be applied, for example:

- Subject to the requirements of medical confidentiality, everything that the regulatory body does must be capable of scrutiny; it must be transparent.
- The work that the regulatory body does must be thorough, careful and of high quality. That means that every aspect of the Fitness to Practise procedures must be properly resourced.
- Each process must be undertaken by persons who are suitably qualified and properly trained to carry it out.
- In the interests of fairness and of the proper maintenance of standards, procedures must be followed and decisions made in a consistent, transparent manner.

The Shipman Report raised a number of concerns in relation to the operation of the FTP process in the General Medical Council. One of those concerns was that those adjudicating on FTP panels may each sit for only a few days a year. They will therefore have little opportunity to develop real expertise and there are likely to be problems with ensuring consistency of decision-making. The Shipman Report states that all healthcare regulators have to appoint and train panellists for their FTP procedures and asks whether it might be feasible to appoint a body of full-time or nearly full-time panellists who could sit on panels of all the healthcare regulatory bodies. This would provide a measure of independence from any one particular body, and would ensure that panellists developed experience and expertise.

The Shipman Report also acknowledges that the adjudication stage presents problems of separation of function. Although a measure of separation may be introduced by using only non-members of the regulatory body for the adjudication stage, the Shipman Report takes the view that in effect there is no real separation at all. The regulatory body selects the FTP panellists (both for inclusion on the list of panellists and for inclusion on a panel in an individual case), trains them, provides them with guidance, audits their decisions
and appraises their work. The regulatory body will also select the legal assessors and any specialist advisers or assessors who may be required. The Shipman Report concluded that the process would be much more satisfactory from the points of view of both patient protection and fairness to doctors (and other healthcare professionals who are similarly regulated) if separation were to be achieved.

The Commission also noted the findings of a recent report published by the Council for Healthcare Regulatory Excellence (CHRE) in the United Kingdom following a performance review of the Nursing and Midwifery Council (NMC). This report identified serious weaknesses in the NMC’s governance and culture, in the conduct of its Council, its ability to protect the interests of the public through the operation of fitness to practise processes and its ability to retain the confidence of key stakeholders. The CHRE report recommends that the NMC commit itself to work towards more effective governance, that there should be no representative members on the Council, that all members should be appointed against defined competencies, and that the responsibilities of the NMC in relation to Conduct and Competence should be transferred to the new Office of Health Adjudicator at an early stage.

The Commission took careful note of the comments in the Fifth Shipman Report and of the recent Irish High Court judgment in Prendiville & Anor v. The Medical Council & Ors (2007) in which Kelly J. found the disciplinary procedures of the Medical Council (operating under the Medical Practitioners Act 1978) to be flawed. The Commission is aware of recent changes in the regulation of the medical profession enacted through the Medical Practitioners Act 2007, some of which introduce new processes to the disciplinary functions exercised by the Medical Council. Similar changes are also likely to take place in relation to the other healthcare regulatory bodies. These important changes will introduce a lay majority to the Medical Council, facilitate the holding of Fitness to Practise Inquiries in public and separate the two stages of the disciplinary process as between a Preliminary Proceedings Committee and the Fitness to Practise Committee so that no person may be involved at both stages of the decision-making process. Those persons who take part in the Fitness to Practise adjudication stage of the process will not participate in the final decision of the Medical Council.

The Commission is aware that some of the potential problems that may arise in relation to the issue of separation of function may be met by the new procedures established by the 2007 Act. However, the Commission remains concerned that the members of the Fitness to Practise Committee who will hear the evidence and submissions in the Inquiry and reach conclusions on the allegation of professional misconduct will be members of the same body that will make the final decision as to professional misconduct (though, as has been stated above, they will not be part of the final decision-making process). The Commission is of the view that the appearance of separation of function must be matched by the reality of the processes and procedures.

At the present time, Fitness to Practise inquiries are generally heard by a small panel of medical and non-medical members of the regulatory bodies. Such members may
sit on inquiries for a number of days per year and each team may be comprised of different members. The Commission is concerned that this system does not facilitate the development of expertise in relation to the disciplinary process and may result in inconsistencies in the application of standards.

In addition, the increase in multi-disciplinary team care and treatment of patients may result in complaints being made against a team rather than an individual practitioner. For example, skills extension for nurses has led to the assumption of specifically defined clinical decision-making, drug-prescribing and the performance of medical procedures such as bronchoscopy and colonoscopy. It is important therefore that consensus is reached between the different professional groups in respect of common standards and ethical behaviour that would ensure patient safety, when therapeutic interventions or the performance of procedures can be carried out by different craft groups. The current disciplinary structures in the professional regulatory bodies do not facilitate an investigation and hearing of such a complaint, which may therefore fall between the regulatory bodies.

Also, certain professions or professional groupings in Ireland are not covered by specific healthcare legislation. Thus, for example, chiropractors, osteopaths, art therapists, audiologists, cardiac technicians etc, who provide services to patients, do not operate in a clear regulatory framework in Ireland.

Following discussion of the foregoing issues, the Commission concluded that there is a role for a coordinating body in professional healthcare regulation. Potential areas for such a body to add value in terms of patient safety and quality assurance in healthcare include ensuring that regulatory bodies pursue a similar objective in protecting the public, requiring regulatory bodies to collaborate on areas of common interest, providing a first point of contact for patient concerns in relation to clinical care, and ensuring that the initial investigation of complaints is managed using a common framework.

The Commission was of the view that there should be greater separation between the investigation and adjudication functions performed by the professional regulatory bodies so that the public might have greater confidence that the disciplinary functions exercised by those bodies are independent and robust. Although there are arguments for removing the entire disciplinary process from the regulatory bodies, the model preferred by the Commission would maintain the involvement of the regulatory body as arbiter of the first stage of the disciplinary process i.e. the regulatory body would make the decision as to whether the professional against whom the allegation was made had a case to answer. The regulatory body would then investigate and prepare a case to be heard by an independent panel of healthcare professionals and lay members.

Under the model proposed by the Commission, the regulatory bodies would also have a role in the development of standards, criteria and thresholds for all stages of the process, including the adjudication stage. They would be able to monitor the outcomes of cases and thereby inform themselves of the need for any adjustment in the standards, criteria and thresholds. With this model, a body of full-time or nearly full-time panellists should be
appointed who could sit on joint panels of all the healthcare regulatory bodies. This would provide a measure of independence from any one particular regulatory body and would also ensure that panellists developed experience and expertise. A full-time legal assessor would be appointed to sit with all adjudicating panels so as to ensure consistency of standards and to address all legal issues arising.

6.3.5 Recommendations

The Commission recommends the following:

**R6.15** As part of the implementation of the recommendations in this Report, a group should be established through which the professional regulatory bodies will collaborate on areas of common interest, such as developing a shared understanding of the professional standards that are common to each body and supporting education and training appropriate to the different professionals operating in multi-disciplinary teams.

**R6.16** The Group will develop plans for a first point of contact for patient concerns in relation to clinical care, with referral to appropriate regulatory bodies as necessary.

**R6.17** The Group will propose the means by which the initial investigation of complaints by the professional regulatory bodies can be managed using a common framework as appropriate and an audit of cases to assure performance in this regard.

**R6.18** The Group will review current Fitness to Practise processes across the different professional regulatory bodies in order to develop plans to achieve greater separation between the investigation and adjudication functions performed by the professional regulatory bodies, and in order to devise means by which Fitness to Practise panels can be independently appointed and trained.

**R6.19** Healthcare providers not currently covered by any of the regulatory bodies should be identified and included within the existing allied healthcare professionals group. Other non-medically trained practitioners in alternative medicine whose treatments may be unsafe or potentially hazardous to patients should be considered by the Department of Health and Children for some type of regulation.

6.4 Credentialing

For healthcare providers in an era of corporate governance and compliance, information is critically important. Recruitment decisions taken by healthcare providers have crucial
significance in relation to providing safe and high quality clinical services to patients. In recent years, concern has arisen in relation to the fact that employers may not have a complete picture of the track record of the potential employee and may therefore be unaware of problems previously encountered in relation to that person’s clinical competence. Although applicants are required to complete application forms, provide professional references and appear at interview, this system will not necessarily capture information relating to previous competence or conduct. For example, locum doctors are occasionally appointed to fill a gap at short notice and in the circumstances of such temporary appointments it may often be difficult to comprehensively check the veracity of application forms and references. This system may therefore expose patients to risk.

The Commission considered ways in which this situation might be prevented, including a strengthened concept of clinical governance, the recent introduction of competence assurance schemes for registered medical practitioners and a system of credentialing of medical staff. The first of these preventative measures is considered elsewhere in this Report in the context of the overall governance framework proposed by the Commission. The second is considered in the context of the Commission’s recommendations on healthcare regulatory bodies. Credentialing is considered in this section.

What is credentialing?

Credentialing is a process whereby healthcare organisations review the qualifications and track record of doctors and other professional staff who are either joining or are already working within their organisations. Credentialing exists to some extent in Canada and Australia, but is most developed in the United States where it is seen as an important element of the risk management process.

The process consists of establishing and reviewing the primary qualification, specialist certification, liability record and disciplinary record of doctors and other healthcare practitioners (Calabrese et al 1997). This review takes place when the practitioner seeks to join an organisation and at regular intervals (typically every two years) during the course of the practitioner’s employment with that organisation.

6.4.1 Credentialing and similar systems in other jurisdictions

The United States

In the US, hospitals are legally liable to monitor the quality of care provided by those who work within them (Ginnar 2005). Most states in the US have statutes to protect those who participate in peer review committees designed to terminate the employment of incompetent physicians. In the mid-1980s Congress enacted legislation in response to the negative impact of rising medical insurance, the cost of defensive medical practices, and the likelihood that doctors who had been censured in one state would simply move to another state to resume practice.

Amongst other reforms introduced by this legislation, the Healthcare Quality Improvement Act 1986 established a national clearinghouse for information on physicians to ensure
that the track record of physicians follows them from one state to another. Credentialing systems have also been integrated into accreditation processes, resulting in hospitals now evaluating the background of practitioners much more vigorously.

One of the vital elements in the credentialing system is the maintenance of an up-to-date, centralised database to which information must be sent in relation to the practitioner’s qualifications and competence and which is then accessible to potential healthcare employers. Not only are there economic arguments in favour of a centralised system, but the use of uniform credentialing forms, such as a single application form, helps to avoid duplication and confusion. In the United States a federal database, called the National Practitioner Data Bank (NPDB), is maintained to which all healthcare organisations are required to notify issues relating to disciplinary actions, medical malpractice judgments or settlements. The intent of the legislation which established the data bank in the US is to improve the quality of healthcare by encouraging state licensing boards, hospitals and other healthcare entities and professional societies to identify and discipline those who engage in unprofessional behaviour; and to restrict the ability of incompetent physicians, dentists and other healthcare practitioners to move from state to state without disclosure or discovery of previous medical malpractice payment and adverse action history.

Access to the information contained in the NPDB is restricted to eligible organisations who register with the data bank, and is confidential. There is a statutory definition of who is eligible to access the information which includes healthcare providers such as hospitals, nursing homes, group practices and those employing locum practitioners. Insurers are not considered eligible and members of the public are not entitled to access the data bank. It is specifically stated that the information contained in the data bank should serve to alert licensing authorities and potential employers that there may be a problem with a particular practitioner’s competence or conduct. The information should be considered along with other relevant information such as evidence of current competence, references, verification of training and experience and relationships with patients and colleagues.

There is a requirement on hospitals to query the data bank when a practitioner applies to practice in the hospital, and every two years thereafter, or when the practitioner wants to expand existing privileges. Hospitals may also query the data bank at other times as necessary for professional review activity. Healthcare practitioners may self-query at any time, may request changes to the reported information if inaccurate, and may add a statement to the report.

In addition to the NPDB, the Healthcare Integrity and Protection Data Bank (HIPDB) became available in 2000 as part of the government response to healthcare fraud. It is a more refined version of the NPDB and contains adverse action information on all healthcare providers, suppliers and practitioners. Information reported to the HIPDB is available to federal and state agencies and health plans, but not to acute hospitals, except by self-query. The HIPDB is maintained by the Department of Health and Human Services and co-ordinated with the NPDB. Actions which must be reported to the HIPDB include: civil judgments against a healthcare provider, criminal convictions against a provider related to
the delivery of healthcare, actions by relevant licensing or certification agencies, exclusion of a provider from participation in a state healthcare programme, and any other action as determined by regulation. Civil settlements are not reportable.

The United Kingdom

In the UK a medical register is maintained by the General Medical Council of all registered doctors. The GMC also maintains a specialist register and it is a requirement for doctors appointed to a consultant post within the NHS to be on the specialist register. An NHS Occupational Health Smart Card system was introduced in 2001 which now has 60,000 hospital doctors and 10,000 medical students using the system. The smart card is a secure means of recording, storing and sharing data to ensure that the holders have undergone all the tests necessary before they are allowed to work in the NHS. The central database holds personal employment details, and accurate, up-to-date health clearance information and is also linked to the GMC register.

A system of alert notices has also been introduced through which an employer can make other bodies aware that a healthcare professional may pose a threat to patients or staff. It is intended as a means of alerting prospective employers to check the applicant’s employment record and take up references in advance of appointment. The alert notice, currently in the form of a letter, will state the person’s name, date of birth and registration number, place of work and in what capacity the person worked there. The notice will give the name and address of a person to contact at the organisation which triggered the alert. No other information about the individual or any details of the case are included in the alert notice. The alert system is not part of the disciplinary process but is an integral part of the system for pre-employment checks.

6.4.2 Current Irish situation

In the Irish context, the Medical Council maintains a register of all medical practitioners and also a Specialist Register. It is not currently a mandatory requirement for consultant posts in the HSE to be filled by those on the Specialist Register. There are similar registers maintained by the Nursing Board, the Health and Social Care Professionals Council, the Dental Council and the Pharmaceutical Society of Ireland. There is no national system of credentialing, no system of alert notices, or no national database to which employers can apply for information relating to the qualifications and competence of healthcare practitioners other than the professional regulatory bodies which record only information relating to the practitioner’s current registration status.

6.4.3 Conclusions

The regulation of healthcare professionals is central to quality improvement. In recent years there has been evidence, both in Ireland and elsewhere, of systemic underperformance and isolated cases of wrongful behaviour in individuals. This points to failures in traditional systems for detecting and preventing unsatisfactory performance at an early stage before patients are at risk of harm.
As part of the governance framework proposed by the Commission, it is imperative that healthcare managers and boards are accountable for all aspects of patient safety and quality in their organisation. This clearly includes decision-making in relation to the employment of practitioners.

The Commission acknowledges that steadily increasing job mobility of healthcare professionals can convey substantial benefits to patients in the form of wider experience and new skills but emphasises that it also poses risks. In a stable and longstanding professional workforce there is a high level of knowledge of the individuals. In an era of increased mobility both within and between countries and where professionals may move from post to post on a much more frequent basis there is an increased need to know the recent employment background of healthcare professionals before they are given access to patients. This can be a particular problem in respect of those undertaking locum posts as they are often recruited at short notice and the possibility of adequate credentialing being carried out is reduced. The informal mechanisms currently in use are not satisfactory for either the employee, potential employers or potential patients.

The Commission concluded that a credentialing system potentially offers an important protection to patients in establishing a means by which the qualifications and competence of healthcare practitioners can be verified prior to and during employment. The information that could usefully be contained in a credentialing database in the Irish context may include:

- registration status with a professional regulatory body
- specialist registration
- results of participation in a Competence Assurance Scheme recognised by a professional regulatory body
- clinical liability judgments or settlements
- involvement in complaints under the HSE complaints mechanism
- disciplinary action by employers
- sanctions imposed by professional regulatory bodies or any of the recognised training bodies.

If Ireland was to adopt a model such as that in operation in the United States, described above, the information to be contained in the relevant database would have to be clearly specified and protected by legislation. There should be an obligation on employers, professional regulatory bodies and healthcare professionals to notify the database in relation to relevant information. Under such a system, the practitioner would be entitled to be notified of each entry in the database pertinent to his/her practice and given the opportunity to correct any inaccuracies. Access to the database would be restricted to registered employers and employers would have a legal obligation to check the database before employing a healthcare professional.

The Commission is cognisant of the fact that many practitioners travel to Ireland for temporary employment, and an Irish credentialing system would have to seek to access information on these. The Commission is of the view that, although there is currently some
communication between comparable regulatory bodies throughout the EU, an EU-wide credentialing system would be of immense benefit to citizens across all member states. Further work is necessary between EU states in order to develop this system within the confines of European law and policy. Irish professional regulatory bodies should strongly endorse any such collaboration and take an active part in its development.

The Commission was also aware that in the United States credentialing is linked to the concept of privileging which is used by healthcare providers to define the scope of practice of healthcare practitioners. Privilege delineation is essentially an institutional function aimed at matching the clinical privileges accorded to each member of the medical staff with his/her demonstrated ability to perform, thereby ensuring patient safety and promoting the quality of patient care. Privileges are related to an individual’s documented experience in categories of treatment areas or procedures, to the results of treatment, and to the conclusions drawn from quality assurance activities. The credentialing process facilitates privileging by enabling informed decisions to be made in relation to the appropriate treatments and services to be provided by each practitioner. The Commission believes that the system of privileging has many potential benefits to offer to a safety and quality framework by ensuring that, for example, doctors who undertake new or novel surgical techniques have been adequately trained in the skills required for the application of such techniques and have been assessed by the relevant training body as competent to undertake such procedures.

It is of crucial importance that a potential employer should be fully aware of any problems in a professional’s previous employment so that a decision to give someone access to patients is made with as full knowledge of that individual as possible. As noted above in Section 6.4.1 a system of alert notices has been established in the UK whereby employers of a professional can request the issuing of an alert notice in respect of an employee who they have good reason to believe may pose a significant risk to patients or staff. Alert notices are sent to potential employers so that employment decisions can be made in the light of full knowledge of previous employment experience.

The Commission believes that healthcare employers have a duty to other potential employers and patients to consider whether there is a potential risk arising from the practice of a healthcare professional. Whilst contacting the appropriate regulatory body, they should also take action to bring the matter of serious concern to other bodies in the healthcare system. The Commission concluded that an alert notice system has been shown to be an effective approach and should be introduced in Ireland.
6.4.4 Recommendations

The Commission recommends the following:

**R6.20** As part of the implementation plan proposed in Chapter Eight, a group should be established to collaborate on the scope, design and implementation of a credentialing system. This system should be commenced on a pilot basis as soon as possible and reviewed after two years with a view to the introduction of legislation to give it statutory effect and universal application in due course to all regulated professionals.

**R6.21** The Group should consider the means by which Ireland could proactively participate in an EU-wide credentialing system.

**R6.22** The Group should also report on the ways in which a credentialing database could potentially be used as part of a privileging system for healthcare professionals. This should be done in collaboration with the postgraduate training bodies who are best placed to advise on the competency of those who have completed specialist training.

**R6.23** The Group should plan a system of alert notices to be established for the exchange of notices between healthcare employers both within Ireland and between Ireland and adjacent jurisdictions in respect of healthcare professionals for whom patient safety issues have arisen.

**R6.24** Healthcare employers should only employ in consultant posts medical practitioners who are registered on the Specialist Register in the Medical Council.
Chapter Seven

Quality Improvement and Learning Systems

7.1  Clinical Effectiveness

It is essential in any healthcare system that healthcare professionals, multi-disciplinary teams, organisations and the wider healthcare service are able to use information to monitor the safety and quality of the services that are being provided so as to enable the sharing of good practice, make improvements as required and inform the planning of services. Clinical effectiveness embraces this approach as part of a well governed healthcare system, and involves a number of processes and behaviours at the various levels of healthcare in order to drive safety and quality. The requirements for good clinical effectiveness include:

- access for healthcare professionals to the most up-to-date information
- use of evidence-based practice relating to the condition or specialty area
- the undertaking of effective clinical audit by individuals, teams, organisations and the wider health system in a well led, organised and effectively managed manner
- strong clinical leadership to support and drive these activities
- establishing clinical standards, guidelines and indicators that enable healthcare professionals to monitor their individual, team and organisation’s performance against national and international comparative parameters
- the provision of support, education and training for staff in clinical audit, information models and the use of information to improve their service.

7.2  Evidence-based practice

It is self-evident that safe and effective treatments are important in ensuring that patients get the best outcomes from their care. However, defining and raising awareness of what effective care is, and ensuring that effective care is made available in a fair and equitable way across the entire system, presents significant challenges.

Effective care encompasses the concept of informed patients receiving care from skilled professionals in appropriate environments with assessed outcomes. Effectiveness is not just about making use of the very latest treatments and technologies. It is also about ensuring that patients receive well co-ordinated and integrated care. Factors that influence outcome include process factors such as timeliness of access to diagnosis and treatment facilities or the availability of the necessary infrastructure and skilled, appropriate staff to deliver care. These process factors will be determined by overall healthcare policy and funding decisions, local geography and infrastructure as well as the judgment and skill of the professionals delivering care.

It is important to include preventative care in the overall definition of effective care. Lifestyle-related diseases are a growing health problem in Ireland and throughout similar health
systems. For example, smoking and unhealthy diet can lead to long-term conditions such as heart disease, diabetes and respiratory problems. If patients can be supported to make healthier choices, they can greatly reduce this burden of ill health. Preventative care can provide better value for money.

Evidence-based practice may be defined as a component of an evidence-based healthcare approach which comprises three stages:

- producing evidence
- making evidence available
- using evidence for decisions regarding individual patients (evidence-based clinical practice and evidence-based patient choice) or for populations or groups of patients (evidence-based public health and health service management).

7.2.1 Approaches to supporting evidence-based practice

Standards offer an opportunity to support evidence-based practice. In the UK, the National Service Frameworks (NSFs) and the National Institute of Clinical Excellence (NICE) guidelines are used in this context. NSFs aim to set standards and identify key interventions for a defined service or care group, develop and enact strategies for implementation and establish performance measures against which progress within an agreed timescale will be assessed. In so doing, they can support evidence-based healthcare. Evidence examining the effectiveness of NSFs is observational. There is evidence that the Coronary Heart Disease NSF, in particular, has been important in improving quality of care; however, some critics have suggested that standards are set too low and that there may be age disparities in the delivery of Coronary Heart Disease Services as a consequence of the NSF. Similarly, improvements in cancer care delivery have been attributed to the Calman Hine Report, an NSF-precursor in the area of cancer care.

The guidelines produced by NICE aim to make rationing decisions in healthcare explicit and evidence-based. Evidence examining the effectiveness of the NICE is also observational. Overall, studies on its impact on quality of care have been mixed; there is evidence that some of its guidance has been adopted and implemented in practice, especially when there has been strong professional support, a stable and convincing evidence base, no impact on costs, and systems for monitoring and evaluating implementation.

An integrated care pathway (ICP) is a multi-disciplinary outline of anticipated care, placed in an appropriate timeframe, to help a patient with a specific condition or set of symptoms move progressively through a clinical experience to positive outcomes (Muir Gray 1996). ICPs can help to reduce unnecessary variations in patient care and outcomes, and can also support the development of care partnerships and empower patients and their carers. ICPs are used as a tool to incorporate local and national guidelines into everyday practice and as such provide an opportunity to support evidence-based practice. They can help to secure the safety and improve the quality of a patient’s journey across the health system, especially when focused on conditions in which there are established routines of
practice and little variation among patients in the clinical course. For this reason they are a popular component of chronic disease management programmes.

Clinical guidelines are systematically developed statements to support healthcare professionals and patients when making decisions about the most appropriate healthcare in particular circumstances and can be used to serve a number of purposes (Muir Gray 1996):

- to make evidence-based standards explicit and accessible
- to make decision-making in the clinic and at the bedside easier and more objective
- to provide a yardstick for assessing professional performance
- to delineate the division of labour in healthcare
- to educate patients and professionals about current best practice
- to improve the cost-effectiveness of health services
- to serve as a tool for external control.

Clinical guidelines are a key intervention to support evidence-based practice and are often used in conjunction with ICPs and managed care. While guidelines offer great promise as a means of supporting evidence-based practice, they also carry risks which arise from issues concerning their quality and their implementation. In Europe, the Appraisal of Guidelines Research and Evaluation Collaboration (AGREE) has been established to undertake a number of tasks in relation to the development of guidelines.

Systematic approaches to the support of evidence-based practice have also been adopted in other countries including the US, Canada, Australia and New Zealand, and the responsibility for researching and developing evidence-based guidelines at national levels has been assigned to specific agencies in these countries. For example, the Institute for Healthcare Improvement (IHI) is a not-for-profit organisation based in the US which leads on the improvement of healthcare globally. It has established a campaign called 5 Million Lives to avoid deaths arising from unsafe or poor quality care. It includes a number of evidence-based interventions to tackle these avoidable deaths, for example:

- deploy rapid response teams… at the first sign of patient decline
- deliver reliable, evidence-based care for acute myocardial infarction…to prevent deaths from heart attack
- prevent adverse drug events (ADEs)... by implementing medication reconciliation
- reduce Methicillin-Resistant Staphylococcus Aureus (MRSA) infection… by reliably implementing scientifically proven infection control practices
- deliver reliable, evidence-based care for congestive heart failure... to avoid readmissions
- get Boards on board… by defining and spreading the best-known leveraged processes for hospital Boards of Directors, so that they can become far more effective in accelerating organisational progress toward safe care.
7.2.2 Irish initiatives in evidence-based practice

At national level in Ireland, the function of systematically developing evidence-based guidance for use by professionals and the health system has not been formally assigned to any one agency. A number of initiatives have been undertaken by individual bodies and agencies in the development of evidence-based guidance for particular areas of practice. These are too numerous to list fully here, but examples include the following: *Guidelines on the prevention of blood-borne disease in healthcare settings*, published by the Department of Health and Children in 2006; guidance published by the Health Protection Surveillance Centre (HPSC) of the HSE in relation to communicable diseases; and *Immunisation Guidelines for Ireland* produced by the National Immunisation Advisory Committee established by the RCPI at the request of the Department of Health and Children.

Health Intelligence is a sub-directorate within the Population Health Directorate of the HSE which aims to provide strategic leadership and co-ordination for the transfer of knowledge across the HSE. Health Intelligence is active in a number of areas relevant to information, enabling technologies and evidence-based practice. It has established an Evidence-Based Healthcare Service for the HSE which aims to develop, manage and transfer knowledge on effective healthcare to decision-makers at every level in the service; for example, it has provided support to Expert Advisory Groups examining the future direction of service delivery in key areas such as diabetes, and for key population groups such as older people.

The Professional Colleges in Ireland and the Health Research Board (HRB) are also active in the areas of health research, health information, enabling technology and evidence-based practice. Besides administering a number of key health information systems for the Irish health system, the HRB provides electronic access to the Cochrane Library, a collection of databases that contain high quality, independent evidence to inform healthcare decision-making, for Ireland.

The Irish College of General Practitioners has established an initiative which supports quality improvement projects through a Practice Quality Improvement Award; in addition, it supports evidence-based practice through the publication of guidelines for general practitioners. The Royal College of Surgeons in Ireland supports evidence-based practice through the production of guidelines across a number of areas.

Despite these initiatives, there is no formal system in place at national level which sets quality assurance standards for evidence-based guidelines, and the implementation of guidelines is not systematically monitored or incorporated into routine health service management processes.

7.2.3 Conclusions and Recommendations

Having reviewed international models in this area, the Commission is of the view that supporting evidence-based practice is a critical element of a health system which aims
Building a Culture of Patient Safety

to deliver safe and high quality care. While acknowledging that some considerable work in the development of professional guidelines has been carried out to date by a number of the professional colleges, value can be added to these initiatives through a strategic, systematic approach, properly resourced and supported, where responsibilities are clearly assigned and where guideline development is quality assured and linked to service delivery priorities. Also, as evidenced in other systems, attention must be directed at ensuring the implementation of evidence-based guidance. The Commission is of the view that the National Service Framework (NSF) model adopted in the UK is of benefit in this regard.

The Commission recommends the following:

R7.1 A leadership role in relation to the analysis of international evidence and research, and to the production of evidence-based information and guidance for use in policy-making, system reform, and individual patient and professional interactions should be developed.

R7.2 A rolling programme should be developed by the Department of Health and Children, HIQA and the HSE to deliver evidence-based service frameworks covering the major health conditions within the public healthcare system, similar to the National Service Frameworks model in the UK. Such frameworks should be reviewed periodically to encompass new evidence on effectiveness and performance.

R7.3 A substantial strand in publicly funded health research strategies, focusing on patient safety and quality, should be developed by the Health Research Board.

R7.4 Evidence-based national standards should be developed, with multi-disciplinary input, in both primary and secondary care settings, and for the transition between care settings.

7.3 Clinical audit

It is recognised that clinical audit needs to be at the heart of clinical practice, and is something that all health practitioners should be engaged in. Clinical audit is about continuing evaluation and improvement by health professionals working towards delivery of safe, high quality care for patients. Clinical audit arguably constitutes the single most important method which any healthcare organisation can use to understand and ensure the quality of the service that it provides. It is one of the principal methods used to monitor clinical quality and the results provided by clinical audit are a source of indispensable information to patients, the public, clinicians and healthcare managers. It also provides a powerful mechanism for ongoing quality improvement, highlighting incidences where standards are not met and identifying opportunities for improvement.
7.3.1 Definition and objectives of clinical audit

Clinical audit is a clinically-led quality improvement process that seeks to improve patient care and outcomes through systematic review of care against explicit criteria and acting to improve care when standards are not met. The process involves the selection of aspects of the structure, processes and outcomes of care which are then systematically evaluated against explicit criteria. If required, improvements should be implemented at an individual, team or organisation level and then the care re-evaluated to confirm improvements.

Clinical audit examines all aspects of clinical care given to patients by the clinical staff providing such services. It is designed to measure and improve the quality of patient care, investigate measures of outcome (e.g. survival, quality of life) and compare these across centres and patient groups. Using this general definition it can be established that the collection of data which is not related to clinical standards (criteria) is not considered as clinical audit. Whilst data collection with the explicit purpose of setting standards of best practice may sometimes be considered to be a legitimate audit activity (called ‘pre-audit’), it is important that the audit cycle is observed and that standards are established as a result of the project.

7.3.2 The stages of clinical audit

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7.3.3 Clinical audit in Ireland

Currently there is no national coordinated integration of clinical audit into quality improvement/service governance. While clinical audit is being advanced in a number of organisations, it is not generally linked to service improvements, planning or resource allocation. The Lourdes Hospital Report (2006) reported that:

- Audit was not seen as an immediate imperative by management.
- The tools for audit were not available.
- Recording systems were inadequate, thereby compromising communication of clinical activity and stifling the opportunity for quality improvement.
- The process of audit was not understood by many of the witnesses to the Inquiry; audit and data collection were often confused.
- No protected time was set aside for hospital wide monthly audit. It was not recognised within the hospital that audit requires time and space and an audit coordinator to help to identify reasons for less favourable outcomes set against the comparators.

The Lourdes Hospital Report concluded that the only process that could have identified the failings and institutional weaknesses of the Maternity Unit of the Lourdes Hospital was robust and effective peer review and audit. It recommended that no maternity unit should operate in isolation from normal standards and without any outside comparisons or audit, and that there should be support systems in place to conduct regular obligatory audit.

In recent years there have been a number of initiatives relating to clinical audit in the Irish context. For example:

- Health Service Executive

  The HSE National Service Plan (2006) states in its Corporate Objectives:

  ‘We will improve people’s experience of our services and their outcomes, through developing, changing and integrating our services, in line with best practice.

  We will pursue, develop and implement quality standards throughout our services and foster a culture of review and audit at all levels.’

  The HSE states it is committed to:

  ‘Pursuing, developing and implementing quality standards throughout our services, driving a culture of safety, review and audit at all levels with particular emphasis on peer review.’
Medical Council

The Medical Council Guide to Ethical Conduct and Behaviour (2004) para. 4.11 states:

‘Doctors must maintain their competence. This is best achieved by taking part in continuing medical education, continuing professional development, peer review and audit. The Council regards the maintenance of up-to-date knowledge and competence as a professional responsibility for every doctor.’

Section 94 of the Medical Practitioners Act 2007 imposes an obligation on registered medical practitioners to maintain their professional competence pursuant to a professional competence scheme applicable to that practitioner. Under Section 91 the Medical Council is obliged to develop, establish and operate one or more such schemes in order to satisfy itself as to the ongoing maintenance of the professional competence of registered medical practitioners. There is a duty imposed by Section 93 on the Health Service Executive or any other employer of a registered medical practitioner to facilitate the maintenance of professional competence of registered medical practitioners pursuant to a professional competence scheme.

In its recent publication entitled Performance in Practice, Maintenance of Professional Standards (2006), the Medical Council stated in relation to clinical audit:

‘Setting of standards, measurement of practice compared to ‘gold standard’, identification of deficiencies and addressing deficiencies (closing the loop) is an accepted model of clinical audit.’

The document goes on to acknowledge the limitations of local audit and states that it is more effective if used to measure established norms at national or international level. It encourages doctors to participate in national clinical audit programmes. In this document doctors are asked to participate in a continuous quality assurance (CQA) programme (50 hours per year), within which clinical audit and peer review activities comprise 50% of the annual hourly total.

Audit in primary care

The Irish College of General Practitioners requires registrars in training to participate in audit and research, in order to obtain their certificate of satisfactory completion of training, and membership of the college. Postgraduate educational programmes delivered through the Continuing Medical Education (CME) network and distance learning programmes also include elements of clinical and managerial audit.

Audit is inbuilt into national and regional programmes such as Heartwatch, the Cervical Screening Pilot Programme, the Midland Diabetic Programme and the Methadone Maintenance Programme. Computerisation and coding of disease will facilitate the growing number of GP practices who will have the skills and IT necessary to partake in audit. The statutory obligation to maintain professional competence introduced in the Medical Practitioners Act 2007, the development of primary care teams and the
development of shared-care programmes for chronic disease will be key drivers in the future for audit in general practice and in the wider primary care sector.

The key barriers currently identified to a wider participation in audit are: time factors, resources and skills deficits for a proportion of primary care health workers. Structures to enable and facilitate both doctors and other primary care healthcare workers to engage in audit in the primary care setting will need to be further developed.

- **Royal College of Surgeons in Ireland**

  The Royal College of Surgeons in Ireland in its policy document *Good Surgical Practice* (2004) confirms its view that each surgeon has a duty to review his/her practice and to strive for continuous improvement. The requirement for audit and audit records will be strictly imposed, particularly during hospital inspections for basic surgical training.

  The Royal College of Surgeons in Ireland established a comparative audit service in the late 1990s. Surgeons contribute data confidentially and voluntarily on-line to the service based at the College. Surgeons are ranked in order of number of a particular operation or number of complications etc. An annual report is produced based on the data received by the College and distributed to each participating surgeon. Only the surgeons themselves are able to identify their own position in the ranking.

- **Royal College of Physicians in Ireland**

  The Royal College of Physicians in Ireland’s Committee on Higher Medical Training states that trainees must demonstrate participation in clinical audit programmes and provide documentation of at least one audit project which the trainee has carried out during the specialist training period.

- **The National Council for the Professional Development of Nursing and Midwifery**

  The National Council for the Professional Development of Nursing and Midwifery states that the specialist nurse or midwife will participate in nursing research and audit and act as a consultant in education and clinical practice to nursing/midwifery colleagues and the wider multi-disciplinary team. It is a core component of the concept of Advanced Nurse Practitioners that the application of evidence-based practice, audit and research will inform and evaluate practice and thus contribute to the professional body of nursing/midwifery knowledge both nationally and internationally.

- **An Bord Altranais**

  As part of their educational function, An Bord Altranais developed *Requirements and Standards for Nurse Registration Education Programmes* which were amended in 2007 to include a requirement that healthcare institutions used for clinical practice placements must have in place evidence-based guidelines to support appropriate standards of care and policies that support audit. The healthcare institution must provide evidence of both clinical and educational audit for each placement site to be used in the education and training of students.
7.3.4 International experience of clinical audit

The Commission examined a selection of other jurisdictions in order to ascertain what methods were used to best effect in order to integrate clinical audit into quality assurance frameworks in other settings and to learn from the positive and negative experiences of other countries in this area.

Australia

In Australia clinical audit is recognised as an important component of the quality assurance framework. In order to encourage and facilitate audit, the Health Insurance (Quality Assurance Confidentiality) Amendment Act 1992 offers legal privilege to qualifying clinical audit and risk management documentation. This medico-legal protection has been cited as an important ingredient in the success of the Australian incident monitoring study in which clinicians across the Australian anaesthetic community combined to produce contemporaneous reports of near-miss and actual adverse events (Runciman et al 1993). Performance indicators have been developed at a national level and these are being used as a basis for audit.

Other examples of audit include the Western Australian Audit of Surgical Mortality which was established in 2001 to independently peer review all surgery-related deaths in Western Australia (Semmens et al 2005). Participation in the audit was voluntary and it was covered by qualified privilege. The audit reviewed surgery-related deaths over a 30-month period. Deficiencies of care were reported in 20% of audited deaths. In 5% of cases the assessors considered that the deficiency of care caused the death. The results of the audit have driven many changes in practice, and in an independent evaluation of the audit 73% of the participating surgeons said the audit changed their practice in some way. The audit also informed training decisions and changes were implemented by the Royal Australian College of Surgeons.

The Royal Australian College of Surgeons established an audit for the treatment of breast cancer. The audit is semi-voluntary but full members of the Breast Section of the College are required to participate. One of the challenges identified to effective national breast audit in Australia is the split between the public and private sector. This split means that there is no single national data repository.

Denmark

In Denmark there are established national quality databases which are used to monitor the quality of services provided. There are approximately 50 publicly funded, nationwide clinical databases relating to the major diseases treated in the Danish healthcare system, with over 50% containing clinical quality data. The aim of these databases is to measure the quality of the health services provided to a number of patient groups, and they also feed into the National Quality Project. For all diseases with a nationwide clinical database, patient information from hospital wards is collected and reported by healthcare professionals to the relevant national database, where it is analysed and used to monitor
the quality of the services provided. The regions finance and support the dissemination of the clinical databases. All the databases are attached to one of three competence centres and data relating to quality are published regularly online.

**Norway**

A systematic framework to improve healthcare services in Norway began with the National Strategy for Quality Development in the Health Service 1995-2001 which set a target for all healthcare providers to establish comprehensive and effective quality improvement systems by the year 2000. The introduction of ‘internal control’ by healthcare institutions for quality assurance purposes was a central component of the strategy. At national level, health-related registries cover the entire population and include data over several decades. Many of these are medical databases containing information related to outcomes and specific treatments or diagnoses, which are used to assess the effects of different treatments on patients’ health in primary and specialised care. These databases have been set up through initiatives by individuals, hospitals or educational institutions and provide valuable information for assessing the effects of different treatments and benchmarking down to ward level. The Norwegian Institute of Public Health is responsible for ensuring good utilisation, high quality and simple access to registry data, as well as ensuring that health information is treated in accordance with privacy protection rules.

**The United States**

In the United States many of the quality improvement initiatives are linked to the market-driven health system. The quality initiatives have been mainly administratively rather than clinically driven. The most famous and studied use of information to improve quality of care began in 1989 when the New York State Department of Health developed methods to collect and analyse data to report comparative crude, expected and risk-adjusted 30-day mortality rates by hospital and surgeon from Coronary Artery Bypass Grafting (CABG). Improvements in New York happened because individual hospitals and cardiac surgery programmes used the data to make specific changes in the way they provided care to CABG patients. Market forces played no role. Managed care companies did not use the data in any way to reward better performing hospitals or to drive patients toward them. Nor did patients avoid high-mortality hospitals (Chassin 2002).

In its landmark 2000 report on patient safety, *To Err is Human: Building a Safer Health System*, the Institute of Medicine (IOM) recommended the expanded use of reporting systems to analyse and reduce errors in the healthcare system. The IOM recognised that reporting systems will not achieve their full potential to foster learning about errors and their prevention without ‘a more conducive legal environment’ in which healthcare professionals can report errors without increasing the threat of litigation. The IOM therefore recommended that Congress should pass legislation to extend peer review protections to data related to patient safety and quality improvement that are collected and analysed by healthcare organisations for internal use or shared with others solely for purposes of improving safety and quality.
The Patient Safety and Quality Improvement Act 2005 designated patient safety work products as privileged and not subject to: a subpoena or discovery in a civil, criminal or administrative disciplinary proceeding against a provider; disclosure under the Freedom of Information Act or a similar law; admission as evidence in any civil, criminal or administrative proceeding; or admission in a professional disciplinary proceeding. The Act defines patient safety work product as ‘any data, reports, records, memoranda, analysis, or written or oral statements which: are assembled or developed by a provider for reporting to a patient safety organisation; are developed by Patient Safety Organisations for patient safety activities and could result in improved patient safety or healthcare quality or outcomes; or identify or constitute the deliberations or analysis of, or identify the fact of reporting pursuant to, a patient safety evaluation system.’

The United Kingdom

In the United Kingdom, the Bristol Report (2001) made the following recommendations in relation to clinical audit:

- Clinical audit should be at the core of a system of local monitoring of performance.
- It must be fully supported so that healthcare professionals have access to the necessary time, facilities, advice and expertise in order to conduct audit effectively.
- There should be a central clinical audit office in every trust that coordinates audit activity, provides advice and support for the audit process, and brings together the results of audit for the Trust as a whole.
- It should be a requirement for all healthcare professionals providing clinical care to participate in clinical audit as part of their contract of employment.

The National Service Frameworks (NSFs) set national standards and define service models for a specific service or care group. The NSFs put in place programmes to support implementation and establish performance measures against which progress within an agreed timescale can be measured. One of the aims of the NSFs is to develop audit tools and performance indicators to ensure that services are being delivered to an acceptable standard. The systematic identification, prioritisation and selection of topics have been identified as being the most important determinants of the effectiveness of clinical audit programmes (Walshe and Spurgeon 1997).

National priorities for audit emerge from Department of Health circulars whilst the corporate agenda may be designed from a variety of sources such as benchmarking and risk assessments. Some specialties will also have a commitment to national or regional agenda and all clinical areas will have topics of local concern. Prioritisation of audit topics on a trust-wide basis is therefore important to accommodate each of these agendas whilst avoiding duplication of effort. Prioritisation will allow resources to be targeted on topics that are most likely to have a major impact.
Criteria that will determine priority include whether serious concerns have been identified by incident reporting or complaints; whether the procedure is of high volume or high risk; the potential to improve cost effectiveness or the potential to improve the patient experience. Trusts provide the support required by individuals and clinical teams for clinical audit including training healthcare staff in the clinical audit process; allocating protected time for audit through the rolling audit programme or as agreed locally within clinical areas; retrieving case notes, data collection and data analysis, as agreed between the clinician(s) and the clinical audit facilitator; providing resources to assist with changes in practice for approved projects.

According to Scally and Donaldson (1998) if clinical audit is to be successful it must:

- embrace and deliver improvements in all aspects of clinical quality (effectiveness, efficiency, equity, appropriateness, acceptability, access) and involve all healthcare professionals
- be well-integrated within the wider approach for enhancing clinical effectiveness
- reflect defined priority areas and topics
- be determined by the best available research evidence for clinical practice and be based on standard setting for clinical practice and/or outcomes
- have a scientifically robust methodology so that its recommendations are valid
- be patient focused, that is, audit topics are both determined by the views and direct experiences of patients, and aim to improve the healthcare experience
- embrace systematic processes for the implementation and subsequent evaluation of recommendations resulting from the findings
- have clear lines of professional and managerial accountability.

Scotland

The Scottish Audit of Surgical Mortality (SASM) is unique in the United Kingdom. The voluntary audit identifies all deaths (approximately 4,500 deaths per annum) that occur in hospital under the care of a surgeon, and whether an operation has taken place or not. This audit undergoes a peer review process carried out by virtually every practising clinician within the audited specialties on behalf of their colleagues. Over 1,100 consultants participate and are reviewed per year.

From its inception, SASM’s main role has been educational and to ensure that feedback from its findings would lead to improved care for future patients. Lessons from this educational process are disseminated either through the actions of individual participating surgeons and anaesthetists, or through the identification of more general improvements in the approach to the care of surgical patients. Feedback is provided confidentially to individual participants and through reports applied to the service all over Scotland and to health boards, trusts and specialties.
7.3.5 Challenges to clinical audit

Disclosure

Many clinicians have fears about participating in a safety and quality activity in an environment where there is an expectation of perfection, accountability tends to be punitive and blame-based, and results may possibly lead to litigation (Leape 1994; Buetow and Roland 1999; Beresford and Evans 1999). The objective of clinical audit is to contribute to improving the safety and quality of care by facilitating greater self-evaluation, measuring clinical practice against evidence-based standards, and the routine investigation of adverse events. If clinicians are to learn and improve from clinical audit, conclusions reached during these processes need to be documented. However, to encourage participation in clinical audit, clinicians need to feel safe with the process and to be assured that it will not be used against them in a punitive manner.

In Ireland safety and quality activities are not protected by statute or by case law. At common law the argument that public interests are better served by attempting to raise clinical standards than by maintaining anonymity remains untested in court. The Freedom of Information Act 1997 establishes a legal right for members of the public to access records held by public bodies and therefore must be taken into account in any discussion of clinical audit activities. There is an exemption in the FOI Act, section 21 (1) (a) which specifically allows for refusal of access where disclosure could reasonably be expected to prejudice the effectiveness of audits. This is subject to a public interest override.

Lack of incentives

Clinical audit has traditionally had a low priority within the health services in comparison with other activities. Compared to research where the rewards include protected time, funding and publications there are few apparent incentives to become involved in audit. Individuals have regarded it as time-consuming, not useful and tedious. At an organisational level there has been very little support from chief executives and clinical audit has not been linked to organisational priorities or funding (Berger 1998). It has been suggested that because risk and safety is commonly divorced from care provision to patients, clinicians may be encouraged to view clinical governance as a management driven exercise that has exploded their paperwork to the detriment of patient care (Degeling et al 2004).

Resources

The apparent low priority given to clinical audit by organisations and individuals has led to a lack of practical support. This is manifest in the poor information support systems, lack of allocated time and paucity of training in audit methods (James 1999). Many clinicians view audit as an expensive addition to clinical practice rather than an intrinsic and effective part of it and, because it is lacking in strategic orientation, is too time consuming to be operationally useful (Kerrison et al 1993; Miles et al 1996; Buetow and Roland 1999). The main barrier to audit reported in the literature is lack of resources especially time
Building a Culture of Patient Safety

(Greenwood 1997; Robinson 1996; Johnston et al 2000). In primary care many practices may not have the infrastructure, record systems or IT support to facilitate audit.

Education and training

Adequate skills and knowledge are essential to undertake effective clinical audit. Studies have identified a lack of training in evidence-based audit skills as a major barrier to implementing audit (Baxter 1998). In particular, there is an ageing population of general practitioners who may not have been exposed to audit as part of their training and who may therefore not currently have the skills necessary to undertake audit in their practice.

7.3.6 Conclusions and Recommendations

Having reviewed the research outlined above and the submissions received in relation to clinical audit, the Commission concluded that clinical audit should be viewed as an essential and integral component of professional practice and thus contribute to improved patient outcomes.

The Commission recommends the following:

| R7.5 | All clinicians, both as individuals and as members of teams or networks, must actively participate in clinical audit in compliance with national standards and priorities. |
| R7.6 | As part of the licensing process recommended in this Report, all licensed healthcare facilities must demonstrate active participation in local and national clinical audit as appropriate to their services. |
| R7.7 | Clinical audit should be considered within an integrated safety and quality governance framework and should be linked to service plans and to local, national and professional priorities. An integrated governance framework for primary care teams should include audit of access, process, quality and outcomes for patients. |
| R7.8 | Every healthcare facility should develop and implement an Annual Clinical Audit Forward Plan as part of its annual planning and delivery cycle for clinical audit activities and the facility’s safety and quality governance framework. This Plan should reflect the national, organisational, team and individual audit requirements on the facility. It should be the responsibility of the Clinical Leader, with accountability for safety and quality at Board level, to ensure that the Plan is developed and implemented with effective clinical engagement and reported to the Board of the facility. |
R7.9 Clinical audit data should be risk-adjusted and clinician-validated.

R7.10 As part of the implementation of this Report, a group should be established to develop national programmes of and standards for clinical and other forms of audit which support the safety and quality of health services and are linked to national health priorities.

R7.11 Legislation should be enacted to give exemption from Freedom of Information legislation and to grant legal protection from disclosure to data related to patient safety and quality improvement that are collected and analysed by healthcare organisations for internal use or shared with others solely for purposes of improving safety and quality.

R7.12 If clinical audit is to be granted any such exemption or legal privilege, organisations or clinicians who participate in clinical audit must publish aggregated information about clinical audit.

R7.13 Such legislation must include routes to refer to appropriate professional regulatory bodies where there is evidence that there are serious and continued variations in performance from agreed standards of care.

R7.14 Such legislation must also include the obligation to refer to other legal authorities such as An Garda Síochána where there is evidence that a serious offence has been committed.

R7.15 Adequate administrative and IT supports must be allocated to ensure the implementation of these recommendations across all health sectors. In particular, support systems must be established in primary care to encourage, educate, assist and support general practitioners and other healthcare providers to participate in audit.

R7.16 Clinical audit should be integrated into all healthcare professional education and training curricula.

R7.17 Research should be undertaken into appropriate audit systems, especially in those areas not already subject to audit.
7.3.7 Confidential enquiries

There is a long history of the effective use of the ‘confidential enquiry’ methodology in the improvement of healthcare. The model was developed in the field of maternal mortality and is designed to encourage openness by clinicians in the analysis of death-related events and to gather together learning through the systematic analysis of causation. Confidential enquiries are credited with improvements in patient care, such as the avoidance whenever possible of undertaking operations during the night, and have high levels of clinical engagement.

There are currently three confidential enquiries operating in the UK under the auspices of the National Patient Safety Agency. These are: the Confidential Enquiry into Maternal and Child Health (CEMACH), the National Confidential Enquiry into Patient Outcome and Death (NCEPOD) and the National Confidential Inquiry into Suicide and Homicide by People with Mental Illness (NCISH).

National Confidential Enquiry into Patient Outcome and Death

The National Confidential Enquiry into Patient Outcome and Death exists to assist in maintaining and improving standards of medical and surgical care for the benefit of the public. As there are not always agreed standards with which NCEPOD can compare current practice it reviews practice against the agreed components of a service in order to determine what standard is achieved by the service. It uses both confidential surveys and research methodology and publishes the results.

In excess of 20 reports have been published by the National Confidential Enquiry into Patient Outcome and Death. Samples for study have ranged from a percentage of all deaths within 30 days of surgery, to those deaths within a specific age range or specific procedures. Four studies are currently in progress: Coronary Artery Bypass Grafting Study, Systemic Anti-Cancer Study, Death in Acute Hospital Study and Acute Kidney Injury Study.

7.3.8 Recommendation

The Commission recommends the following:

R7.18 The Department of Health and Children should seek to negotiate the participation of Ireland in the three Confidential Enquiries in operation in the United Kingdom, namely the Confidential Enquiry into Maternal and Child Health (CEMACH), the National Confidential Enquiry into Patient Outcome and Death (NCEPOD) and the National Confidential Inquiry into Suicide and Homicide by People with Mental Illness (NCISH) as well as any future such enquiries.
7.4 Reporting, managing and learning from adverse events

There is significant international evidence regarding the extent of adverse events arising in healthcare. Studies conducted in the US, the UK and Australia found that adverse events occur at rates of between 4% and 16% of hospitalisations.

In considering adverse event reporting processes, it is important to examine event notification requirements, the quality of the information reported and the availability of tools for analysis of events by personnel. The personnel need to have the expertise to undertake the review, to identify the contributory factors and make recommendations relating to actions required for improvement strategies. There must also be mechanisms in place for monitoring and evaluating the implementation of these improvement strategies.

It is essential that the lessons learned in one healthcare establishment are communicated regionally, nationally and internationally. This requires consideration of improved mechanisms for deliberate communication between other jurisdictions in relation to patient safety issues, rather than relying on constantly scanning all horizons.

7.4.1 Definition of adverse event

Various definitions of adverse events are currently in use in Ireland. The Clinical Indemnity Scheme (CIS) defines a clinical incident as ‘an event arising as a consequence of provision of, or failure to provide clinical care that results in injury, disease, disability, death or prolonged hospital stay for the patient’. The Health and Safety Authority defines an adverse event as ‘an event or circumstance which could have or did lead to actual or possible personal injury, personal harm, property damage or loss’.

The World Alliance for Patient Safety of the World Health Organisation (2007) states that patient safety is compromised by variation in definitions internationally. It has proposed an international classification for patient safety in which a patient safety incident is defined as ‘an event or circumstance which could have resulted, or did result, in unnecessary harm to a patient’, and an adverse event as ‘an incident which results in harm to a patient’. In addition WHO provides a definition for healthcare-associated harm as ‘harm arising from or associated with plans or actions taken during the provision of healthcare rather than an underlying disease or condition’.

The Commission agreed to adopt the WHO definition of adverse event above for the purposes of this Report.

7.4.2 Analysis of adverse events

The stages of event reporting involve:

- identification of occurrence of the event
- response
When an adverse event occurs, a number of factors have usually contributed to this. Vincent et al (1998) developed a framework as a basis for analysing adverse events by considering a complete range of possible influencing factors i.e. getting to the root causes of adverse events. The table below presents the range of factor types and influencing factors that can contribute to the occurrence of an adverse event.

<table>
<thead>
<tr>
<th>Factor types</th>
<th>Contributory influencing factors</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient factors</td>
<td>Condition (complexity and seriousness)</td>
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<tr>
<td></td>
<td>Language and communication</td>
</tr>
<tr>
<td></td>
<td>Personality and social factors</td>
</tr>
<tr>
<td>Task and technology factors</td>
<td>Task design and clarity of structure</td>
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<tr>
<td></td>
<td>Availability and use of protocols</td>
</tr>
<tr>
<td></td>
<td>Availability and accuracy of test results</td>
</tr>
<tr>
<td></td>
<td>Decision-making aids</td>
</tr>
<tr>
<td>Individual (staff) factors</td>
<td>Knowledge and skills</td>
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<tr>
<td></td>
<td>Competence</td>
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<tr>
<td></td>
<td>Physical and mental health</td>
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<tr>
<td>Team factors</td>
<td>Verbal communication</td>
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<tr>
<td></td>
<td>Written communication</td>
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<td></td>
<td>Supervision and seeking help</td>
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<td></td>
<td>Team leadership</td>
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<tr>
<td>Work environment factors</td>
<td>Staffing and skills mix</td>
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<td></td>
<td>Workload and shift patterns</td>
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<td></td>
<td>Design, availability and maintenance of equipment</td>
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<tr>
<td></td>
<td>Administrative and managerial support</td>
</tr>
<tr>
<td></td>
<td>Physical environment</td>
</tr>
<tr>
<td>Organisational and management factors</td>
<td>Financial resources and constraints</td>
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<tr>
<td></td>
<td>Organisational structure</td>
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<tr>
<td></td>
<td>Policy, standards and goals</td>
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<tr>
<td></td>
<td>Safety culture and priorities</td>
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<tr>
<td>Institutional context factors</td>
<td>Economic and regulatory context</td>
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<tr>
<td></td>
<td>National health service executive</td>
</tr>
<tr>
<td></td>
<td>Links with external organisations</td>
</tr>
</tbody>
</table>
Two main approaches are cited as to why adverse events occur, namely the ‘person approach’ and the ‘systems approach’. The ‘person approach’ predominantly focuses on the error of an individual as a result of inattention, carelessness, poor motivation, recklessness and negligence. The ‘systems approach’ focuses on a number of factors within the system or organisation that ultimately led to the occurrence of the adverse event.

Although there are generally a number of layers of defences in existence to minimise the potential for occurrence of an adverse event, such events do occur due to active failures and/or latent conditions. Active failures are described as unsafe acts, errors, or violations performed by staff at the ‘sharp end’ of the system or patient (Reason 2000). They include the following:

- action slips or failures, such as picking up the wrong medication
- cognitive failures, such as memory lapses and mistakes through either ignorance or misreading a situation
- violations such as deliberate deviations from safe practices, policies, procedures or standards.

Latent failures are created as a result of decisions taken at a higher level within the organisation and their damaging consequences may lay dormant for a while, becoming evident only when they combine with local triggering factors such as:

- understaffing
- inadequate equipment
- inadequate supervision.

Latent conditions can be identified and remedied before the occurrence of an adverse event, thus leading to proactive as opposed to reactive risk management following the occurrence of an adverse event.

Although individual clinicians may have reflected on the reasons for adverse outcomes in the past, the lessons learned may not have been widely shared. This reflected the fact that reasons for success or failure were usually described in terms of the quality of the individual clinician’s diagnostic and therapeutic abilities (Woloshynowych et al 2005). Medicine is now more complex and reliant on high technology, moving away from individual delivery of care to a more team-based approach, resulting in a wider range of factors determining the quality of care and the occurrence of adverse outcomes.

Incident reporting has proved to be a useful tool for decades in error prevention in high risk industries such as the aviation, nuclear and petro-chemical industries and has resulted in significant investment in the development of proactive and reactive safety systems. These industries do not compete on safety matters. For example, aviation accidents are exhaustively investigated and the lessons learned are disseminated widely. When significant changes are required, these are made mandatory by the regulatory authorities.
The opposite can be said about healthcare where the learning is fragmentary, uncertain and usually confined to individuals or teams.

### 7.4.3 Objectives of adverse event reporting

The primary purpose of event reporting is to learn from the experience of adverse events and near-misses in order to reduce or prevent patient injury or harm. The objective is specifically to utilise the results from data analysis and investigation to formulate alerts and enable the lessons learned by healthcare organisations to be disseminated more widely (World Alliance for Patient Safety 2005). Analysis of many reports by the receiving agency or others can reveal otherwise unrecognised trends and hazards that require specific attention and can lead to insights into underlying systems failures and generate recommendations for ‘best practices’ for all to follow (World Alliance for Patient Safety 2005).

The information gained from the identification, analysis and learning from events can be utilised at a local level to identify trends and patterns that will enable prioritisation of the development of safety improvement programmes. Information gained from event reporting can contribute to the identification of gaps in the local organisation that require attention.

The information gained from the identification, analysis and learning from events can be utilised at a national level to identify trends and patterns that may not necessarily be evident in an individual local reporting system. For example, a catastrophic event may occur as a once-off in an organisation, leading to local management of the event and subsequent learning. However, the replication of this adverse event across a number of organisations, if reported nationally, will raise the awareness of the problem and enable prioritisation of the development of national safety improvement programmes. To enable effective analysis of adverse events across organisations within Ireland, there is therefore a need to standardise classifications of adverse events.

### 7.4.4 Effective adverse event reporting systems

A report commissioned by WHO and prepared by the Joint Commission on Accreditation of Healthcare Organisations (JCAHO), defines the attributes of an ideal classification scheme as follows:

- It should address a broad and diverse range of patient safety issues and concerns across multiple healthcare settings.
- It should identify high-priority patient safety data elements that are important to healthcare systems.
- It should classify information related to what, where and how medical management goes wrong, the reasons why medical incidents occur, and what preventative and corrective strategies can be developed to keep them from occurring or to ameliorate their effects in healthcare.
It must provide a meaningful and comprehensive linkage between the contributory factors and the errors and systems failures that lead to adverse events.

It should facilitate the monitoring, reporting and investigation of adverse events and near-misses at the public health level – allowing aggregated data to be combined and tracked.

It is clear that in order to be effective a system of reporting should be accessible, useful and useable. It should be capable of being used for managing events at a local level and the information gathered should be able to be used at state, national and international levels, with the capability to interface with existing local systems and be applicable across all areas of healthcare. Runciman et al (2006) advocate that the system should be:

- based on an underlying information model consistent with those used in other high risk industries such as aviation, rail, oil rigs and nuclear power
- supported by a comprehensive, universal patient safety classification
- able to elicit, classify, store, analyse and manage things that go wrong across the entire spectrum of healthcare from near-misses to adverse or sentinel events
- able to accommodate information from other sources
- populated by concepts shown to be needed from ‘real world’ data
- able to be used by funders, administrators, providers, carers, patients and other clients or consumers

Finally, the system should complement other members of the family of International Classifications of the World Health Organisation by incorporating subsets of concepts or cross mapping directly where relevant.

From the national or international perspective the system should be:

- able to be presented using local terminology and in different languages, using terms that are commonly used and understood in that particular region or jurisdiction
- customisable so that it can take account of legal, ethical and privacy requirements which may vary from region to region
- able to be used in conjunction with existing ‘home grown’ or proprietary systems for importing or collecting data by using mapping interfaces
- able to be used in a number of ways suitable for developing, transitional and developed countries
- able to be used in such a way as to elicit and capture simple basic sets of information as well as complicated detailed sets of information about all of the components of the underlying information model
- able to be applied across all of healthcare from self-care and domiciliary care through to high technology intensive care and transport of the critically ill
- able to have additional streams of local relevance e.g. accommodating various forms of alternative or herbal medicine.

Finally, the system should allow the use of locally approved ‘reference lists’ for items such as drugs and devices.
From the perspective of local administration the system should:

- allow for anonymous reporting and for high level confidentiality
- have mechanisms for authenticating quality control with respect to reliability and validity
- have comprehensive flexible security, allowing access to data and for fields to be user-specific
- have comprehensive audit trails
- be able to guide users and facilitate compliance with statutory immunity and privacy requirements wherever relevant
- allow for comparisons across like units throughout a jurisdiction, with the identity of the other like units being masked
- have explicit arrangements for support, backup, maintenance and updating
- have suitable mechanisms for communicating information about ‘bugs’ and desired enhancements.

7.4.5 Current adverse event reporting structures and processes in Ireland

A number of different adverse event reporting systems are in place throughout the health service in Ireland e.g. those operated by the CIS, Mental Health Commission and the Irish Medicines Board. However, there is no universal system that collects and collates adverse event data from all elements of the health sector.

A national confidential web-based clinical incident reporting system, STARSWeb, has been developed and rolled out nationally by the Clinical Indemnity Scheme (CIS). This system is designed to capture all clinical adverse events and near-misses occurring in enterprises covered by the scheme. All such enterprises have a statutory obligation to notify these events to the CIS. This, however, covers only those enterprises indemnified by the scheme i.e. all public hospitals and health services in the Republic of Ireland managed by the HSE. It does not include primary care or the private sector. Numbers of adverse events notified via STARSWeb continue to rise each year. From January 2004 up to the end of March 2008, over 160,000 clinical incidents, the most common of which were slips/trips and falls, had been notified via the system. This system supports local risk management initiatives at enterprise level and also allows for national trend analysis.

Since feedback to staff who report incidents is of paramount importance in supporting a reporting culture, a variety of methods are used to share the learning from data on the system. These include the quarterly CIS newsletter, website, topic-based fora, seminars and specific reports on an ad hoc basis to HSE enterprises.

This system is subject to ongoing quality improvement initiatives. One such initiative, commissioned by HIQA, the HSE and the CIS working in partnership, undertook a review of the quality of data on the system. The Commission suggests that recommendations contained in the recent report on this review (STARSWeb: Evaluation Project, 2008) should be considered in the light of future quality improvement opportunities to develop adverse event reporting in Ireland.
7.4.6 Adverse event reporting structures and processes in other jurisdictions

Denmark

A Patient Safety Act was passed in Denmark in June 2003 to gather, analyse and communicate adverse events in order to reduce adverse events in the Danish healthcare system. The Act defines an adverse event as ‘... an event that results from treatment at or stay in a hospital and which is not caused by the patient’s illness, and which is concomitantly either harmful or could have been harmful, but was prevented from occurring or did not occur for other reasons. Adverse events include both previously known and unknown events and errors’.

A particular feature of this Act is that it obliges frontline personnel to report adverse events, hospital managers to act on the reports and the National Board of Health to disseminate learning from the reports. Although reporting is mandatory, no sanctions exist with regard to non-compliance. Healthcare professionals cannot be subjected to ‘disciplinary investigations or measures by the employing authority, or to supervisory sanctions by the National Board of Health, or to criminal sanctions by the courts’, as a direct result of reporting adverse events as stated within the Act. To secure this, the learning system is strictly separated from the complaint system, the supervision system and the patient insurance system. Reporting results for 2006 show that 25% of the incident reports were submitted by physicians.

The Danish Patient Safety Database is the national reporting system held by the National Board of Health. It currently receives reports pertaining only to the hospital sector; however, during 2007 a Bill was put forward to extend the system to the primary sector, to patients and to their relatives. The database receives analysed reports from all of the five Danish regions and is therefore in a position to identify trends and patterns and feed back information to the regions regarding specific risk issues in the form of newsletters, alerts and specific safety reports. Patient safety alerts are published along with quarterly and annual reports. The information from the national reporting system is used to underpin the development of national patient safety standards.

The United States

In the United States, the Patient Safety and Quality Improvement Act 2005, was enacted in response to growing concern about patient safety and also the Institute of Medicine’s 2000 report, *To Err is Human: Building a Safer Health System*. The goal of the Act is to improve patient safety by encouraging voluntary and confidential reporting of events that adversely affect patients (AHRQ 2006). This Act sets out the federal Government’s commitment to developing a patient safety culture. Patient Safety Organisations (PSOs) have been created to collect, aggregate and analyse events reported to them confidentially by healthcare providers. This data collection is used to identify patterns of failures and propose measures to eliminate patient safety risks and hazards. The Act provides legal privilege and confidentiality protections for information that is assembled and reported by providers, or developed by a PSO, for the performance of patient safety activities.
It also significantly limits the use of this information in criminal, civil and administrative proceedings. Monetary penalties can be imposed for breaches of confidentiality or privilege protections.

The Act called for the establishment of a Network of Patient Safety Databases (NPSD) to provide an interactive, evidence-based management resource for providers, PSOs and other entities. It will be used to analyse national and regional statistics, including trends and patterns of patient safety events. The NPSD will employ common formats such as definitions and data elements.

Twenty seven state governments currently operate an adverse event reporting system, twenty six of which are mandatory and one is voluntary. The twenty six states operating a mandatory system are underpinned by either statute or regulations determined by the state. The aims of these reporting systems are to hold healthcare facilities accountable for weaknesses in their systems and to improve patient safety through analysis and dissemination of best practices and lessons learned (Rosenthal 2007).

The reporting requirements vary widely from state to state, though all require disclosure of events that result in unanticipated death (Redhead 2005). For example, Washington requires the reporting of medication-related errors, whereas Tennessee requires healthcare facilities to report any ‘unusual events’. In Florida, hospitals are required to report errors that result in certain specified injuries (e.g., brain or spinal damage), whereas in Pennsylvania they must report ‘any situation or occurrence that could seriously compromise quality assurance or patient safety’. Arizona requires healthcare facilities to review reports made by medical practitioners regarding violations of professional standards or the law. In contrast, New Jersey requires hospitals and other institutions to report ‘serious medical errors’ to regulators and patients. Some states also include in their reporting mandates provisions to prevent the discovery of error information in civil or administrative proceedings. Few states have the experts to analyse more than a fraction of the reports they receive. Most reports are not investigated and few hospitals receive any feedback (Redhead 2005).

**United Kingdom**

The National Patient Safety Agency (NPSA) is a special health authority that was created to co-ordinate the efforts of all those involved in healthcare and to learn from adverse events occurring in the NHS. The NPSA aims to improve patient safety by:

- collecting and analysing information on adverse 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 healthcare and that treatment is organised and delivered
- ensuring that where risks are identified, work is undertaken on producing solutions to prevent harm, specify national goals and establish mechanisms to track progress.
In 2004 the NPSA implemented the National Reporting and Learning System (NRLS), in England and Wales, enabling 607 NHS organisations to report patient safety incidents. The system was designed to complement local reporting arrangements by ensuring that all local incident reports would be pooled anonymously in a national system. This was designed to allow trend analysis and to facilitate learning from these events.

The reports are analysed with expert clinical input to enable a clearer understanding of the frequency, patterns and trends and any contributory factors. Lessons learned from the analysed data are disseminated in a number of ways, including the publication of the NPSA Patient Safety Observatory Reports, NPSA Patient Safety Alerts (twenty six issued to date) and provision of feedback to reporting agencies of data on incident trends and potential solutions. An electronic reporting form is available to facilitate anonymous reporting, and patients and carers can also report patient safety incidents verbally to the Patient Advice and Liaison Service.

**Australia**

The Australian Patient Safety Foundation (APSF) is a non-profit, independent organisation dedicated to the advancement of patient safety and the provision of leadership in harm reduction to patients in all healthcare environments. It provides the Advanced Incident Management System (AIMS) which is designed to facilitate capture of data including near-misses and sentinel events from a wide variety of sources to enable de-construction and trend analysis. This system is currently in use across the universal public health system in five of the eight states and territories of Australia, with additional sites in other states and in New Zealand, and a pilot site in the US. The data from this system have been used for research purposes in other countries.

### 7.4.7 Other methods for measuring errors and adverse events

It is important to note that incident reporting is only one tool in the patient safety/quality improvement armoury. Other methods for identification and measurement of latent errors, active errors and adverse events include (Thomas and Peterson 2003):

- morbidity and mortality conferences and autopsies
- malpractice claims analysis
- error reporting systems
- clinical surveillance
- administrative data analysis
- chart review
- electronic medical record
- observation of patient care.
Advantages and disadvantages are associated with each method. Some methods are more suitable for detecting latent errors whilst others are better suited to detecting active errors. Analysis of settled malpractice claims can involve non-standardised sources of data and can be associated with hindsight and reporting bias. However, it is useful for detection of latent errors and is therefore a potentially significant source of patient safety information.

### 7.4.8 Voluntary v mandatory reporting

One particular aspect of reporting systems that has generated much debate is the question of whether reporting adverse events should be voluntary or mandatory. Voluntary reporting systems rely on strong educational initiatives, institutional supports and professional codes of conduct to encourage, promote and support healthcare professionals in reporting adverse events. Mandatory systems such as those in operation in the United States seek to make healthcare providers accountable for serious mistakes by requiring that they be reported, and by providing disincentives such as sanctions for the continuation of unsafe practices.

Proponents of mandatory reporting view it as a way to make healthcare organisations responsive to public expectations for safe, high quality healthcare. Mandatory reporting systems are intended to hold providers accountable for performance in two ways: first, they may help assure that serious mistakes are reported and investigated and that appropriate follow-up action is taken and second, they provide disincentives (e.g. citations, penalties, sanctions, possible public exposure and possible loss of business) for organisations to continue unsafe practices (Flowers and Riley 2001).

**Comparison of Mandatory and Voluntary reporting systems in US**

<table>
<thead>
<tr>
<th>Purpose</th>
<th>Mandatory</th>
<th>Voluntary</th>
</tr>
</thead>
<tbody>
<tr>
<td>Purpose</td>
<td>Accountability</td>
<td>Safety improvements; detection and analysis of systemic problems before serious injury or death occurs</td>
</tr>
<tr>
<td>System administration</td>
<td>State government</td>
<td>Private organisation</td>
</tr>
<tr>
<td>Obligation to report errors</td>
<td>Establishes legal obligation to report; relies on penalties and sanctions to encourage compliance</td>
<td>Relies on trust in the reporting system and a commitment to its purpose</td>
</tr>
<tr>
<td>Type of data reported</td>
<td>Medical errors that result in serious injury or death</td>
<td>Medical errors that result in no harm (close calls) or minimal harm</td>
</tr>
</tbody>
</table>
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<table>
<thead>
<tr>
<th>Public disclosure of data</th>
<th>Mandatory</th>
<th>Voluntary</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Validated information available to the public</td>
<td>Strictly confidential; only de-identified data publicly available</td>
</tr>
</tbody>
</table>

| Use of reported data | Verification of data to ensure consistency with reporting definitions and attribution to error; analysis of data and identification of ways to avoid a recurrence of the error; oversight and evaluation of corrective actions taken | Analysis and interpretation of errors; identification of system vulnerabilities; development of preventative strategies |

(Rehead 2005)

As can be seen from the table above, the objective of both systems is to improve patient safety through analysis of data and dissemination of best practice and lessons learned (Rosenthal 2007). However, from the available research in relation to both voluntary and mandatory systems, it seems that the two systems fall short of their objectives (Leape 2002). Leape’s analysis of the implementation of the mandatory systems in the United States demonstrates the following:

- Few states have the experts to analyse the reports so most hospitals do not get feedback and no state tracks trends.
- Some findings are made public but detailed information is generally insulated from legal discovery.
- Those who administer the programmes have no doubt that mandatory reporting and investigations of serious events have led hospitals to introduce changes to prevent recurrences, but the evidence is anecdotal. No controlled studies have been performed.
- Low reporting rates suggest that the effect of these systems is small.
- The effect of newsletters is not known.
- It is also not known whether state oversight makes hospitals more careful. If the measure of success is the number of reports received, the systems are fairing poorly – only six state systems received more than 100 reports annually.

The international evidence demonstrates that making mandatory reporting systems safe and productive is a challenge. Reporting can never be safe – to ensure accountability, there must be a power to impose sanctions. However, if sanctions are limited to serious violations and if useful information is provided, it may be seen by hospitals as just and justifiable (Leape 2002).

One of the main challenges in relation to reporting is the fear of litigation. Providers are reluctant to report adverse events because they fear that it will lead to an increase in legal
actions for negligence. The more comprehensive and organised the reporting system database, the greater the legal threat it may pose to providers. Patient safety lies at the heart of the current debate on medical malpractice reform in the United States (Redhead 2005). Many trial attorneys defend the current tort system, claiming that the threat of litigation makes providers practise safer medicine. They view tort law as an important driver of healthcare quality. But experts on healthcare quality reject this argument. Echoing the IOM’s recommendations, they contend that the only way to realise significant improvements in patient safety is by improving healthcare systems which requires the analysis of medical errors. By discouraging the reporting of such information, the tort system is in conflict with this approach to safety improvement.

In reality, the fear of litigation may be overstated. No link between reporting and litigation has ever been demonstrated. In fact, several reports indicate that full disclosure reduces the risk of litigation. In addition, hospitals have an ethical obligation to inform patients fully of the causes of their injuries. If patients know, then so could their lawyers in any event.

In an effort to encourage providers to report errors, most US states have adopted measures to protect reporting system data from use in litigation (Redhead 2005). Policymakers have had to balance provider concerns about the legal consequences of making information available to lawyers and patients with the desire for public accountability. Accountability does not require the release of all information, but the public wants evidence of oversight. A compromise might be to withhold details of a serious event but provide public notice of its occurrence and the actions taken to address it, or produce annual reports with aggregate data. Neither alternative will satisfy either hospitals or advocates of full disclosure, but will represent a reasonable middle ground.

The fear of liability is just one of several factors that lead to the underreporting of medical errors in the United States. Other identified factors include facilities’ lack of internal systems to identify events, the culture of medical practice that discourages drawing attention to errors, fear of institutional sanctions, anxiety about maintaining good relationships with peers, loss of business, damage to reputation and whether the amount of feedback and the potential benefits from reporting justify the time and effort it takes to report. There is not enough evidence to predict the impact that eliminating one or more of these disincentives would have on reporting behaviour (Redhead 2005).

Overall, it appears that state reporting systems in the US have had at best a modest impact on improving patient safety (Redhead 2005). Evidence from hospitals that the reporting and investigation of serious events has led to improvement in patient safety is largely anecdotal. Most state programmes are plagued by underreporting, especially in their early years of operation. The IOM report observed that few states aggregate the data or analyse them to identify general trends. Analysis and follow-up tend to occur on a case-by-case basis. The report cited limited resources and the absence of standard reporting requirements as major impediments to making greater use of the reported data. It concluded that ‘state programmes appear to provide a public response for investigation of specific events, but are less successful in synthesising information to analyse where broad system improvements might take place or in communicating alerts and concerns to
other institutions’. In some states, reporting systems established by law are not operating because of a lack of funds.

Comparison with aviation industry

The IOM report and several more recent analyses have all highlighted the Aviation Safety Reporting System (ASRS) as a potential model for establishing national voluntary systems for reporting medical errors (Redhead 2005). ASRS was created in 1975 to encourage pilots, controllers, flight attendants, maintenance personnel and others in the civilian airline industry to report incidents or situations in which aviation safety was compromised. The programme has become well-established and trusted within the airline industry and is credited with contributing to improvements in aviation safety over the past 28 years. ASRS analyses the voluntarily submitted aviation safety incident reports to identify deficiencies and discrepancies in the national aviation system so that corrective action can be taken. ASRS data are also used to support policies and planning for improving the national aviation system, and to strengthen the foundation of aviation human factors safety research. This is especially important given estimates that as much as two-thirds of all aviation accidents and incidents are rooted in human performance error. ASRS provides feedback to the aviation community in the form of alert messages identifying problems that may require immediate action, analytical reports, an online database, a monthly safety newsletter and a quarterly safety bulletin.

Persons who submit reports are given two types of protection: confidentiality and limited immunity from disciplinary action in the case of a potential violation of federal air regulations. The Federal Aviation Administration (FAA) will not impose penalties upon individuals who complete and submit written incident reports to ASRS within 10 days after the violation provided that:

- the violation was inadvertent and not deliberate
- the violation did not involve a criminal offence or action which discloses a lack of qualification or competency
- the person has not been found in any prior FAA enforcement action to have committed a violation for a five-year period prior to the date of the incident.

ASRS administrators attribute the programme’s success to various factors:

- Reports are held in strict confidence and reporters are immune from disciplinary action if they report promptly.
- Reporting is simple and involves a one-page form.
- The programme is responsive – reporters receive timely feedback – and viewed as worthwhile by those who use it.
- The programme is administered by an agency that is independent of the FAA, which regulates the aviation industry. ASRS is seen as complementing the work of the National Transportation Safety Board (NTSB), which investigates aviation accidents that result in death or serious injury or in which the aircraft sustains significant damage.
7.4.9 Impact of medical error on healthcare professionals

Medical errors not only affect patients and their families but can also have a significant impact on clinicians. Patients are clearly the first victims of medical errors, but in many instances, healthcare practitioners are the ‘second victims’ and commonly experience distress, guilt, shame and depression in relation to medical errors. Studies demonstrate that these feelings can be long-lasting, with some doctors feeling permanently affected as a result (Wu 2000).

The institutional reaction to a medical error is often to seek out an individual to blame rather than to focus attention on systematic improvements that could decrease errors in the future. Many errors are built into existing routines and systems, potentially setting up the patient and doctor for disaster. Doctors who have made bad mistakes describe the sickening realisation that something has gone wrong. They feel isolated, vulnerable and exposed as they panic over whether anyone has noticed the error, and then whether to confess (Wu 2000). The error replays itself over and over in the mind of the clinician, causing self-doubt and anxiety often for years after the event.

Medical errors have been shown to represent an important contributor to personal distress and loss of compassion amongst doctors. This is significant not only because of the personal effects of making an error, but also because it appears to negatively affect future patient care. The perception of having made an error affects the clinician’s self-belief and expectation of perfection, as well as causing great personal anguish. Sometimes clinicians react to their own errors with anger or by attempting to pass the blame to someone else. Sometimes this escalates in circumstances where litigation results from the error and the clinician may become depressed, immerse himself/herself in work, or seek relief in alcohol or drugs (Wu 2000).

When errors do occur, studies show that clinicians often have limited support mechanisms to turn to. The majority seek support from colleagues, supervisors, close family and friends. However, the unconditional sympathy and support that is needed is often lacking. Confession is not actively encouraged, and even when the error is discussed with colleagues, it is usually simply the medical facts that are analysed rather than the reaction of the patient and clinician. Studies indicate that specific curricula on personal awareness and self-care to promote strategies for coping with the personal impact of errors are needed but are seldom available (West et al 2006).

The literature reports some clinicians availing of support structures such as discussing the error with patients, accepting responsibility and working to put prevention methods in place for the future. Clinicians report great relief in disclosing the error to patients who are often forgiving and supportive. A problem-solving focus which explores what could have been done differently, and what changes can be made to prevent recurrence, can also transform the experience for the clinician involved. Open discussion and acknowledgement of mistakes by other colleagues can provide valuable educational and emotional support (West et al 2006).
Medical error not only affects doctors, but also impacts on nurses and other members of the multi-disciplinary team who sometimes are conflicted between loyalty to their patient, the institution and their medical team.

7.4.10 Patient and family reporting

A facility for service-user reports is necessary in order to create a safety culture and increase safety knowledge, although significant progress in this area has not been realised and service-user experience represents a valuable but so far relatively untapped source of information. Preliminary research suggests that patients will report errors when there is a mechanism for doing so (Agoritas et al 2005; Wasson et al 2007). The experiences of individuals should be collected to be pooled and aggregated so as to enable system-wide lessons to be learned.

Service-user reports are unique because they can provide information across the health system, whereas most of the other sources tend to be focused on particular care settings which see patients periodically and as a result they offer great potential to highlight problems across the transition of care settings. Such reports will also give the unique patient perspective which cannot always be appreciated by health service providers who are working to routines. Such a development would also provide transparency. It is reasonable to infer that once service-users are engaged in understanding the importance of reporting – by them as well as by providers and healthcare regulators – their trust that inherent healthcare risk is being optimally managed would increase.

7.4.11 Conclusions

It is essential that an effective and holistic patient-centred approach is taken to governance, management, reporting and communication following adverse events. The effectiveness, speed and style of communication of the local response to the adverse event or near-miss are key from the perspective of the patient, the patient’s family and the staff involved. The culture within the healthcare facility will influence this response and an open and transparent culture within facilities will enhance the communication and learning following such events.

In order to ensure that the appropriate action is taken to support the patient and staff involved, every healthcare facility should have effective arrangements in place to ensure that reporting, investigating, monitoring, feedback, learning and management of adverse events and near-misses is discharged effectively and is a priority of the Board of the facility.

However, it is also essential that there is a national surveillance resource that receives reports of serious adverse events from across the system in order to ensure that the appropriate action has taken place, that trends are monitored and that learning takes place to inform the existing and future healthcare delivery and governance arrangements. The licensing regulatory framework proposed in Section 6.2.6 of this Report should also
require the mandatory reporting of serious adverse events to the licensing authority as a requirement of a healthcare facility.

The creation of a mandatory reporting system is very complex and there is no direct evidence to show that it results in meaningful improvement in practice. Opposition to mandatory systems is based on the belief that any reporting that is tied to punitive action or public disclosure will encourage making the system a ‘numbers game’ and drive reporting underground by perpetuating a culture of blame. Some argue that non-punitive and confidential voluntary systems provide more useful information about errors and their causes than mandatory systems because they provide the opportunity to practitioners to tell the complete story without fear of retribution. It is argued (Cohen 2000) that practitioners who are forced to report errors are less likely to provide in-depth information because their primary motivation is self-protection and adherence to a requirement, not to help others avoid the same tragedy. Voluntary programmes also encourage practitioners to report hazardous situations and errors that did not cause harm but have the potential to do so. It is not feasible to require reporting of near-misses and as a result critical information is lost and error prevention strategies less likely.

There is a central conflict underlying the development of mandatory reporting systems and this creates a significant barrier. The public desires accountability while hospitals and doctors fear liability and damage to their reputations. Doctors and hospitals generally support voluntary reporting and sharing of information to improve patient safety by learning from prior mistakes and experience. However, the public feels that mandatory reporting improves accountability. The challenge is to integrate these elements by providing accountability within a learning environment.

The Commission discussed the advantages and disadvantages of both voluntary and mandatory reporting systems. It considered systems in operation in other jurisdictions as well as the current reporting system in place in Ireland under the aegis of the Clinical Indemnity Scheme (CIS). The current position is that there is a de facto requirement for mandatory reporting of all clinical adverse events occurring in enterprises covered by the scheme, as the legislation governing the CIS stipulates a statutory requirement to report such events. There is however no sanction in the event of non-reporting. This mirrors the national reporting system in place in Denmark.

The Commission concluded that systems that rely wholly on spontaneous reporting are ineffective and result in underreporting. The Commission believes that a mandatory system will improve patient safety and ensure greater accountability by requiring specific reports of serious injury to be made by healthcare providers, and disseminating lessons to be learned throughout the system. The development of a complementary voluntary system of reporting of close calls or near-misses will contribute to further learning and dissemination of best practice. This is already in place for enterprises covered by the CIS but should be extended to cover all future licensed establishments.
7.4.12 Recommendations

The Commission recommends the following:

R7.19 The WHO standardised taxonomy, which describes definitions of adverse events, should be adopted on a national basis.

R7.20 Standards should be developed for adverse event reporting across both public and private healthcare providers.

R7.21 A national mandatory reporting system should be introduced for the collection of standardised information on adverse events that result in death or serious harm. The system must clearly delineate the events which must be reported, such as those listed in the National Quality Forum’s 28 Never Events, but should not be confined to those events. The system should include provision for the voluntary reporting of other non-serious adverse events and ‘near-misses’.

R7.22 In order to be effective, the collection and dissemination of this information must be the responsibility of a national agency that can provide national leadership on learning from errors. The agency should provide analysis and feedback in order to ensure that lessons are learned and models of best practice are implemented effectively.

R7.23 Effective governance arrangements should be put in place to ensure that the Clinical Leaders responsible for safety and quality in healthcare facilities, and other relevant individuals, should exchange learning and improvements resulting from adverse events and near-misses at regional and national levels. Where these are employees of facilities within the Health Service Executive, these arrangements should connect seamlessly into the HSE’s corporate governance arrangements.

R7.24 A group should be established to collaborate and report on the detailed implementation of these recommendations and in particular the most appropriate repository for the maintenance of such a comprehensive database and the dissemination of learning throughout the system including the facilitation of rapid alerts as necessary.

R7.25 The national reporting system should be compatible with and capture data from all existing incident reporting systems, or may replace local systems. The information collected in this database should inform all safety and quality initiatives, policies and clinical protocols.
R7.26 Every healthcare facility must have a serious adverse event policy which is immediately triggered when a serious adverse event takes place. The Group needs to consider the reporting arrangements and timeframe for reporting such events into the proposed national system.

R7.27 Every healthcare facility should ensure that, as part of its safety and quality governance arrangements, the reporting, investigating, monitoring, learning and management of adverse events and near-misses is discharged effectively and reported to the Board of the facility.

R7.28 Professional regulatory bodies should include mandatory reporting as an ethical obligation within their Codes of Professional Practice.

R7.29 Professional regulatory bodies should collaborate to develop clear guidelines for health professionals in relation to reporting of adverse events and unsafe practices.

R7.30 The design of the reporting system must also facilitate patient and family reporting of adverse events, and patients should be advised accordingly.

R7.31 Aggregated validated data should be made available to the public in the form of annual reports.

R7.32 Information collected under the reporting system (both mandatory and voluntary) must be strictly confidential, protected from legal discovery and exempted from Freedom of Information legislation.

R7.33 Such legislation must require disclosure to appropriate professional regulatory bodies where there is evidence of significant deviation from agreed standards of care. If a criminal act has taken place, the appropriate legal authorities must be notified.

R7.34 There must be adequate administrative and IT resources in place to support the reporting system.

R7.35 Education and training supports in relation to reporting systems, including the development of appropriate skills for dealing with adverse events, must be provided at all levels of the health system, from undergraduate and postgraduate education to continuing professional development programmes.
There should be continued research on the impact of adverse events on healthcare workers, the results of which must be integrated into continuing professional development and ongoing education programmes. This research will be complementary to that recommended in R4.21 in Chapter Four on the impact of adverse events on patients and their families.

7.5 Medication safety

The Commission considered specific issues pertaining to medication safety and were of the view that patients are entitled to expect the highest standards of safety, quality and efficacy of medicinal products, their ethical marketing, and the safe use of medicinal products in the hands of healthcare professionals, carers and patients themselves. To that end the Commission strongly encourages pharmaceutical companies to ensure the safety, quality and efficacy of the medicinal product, including ensuring freedom from contamination or counterfeit contents.

The Irish Medicines Board (IMB) is responsible for the regulation of medicinal products. The Commission supports the continued promotion of pharmacovigilance by the IMB and the capture of information regarding adverse drug reactions, the provision of effective feedback and the uptake of this information by healthcare professionals and patients.

Medication reconciliation

When patients move from one care setting to another – between home and hospital; between long-term care facilities and hospitals; and within hospitals between units such as from ICU to regular wards – a significant level of discrepancy between actual medication treatment and what was intended can arise. It has been estimated that as much as 46% of all medication errors occur at these transition points. For example, an American study (Cornish et al 2005) found that 53.6% of patients had at least one unintended discrepancy in their medication at admission to hospital. The most common error was drug omission (46%). Of these errors, 38.6% had the potential to cause moderate to severe discomfort or clinical deterioration of the patient. Recent Irish research (Grimes et al 2008) into discrepancies at discharge from hospital found that 65.5% of patients had an unintended discrepancy in their prescription. The most common inconsistency was drug omission (20.9%).

Medication reconciliation is the process of obtaining a complete and accurate list of each patient’s current medications from all available sources at all points of contact and verifying and reconciling medications to reduce medication errors. In order to succeed, medication reconciliation must be a formal, standardised process that is built into the system of care. Each time a patient moves from one setting to another, clinicians must compare previous medication orders with new orders and plans for care and reconcile any differences.
7.5.1 Recommendations

The Commission recommends the following:

**R7.37** There should be national analysis of the problems and potential solutions to the issues surrounding unlicensed medicines and medicine shortages by the Irish Medicines Board (IMB), the Irish Pharmaceutical Healthcare Association (IPHA) and other key stakeholders such as the Health Service Executive (HSE).

**R7.38** The powers of the IMB should be enhanced to ensure that all medicinal products, herbal, homeopathic and traditional remedies undergo rigorous control of safety, quality and efficacy, both at the licensing stage and post-marketing.

**R7.39** The licensing requirements of the IMB should include risk assessments of the medicinal product in use, in order to identify risks in prescribing, dispensing, administration in primary and secondary care and patient evaluation of the information in patient information leaflets (currently included in requirements), packaging and labelling. Risks identified should be minimised and user testing repeated to ensure risk reduction is brought to an acceptable level.

**R7.40** Problems identified with products on the market through emergence of medication errors where product name, labelling and packaging were contributory factors should be monitored, collated and result in rapid changes where appropriate. Communication, coordination and cooperation between all agencies involved will be necessary.

**R7.41** Communication structures between all bodies with a stake in the medication use process or in medication safety should be clearly established e.g. the IMB, pharmaceutical companies, professional societies and regulatory bodies and the CIS. There should be linkages between the pharmaceutical industry and the IMB to ensure that safety issues identified which may be improved by changes to pharmaceutical products (e.g. packaging, labelling, patient information) are acted upon as a matter of urgency. Linkages with all professional bodies are needed to ensure that safety messages are being promoted through professional channels as well as by the safety body.

**R7.42** As part of the safety and quality governance framework, healthcare organisations must prioritise the implementation of formal medication reconciliation systems. This would include regular tracking audits and the deployment of suitable resources for this purpose.
7.6 Appropriate environment/setting

It is impossible to consider the concepts of safe and effective care being delivered by skilled professionals in isolation from the physical environment and setting in which that care is provided. Although the Commission did not undertake detailed research into these aspects of care, it is aware of work that is being done within other areas of the healthcare system to identify best practice and make recommendations in respect of both the setting of care and the built environment in which care is delivered to optimise safe, high quality and patient-centred care.

The setting of care

The Commission notes the thrust of several national strategy documents such as the Primary Care Strategy (2001) and the HSE Acute Hospital Bed Capacity Review (2007) that care should ideally be delivered as close as possible to where the patient lives. With the advent of new technology and new options for service delivery it will be increasingly possible to provide treatments very close to where people live. However, the Commission recognises that there is a need to get the balance right between accessibility and effectiveness, and in some cases treatment services will have to be centralised for reasons of effectiveness and safety. In such situations, every effort should be made to ensure patient-centred care through the provision of adequate practical patient supports such as transport facilities and family and visitor facilities etc.

The built environment

As described in the recent draft Healthcare Infection Prevention and Control Building Standards report produced by the National Committee of the Strategy for the control of Antimicrobial Resistance in Ireland (SARI), the design of the built environment in which patient care is delivered should meet the requirements of safe, high quality care by:

- maximising patient comfort and dignity
- ensuring ease of delivery of professional care
- making appropriate provision for family members and visitors
- minimising the risk of infection
- minimising the risk of other adverse events such as falls or medication errors
- managing the flow of patients
- allowing for flexibility of use over time and planning future service requirements.

The recommendations contained in the draft SARI report are designed to minimise the risk of infection in hospitals. However, many of the same design factors that help to prevent the transmission of infection, such as adequate space around beds and increasing the proportion of single rooms, also address a number of the other design requirements listed above.

In 2007 the Irish Hospice Foundation published a report entitled Hospice Friendly Hospitals Project Design and Dignity Review. As background to the report, a literature review on
how design and configuration of facilities can be supportive to dignity and privacy around end-of-life care in hospitals was carried out. Similar to the draft SARI report noted above, this report makes recommendations in the areas of single room provision, management of the internal and external environment, configuration of care provision and provision of family and visitor facilities.

7.6.1 Conclusions and Recommendations

The Commission did not comprehensively examine the growing body of work in relation to the concept of evidence-based design of hospitals and other healthcare facilities. However, the Commission is persuaded by such evidence as has been made available to it and by submissions made on this issue that the implementation of evidence-based design will result in safer and higher quality care for patients, with resultant economic benefits for the health system.

The Commission acknowledges that capital investment in public health facilities has traditionally also involved increases in staffing and revenue costs. This has, inevitably, had an impact on the scale and nature of capital investment in health. However, the evidence now available would indicate that there may be a strong case for investing in public health facilities in a way which would not only improve the quality of care provided to patients but also increase the cost-effectiveness of the service.

The Commission recommends the following:

R7.43 Having regard to the need to balance accessibility, safety and effectiveness, care should ideally be delivered as close as possible to where the patient lives. Standards should be set for built healthcare environments in the State, in public, private and voluntary health and social care facilities, and those standards should be governed by considerations of safety and quality.

R7.44 The Department of Health and Children should commission an independent report on the principles and implementation of evidence-based design of healthcare facilities for the Irish health system.

7.7 Health information and health information technology

Introduction

Information is at the heart of understanding and knowledge. It is fundamental for a country to have accurate, meaningful and accessible information to assist patients, the public, healthcare professionals, planners and politicians in improving the safety and quality of the healthcare provided at all levels of the system. Consequently, it is impossible to think about improvements in safety and quality in healthcare, and the development of a high reliability healthcare system, without also considering the health information and health
information technology (HIT) developments that are required to enable and sustain these improvements and further the understanding and knowledge of the health system.

High quality information should be at the core of decision-making concerning health at all levels, from individual patient care to the planning and management of services at local and national levels. However, access to information in healthcare is frequently limited and fragmented. Patient records in many areas of care are paper-based or, if computerised, are in formats that cannot be shared easily between providers. The management information collected within health is usually for financial or administrative purposes rather than being directed at the outcomes of clinical care and the safety and quality of services.

However, fit-for-purpose health information technology, and therefore the necessary information communication technology (ICT) systems, are essential to underpin a modern health system and to support the provision and accessibility of accurate and meaningful health information. HIT is commonly regarded as critical to the transformation of healthcare. However, the sector has lagged behind other sectors in the adoption of technology, and the underpinning foundations of an effective ICT infrastructure in healthcare are often seen as a low priority, particularly when decisions to invest in ICT to improve patient safety are competing with other service delivery priorities. The implications of the delays in building these foundations often result in increasing cost requirements and risks to the implementation of new information systems when the existing legacy systems are out of date and inoperable with new technology.

Despite some localised examples of good practice in HIT and health information within the Irish health system, technology for the delivery of clinical care has lagged behind administrative and financial applications. As a result, the available information tends to be limited more to financial and administrative information rather than the impact of care on the patients, and therefore meaningful information on the assessed outcomes for patients is restricted.

Multiple studies and international experience show that the effective use of information systems and HIT can lead to considerable benefits in improving patient safety, quality of care and the use of health information to drive improvements and knowledge. Consequently, in other major health systems which have sought to systematically address patient safety and quality, health information and HIT developments have been identified as central to this health reform agenda.

The eHealth for Safety: Impact of ICT on Patient Safety and Risk Management Report (European Commission 2007), undertaken on behalf of the European Commission, identified that in many European countries, one of the most important developments in eHealth in recent years has been the implementation of electronic health records at national, regional and local levels. Similarly, the Institute of Medicine in the US advises that moving from a paper to an electronic-based patient record system would be the single step that would most improve patient safety.
In the Irish context, the effective use of quality-based information systems, modern communications technology and the effective use of health information has the potential to make a major contribution to improved patient safety and quality through the following means:

- reducing errors in drug prescribing by flagging allergies and contra-indications and in the dispensing and administration of medications
- providing more evidence-based care and seamless integrated care across all healthcare sectors and environments because information will accompany the patient through the system and be available where it is needed and when it is needed
- empowering patients and other healthcare service-users by opening up health-related knowledge bases to assist choice thereby facilitating a new information based relationship between patients and healthcare professionals and health agencies
- improving planning, management and the delivery of health services and health projects through better information management, enhanced business planning and control and greater risk management
- better research and disease management outcomes which benefit both individuals and society, due to total population studies rather than limited sample ones
- establishing new data collections and data sets that will help identify and manage the specific health needs of defined population groups across different care settings
- mitigating public health and other population threats by improving our ability to detect and respond quickly, for example to disease outbreaks
- extending the scope of healthcare beyond its current boundaries through, for example, telemedicine and home-based care, especially for patients with chronic conditions, which has particular relevance for rural and island communities
- more accessible continuing education for healthcare professionals through online training models
- enhancing the privacy, confidentiality, integrity and security of patient information through the computerised tracking and auditing of access to patient records.

Discussion Paper on proposed Health Information Bill
(Department of Health and Children 2008)

The achievement of the Commission’s vision for the health system of ‘knowledgeable patients receiving safe and effective care from skilled professionals in appropriate environments with assessed outcomes’ is dependent on all of these factors being realised and the necessary support for patients and healthcare professionals in embracing the developments and changes in behaviour that are necessary with improved health information and HIT. It is therefore evident that the development of health information and HIT is critical to the achievement of the strategic recommendations outlined elsewhere in this Report.

This section reviews the international and Irish experience to date in this area, and outlines the health information and HIT developments that are most important in terms of their potential to enhance safety in the Irish system.
7.7.1 International experience from other health systems

Health information and HIT have been identified as key areas for development for patient safety and quality in several countries including the United States, the United Kingdom, Finland, Canada, Australia and New Zealand. The responsibility for researching, developing and implementing HIT projects at national levels has been assigned to specific agencies in these countries.

In general, comprehensive evidence for the benefits realised from HIT is variable. A number of health systems have been identified and benchmarked through systematic reviews in which the following effects from implementation of HIT were demonstrable (Chaudhry et al 2006):

- Overall, adherence to guideline or protocol based care was the major quality-promoting impact of HIT; this was facilitated by decision support functionality usually embedded in electronic health records or computerised provider order entry systems.
- Enhanced capacity to perform surveillance and monitoring for disease conditions and care delivery also improved quality; this included surveillance of adverse events and evidence-based quality enhancing processes of care. Information for surveillance and monitoring was gathered from electronic health records and would not have been feasible to collect using paper-based systems.
- Decreased utilisation of care was observed largely in the area of diagnostics and was facilitated by computerised provider order entry systems with embedded decision support applications that provided information on pre-test probability, previous results and costs of results and provided reminders.

Similarly, uniform recognition exists for the importance of having national health information standards in place in order to facilitate information sharing and re-use. This includes standard data definitions, coding, classification, terminology, messaging and Electronic Health Records.

However, international research literature also emphasises the major lessons that have been learned that need to be considered when implementing ICT tools in order to accomplish fully increased patient safety (eHealth for Safety: Impact of ICT on Patient Safety and Risk Management 2007). These are as follows:

- Systems should be delivered with the end user in mind.
- Systems should be fast and display all the relevant information in a coherent and easy-to-use manner.
- Organisational culture, including barriers to reporting errors, will play a key role in the acceptance of electronic tools such as incident reporting systems.
- The optimal benefits from ICT tools will only be reaped if these tools do not merely operate alongside each other but are integrated with each other.
The United States

The RAND Corporation has undertaken a large study of the potential impact of more widespread adoption of HIT in the United States (Bigelow et al. 2005). For the US, the costs of implementation were estimated at $8 billion per year (compared with an annual investment of approximately $1.7 trillion per year in healthcare) with an estimated saving of $77 billion per year in efficiency, which could be doubled if health and safety benefits were valued. Key policy options for moving forward on the implementation of HIT have been recommended from the RAND project:

- Legislative and regulatory changes, national leadership and collaboration of stakeholders are necessary to maintain momentum on efforts to enable HIT including uniform standards, common frameworks, HIT certification processes, common performance metrics, and supporting technology and structures.
- Market forces should be created to encourage HIT adoption including pay-for-use programmes in the short term and national performance reporting with alignment of payments in the longer term.
- Investment should be targeted to help overcome barriers and speed adoption of HIT.

An example of progressive developments in health information and HIT is the Veterans Health Administration Computerised Patient Record System in the US. This provides a single interface where healthcare providers can review and update patients’ medical records, and place orders for medications, special procedures, x-rays, imaging, nursing care, dietary requirements and laboratory tests.

The United Kingdom

In the UK there are a number of organisations and initiatives that aim to underpin the development of robust health information and health information technology. These include:

- **Connecting for Health (formerly the National Programme for IT):** This is an ambitious programme that aims to connect health across the community to provide better, safer services and includes the development and implementation of:
  - a system-wide electronic summary (care) record
  - a system-wide picture archiving and communication system (PACS) for digital imaging and the transmission of radiological images
  - improved GP electronic booking for referrals appointments
  - electronic transmission of prescriptions and electronic prescribing
  - development of the information technology infrastructure.

- **National Knowledge Service:** This aims to support evidence-based practice across the health system including supporting the development of decision-support software.
Building a Culture of Patient Safety

**NHS Direct:** This is a key national provider of information for the public providing telephone and e-health information services day and night. It provides information and advice relating to health, illness and health services in order to enable patients to make more informed decisions about their healthcare. Reviews of the impact of NHS Direct on the effectiveness of patient-focused interventions found that patients were generally satisfied with the service and that it could reduce healthcare utilisation without impacting negatively on patient safety (Coulter and Ellins 2006).

**National Patient Safety Agency:** This supports evidence-based safety initiatives.

**National Institute for Health and Clinical Excellence:** This leads in the area of appraisal, guidance and dissemination of guidance relating to public health, health technologies and clinical practice.

**Canada**
In Canada there are a number of key players with a breadth of roles across health information and health information technology. These include:

**Health-Infoway:** This was established to promote the implementation of health information technology, particularly the electronic health record, across Canada. Infoway acts as a strategic investor, providing leadership on investment decisions and collaborating with health ministries, regional authorities, other healthcare organisations and information system vendors.

**Canadian Institute for Health Information:** This is an independent organisation established jointly by federal, provincial and territorial ministers of health to provide essential information on the public health of Canadians and the health system. It does this by co-ordinating the development of a comprehensive and integrated approach to health information for Canada and providing timely information on public health and the health system.

**Canadian Agency for Drugs and Technology in Health:** This provides healthcare decision-makers with advice relating to health technology assessments and drug reviews and provides a Canadian Optimal Medication Prescribing Utilisation Service which promotes evidence-based, clinical and cost-effectiveness information on optimal drug therapy.

### 7.7.2 Strategic context in Ireland

The importance of health information and HIT to underpin the wider health reform programme, including the safety and quality agenda, has been set out in a number of key national strategy documents in recent years, including *Quality and Fairness – A Health System for You*, the *National Health Information Strategy* and *Primary Care: A New Direction*. 
National Health Information Strategy (NHIS) (2004)

This strategy arose from *Quality and Fairness – a Health System for You* (2001) and had the use of information to support safe and high quality client/patient care and in planning, developing, evaluating and accrediting the quality of the health services as its central theme to support the implementation of the *Quality and Fairness* Strategy and the Health Service Reform Programme. The main actions of the NHIS were:

- to establish a legislative and information governance framework to underpin health information
- to adopt an integrated, national approach to the development and expansion of information sources and systems
- to establish processes and structures that ensure the fuller use of health information in policy-making, service planning, care provision and to underpin quality assurance and accountability
- to improve access to health information for all stakeholder groups to be promoted through the development of a health portal for the public
- to establish health information standards that ensure the quality and comparability of health information and enable sharing
- to develop and implement an electronic health record supported by unique identification and information governance
- to exploit the enabling technologies in the collection, processing, analysis and dissemination of health information and its application in the delivery of health services.

The NHIS was published in 2004 prior to major structural changes involving the establishment of the HSE and HIQA. The Strategy is not fully implemented and needs to be reviewed in order to clarify the roles and responsibilities of the Department of Health and Children, HSE and HIQA arising from structural changes. This work is being advanced by the recently established Health Information Inter-Agency Group which includes representatives from each of the three bodies in question.

Primary Care: A New Direction

This strategy was developed to set out an approach to strengthen primary care as a framework for change to support the goals of *Quality and Fairness – a Health System for You*: (Department of Health and Children 2001). The main aims were to develop:

- a greatly strengthened primary care system which will play a more central role as the first and ongoing point of contact for people with the healthcare system
- an integrated, inter-disciplinary, high quality, team-based and user-friendly set of services for the public
- an enhanced capacity for primary care to complement the existing diagnosis and treatment focus in the areas of prevention, early intervention, rehabilitation and personal social services.
Information communication technology (ICT) was envisaged as a fundamental requirement for implementation of this strategy in order to strengthen primary care and the integration of the patient journey. Limited information from primary care for planning, development and evaluation was recognised as a weakness of the system, and a need for considerable investment in information and communications technology infrastructure was identified, including the development of an electronic health record based on a unique patient identifier.

7.7.3 Initiatives and roles in relation to health information and health information technology in Ireland

There are a number of stakeholders with an involvement, and/or interest, in the development of health information and health information technology across Ireland. These include the public, patients, healthcare professionals, patient associations, professional bodies, regulatory bodies, the HSE, voluntary and private providers of healthcare, insurers, HIQA, the Department of Health and Children, the government and international stakeholders.

This section focuses in particular on the roles and initiatives of the Department of Health and Children, HIQA and the HSE in the development and implementation of underpinning health information policy in Ireland.

Department of Health and Children

The role of the Department of Health and Children is to work with other key stakeholders to develop policy and the necessary legislation to underpin the development and implementation of effective and reliable health information and HIT in order to improve patient safety and quality in Ireland.

At the time of writing this Report, a Health Information Bill for Ireland was in the process of being developed and consulted on in order to provide a legislative platform for the necessary changes set out in the NHIS, to promote the use of information to support safe and high quality client/patient care and in planning, developing, evaluating and assuring the quality of the health services.

The Minister for Health and Children established the Health Information Inter-Agency Group in April 2008. Its function is to provide leadership and co-ordination in the areas of health information and HIT through the membership of the Department of Health and Children, the HSE and HIQA in respect of their individual roles and responsibilities.

Health Information and Quality Authority

The Health Information and Quality Authority (HIQA) was established in May 2007 by the Health Act 2007, and will give effect to much of the information, enabling-technology and evidence-based practice agenda set out in Quality and Fairness and the National Health
Information Strategy. It has a number of functions across health and social services previously listed in Section 2.5.2 of this Report.

The Authority has a statutory function in health information and HIT which will be discharged in a collaborative way with key stakeholders. Health information can be used to support decisions made by patients or clinicians as well as monitoring and improving the quality of care through monitoring performance against standards and supporting clinical audit. The functions of the Authority in relation to health information and HIT support these developments. They include:

- identifying and advising on health information deficiencies
- collaborating with key stakeholders to co-drive the development and implementation of effective ICT across the health system
- setting standards for health information to support the inter-operability of health information systems
- developing minimum data sets and key indicators to support the provision of care, planning of services and monitoring of the health system to improve patient safety and quality
- supporting the development of the national unique identifier
- establishing an information governance framework for the health system
- evaluating and providing information on the provision of health and social services and developing a framework for a national health information portal that will provide wide-ranging information for patients in relation to their care.

The Authority also has the statutory responsibility for health technology assessment in Ireland. This function supports informed decision-making and evidence-based practice in assessing the clinical effectiveness, cost-effectiveness, patient impact, social and ethical issues for specific medicines, medical devices, diagnostics, and health promotion activities used across the Irish health system.

Health Service Executive

The HSE has overall responsibility for the development and application of HIT systems within the public health sector. However, historically this activity has focused more on the development and implementation of administrative systems rather than clinical systems. At the time of writing this Report, an ICT strategy was being developed by the HSE which focuses on a three year programme of work that includes ICT infrastructure and the development of a number of clinical systems.

One of the successful health information and HIT developments in the Irish health system is Healthlink which is a HSE-funded national ICT project. The objective of the Healthlink project is to implement a prototype healthcare communications network with specific reference to GPs and acute hospital relationships through data exchange. The service is available free of charge to all GPs although some initial investment is required by hospitals to become involved. Some key initiatives at Healthlink revolve around supporting ICT-links
between primary and secondary care to allow the secure transfer of patient information over the internet to GPs including:

- laboratory and radiology results
- accident and emergency attendance
- death notifications
- discharge notifications and discharge summaries
- out-patient clinic appointment updates
- waiting list updates as well as allowing GPs to order tests and make referrals.

7.7.4 Patient and public focused health interventions

Health information is information about, provided by, and owned by patients and the public. Patients therefore have a right to have access to the breadth of information about them, their care, where best to access health services and the performance of the health system. They also have a right to express their views regarding the quality of their experience.

There are a variety of interventions that focus on empowering patients and the public to enhance access to health information and to express their views of the health service. Patient and public-focused interventions may be defined as interventions that recognise the role of patients/public as active participants in the process of securing appropriate, effective, safe and responsive healthcare, many of which are based on information and enabling HIT. A major review of the evidence to support these types of interventions was undertaken in 2006 (Coulter and Ellins 2006). The outcomes considered were patients’ knowledge, experiences, service utilisation and costs and health behaviour and health status.

There is some evidence to support several patient and public-focused interventions, although most interventions had a positive impact on only some of the above outcomes, most particularly patient satisfaction. Among the interventions found to have positive impacts were:

- health literacy interventions (written and internet-based) designed to improve the public’s ability to navigate the health system, comprehend and use information, to self-manage health problems and overcome structural barriers to health
- mass media campaigns
- shared decision-making
- communication skills training for clinicians
- self-management programmes e.g. the Expert Patient Programmes (UK)
- improving access to health advice e.g. NHS Direct which provides 24 hour access to nurse-led telephone advice
- improving patient experience using patient surveys e.g. the Picker survey (UK).
7.7.5 Assessed patient outcomes

As previously mentioned, many health systems, including Ireland, have historically focused on the development of more administrative and financial-based information systems. However, without clinical systems that are established and implemented with extensive clinical engagement and patient involvement in order to ensure that they are capturing comprehensive, meaningful, accurate and accessible information relating to every patient episode across the health system, it is impossible to assess the impact and outcomes of the care that is delivered to every patient and to the wider population. Such information may, in turn, facilitate better decision-making in relation to the use of resources across the health system and the planning of future services based on public health priorities at local, regional and national levels.

This means of health surveillance is fundamental to the continuous improvement of a health system, particularly in relation to patient safety. It is previously referred to in consideration of health surveillance relating to adverse event reporting in Section 7.4.

The Irish health system needs to move towards a more robust and strategically managed approach to ensuring that patient outcomes can be measured and assessed at all levels of the service. This will involve the following:

- the implementation of a modern fit-for-purpose Health Information Strategy that puts safe high quality services at the core of its design
- the provision of a suite of health information supports for patients and the public which provides the necessary development in skills and tools for clinical audit, evidence-based practice and data mining for all healthcare professionals
- the development of meaningful, evidence-based standards, clinical guidelines and key performance indicators that provide a benchmark and comparison for professionals, services and providers across the system
- the development and implementation of a unique identifier for every member of the population to ensure that every time, and wherever, a patient uses the health service, the information relating to that episode is identifiable to that person and can be accessed by healthcare professionals, subject to appropriate information governance arrangements, in order to ensure that the information for every patient travels with the patient and supports the provision of safe, seamless care
- the development and implementation of an electronic health record that acts as the information system platform for every episode of care experienced by every patient as above.

7.7.6 Public reporting of health service performance information

Public reporting of performance information relating to health systems is an increasingly popular intervention used in many countries as an incentive to improve quality through transparency and comparative performance information. The US has been at the forefront of activity in this field, with the New York Cardiac Surgery Reporting System providing the archetype. However, it is also increasingly gaining popularity in other health systems.
Assuming that public reporting of performance information is based on valid data and methodology, Sutherland and Leatherman in their review of regulatory interventions to improve the quality of healthcare set out a number of potential advantages and disadvantages as follows: (Sutherland and Leatherman 2006b).

**Advantages:**
- informs healthcare professionals about relative levels of performance and areas for improvement
- focuses organisational attention on areas of suboptimal performance
- guides decisions by payers and purchasers
- informs patients on their choice of providers
- alerts healthcare organisations to poor performing professionals.

**Disadvantages:**
- providers may avoid high-risk patients
- data can be used to unfairly or inaccurately compare performance
- can confuse by providing an oversimplified account of a complex situation.

The evidence supporting the use of public reporting as a quality driver is mixed. Unintended consequences were reported in the literature, notably selective acceptance of referrals (cherry-picking). Better performing providers are more likely to participate in public reporting activity. Evidence that better performing institutional providers are more likely to be selected by patients or to receive referrals was weak. However, evidence does suggest that it stimulates quality improvement activity by providers (Fung, Lim *et al* 2008).

There will be an increasing expectation on health systems to publish information about the performance of the services, and this includes the Irish health system. Evaluating, monitoring and reporting on the performance of the system is a key role of the Health Information and Quality Authority.

### 7.7.7 Conclusions

The Commission is of the view that the ability to reliably and rapidly share the right information in the right way and at the right time is an essential component of ensuring safety in the care of patients. Achieving this requires more than simply the development and implementation of electronic health record systems. It requires common standards for information, the ability to correctly match records to the individual patient, appropriate arrangements which govern the handling and use of the information, the necessary legal enablement to share information across institutional boundaries, including the interface between public and private healthcare, and providing healthcare professionals with the business change skills required to adapt to an information-rich environment.

Complex healthcare processes, missing information, regular interruptions of ongoing activities, and at times chaotic communications, all contribute to medical errors and adverse events. The development and implementation of effective health information and
HIT solutions are essential in order to address these challenges. HIT applications can guide care processes and support workflows, improve communication, make knowledge more readily accessible, acquire key pieces of information (such as the dose of a drug), assist with calculations, perform checks in real time, assist with monitoring and provide decision support.

Through the provision of timely health and lifestyle information, health information contributes to improved information for patients and the public and, therefore, to more effective prevention and improved public health. Through support for research, HIT solutions support the discovery of better medical knowledge and the development of improved and new guidelines. Health information and HIT, in time, will have a significant impact on better training, improved preparation for surgery, and the management of long-term or chronic disease conditions. All of these effects improve patient safety in a wider sense, and lead to improved health and quality of care.

In order to drive the realisation of these requirements there should be clear national leadership to drive the development and implementation of health information and HIT, with the ultimate goal of an electronic health record, supported by unique identification, the spread of modern personal technologies and the provision of accurate and meaningful published information on the performance of the health system that empowers and engages patients and that supports safe and high quality care.

### 7.7.8 Recommendations

If Ireland is to realise the significant potential of information and HIT in the pursuit of patient safety, it is critical that a number of major developments take place.

The Commission recommends the following:

**R7.45** The National Health Information Strategy (NHIS) which was published in 2004 and is still not fully implemented should be reviewed in order to clarify the roles and responsibilities of the Department of Health and Children, the HSE and HIQA and the recently established Health Information Inter-Agency Group should ensure that these key bodies work together to progress the implementation of the Strategy as quickly as possible.

**R7.46** The planning of health information and HIT developments should be an integral part of the planning of health service developments to ensure that the full potential of health information and HIT to improve patient safety is realised. This should be driven by a patient-centred approach, with full clinical engagement learning systems design, in order to enable the delivery of health services to the patient in whatever setting.
R7.47 The underlying information communication technology (ICT) infrastructure, and applications within all aspects of healthcare, should be recognised as the foundation for all patient-centred systems. The infrastructure should therefore be seen as a key enabler of patient safety and quality and ICT infrastructure standards should be set at a national level to ensure good levels of reliability, performance, security and interoperability.

R7.48 All healthcare ICT projects, including those driven within the HSE, should formally consider the impact that the information system(s) will have on the patient journey, to include safety, quality and benefits to be realised, and should be planned and implemented in the context of the overall National Health Information Strategy.

R7.49 Immediate development priorities in health information and HIT in areas of high risk, from a patient safety perspective, should be identified and implemented rapidly in order to create engagement across the relevant stakeholders and continue to build the momentum of improved patient safety and quality through health information and HIT.

R7.50 Rapid progress must be made on the development and implementation of a unique identifier for the health system.

R7.51 There must be a standards-based approach to HIT developments that will be led by HIQA. These standards should apply in areas such as clinical terms, coding and classification as well as messaging and electronic health record. Such standards are necessary requirements for the effective interoperability of HIT systems, i.e. the ability to share information that has a consistently understood meaning and interpretation wherever and by whomever it is accessed, and this approach will enable reliability, performance, security and interoperability.

R7.52 The health system must commit itself to the full implementation of an appropriate standards-based electronic health record, with appropriate sharing of information within and between providers so that critical information about the care of patients is available at the point of care. This should include the sharing of critical clinical information between the public and private sectors.
An effective information governance framework, and underpinning legislation, should be developed and implemented across the health system. This should include the requirement of providers to implement clear plans and the allocation of responsibility that forms the basis of business rules governing how health information is exchanged and utilised.

The NHIS review should consider the ICT requirements, skills and tools necessary to support healthcare professionals in implementing the recommendations in this Report.

A managed approach to health surveillance which includes patient safety data should be developed across Ireland. This should involve the coherent collation, interpretation, learning and dissemination of sources of information from across the system, including information from the national mandatory reporting system for adverse events.
Chapter Eight

Conclusion and Implementation

The Commission on Patient Safety and Quality Assurance was established to make recommendations for a system-wide safety and quality framework across the Irish health service. Following comprehensive discussion of the issues within its Terms of Reference, the Commission agreed that there are significant problems with existing internal and external regulatory mechanisms for ensuring patient safety in Ireland. The problems identified in the system through a number of investigations and reports of adverse events were considered by the Commission as well as submissions and presentations received during the course of its work. These highlight, amongst other things, weak governance structures, poor communication processes, failure to implement clinical audit, poor working relations between clinicians and management, lack of senior clinical leadership and accountability and lack of structured systems of reporting, analysing and learning from adverse events.

As discussed earlier in the Report, the vision around which the recommendations in this Report are based is as follows:

*Knowledgeable patients receiving safe and effective care from skilled professionals in appropriate environments with assessed outcomes.*

The values underpinning this framework include openness, patient centredness, learning, effectiveness and efficiency, good governance, leadership and accountability, evidence-based practice and service-user involvement. The Commission considered ways in which the gaps in the current system might best be remedied so that responsibility, accountability and safety are clearly embedded as key priorities for all participants in the healthcare system. Key themes which have been developed in the Report include:

- the integration of patients, service-users and carers as partners into the healthcare system in order to ensure that safety and quality is embedded into the development of policy for healthcare delivery, development and evaluation
- the importance of good communication between clinicians and patients as part of a patient safety culture
- the need for clear governance structures in each healthcare facility which ensure that leadership and accountability for patient safety are core elements of all such structures
- the prioritisation of education, training and research on patient safety in undergraduate and postgraduate courses, as well as through systems of lifelong learning and professional development for clinicians and healthcare managers
- the regulation of all public and private healthcare facilities to ensure compliance with core and developmental standards in relation to safety and continuous quality improvement
the need for effective collaboration between professional regulatory bodies to ensure the pursuit of a common objective of protecting the public by the development of consistent professional standards, and appropriate investigative and adjudicatory functions in cases of alleged professional misconduct

- the importance of providing healthcare employers with adequate and accurate information in relation to the recruitment of healthcare professionals in order to ensure the delivery of safe and high quality care

- the use of information to evaluate and monitor the safety and quality of services so as to enable the sharing of good practice

- the importance of reporting, analysing and learning from adverse events.

The Commission is of the view that there is a need to modify existing mechanisms to create new solutions that can be integrated into the current framework in order to build a comprehensive approach to patient safety and quality assurance. The Commission acknowledges the challenge in trying to find the correct balance between formal and informal strategies to improve safety and quality. While regulation is not the answer to every problem as it may be burdensome in terms of time, resources and financial expenditure, the Commission believes that there are nonetheless distinct advantages in regulating for patient safety in terms of ensuring compliance with agreed national standards and achieving valued policy objectives.

In devising an implementation plan for the recommendations in this Report, the Commission stresses that the ultimate objective must be to provide clear national leadership on patient safety for the Irish health service which will ensure sharing of information and expertise as well as the integration of similar regulatory functions within one agency. The Commission acknowledges that the achievement of this objective will require significant medium to long-term planning for legislative, organisational and structural reform, which will inevitably take some time to implement. The Commission nonetheless believes that this long-term objective would be the most effective means of implementation of the recommendations of this Report.

In conclusion, the Commission strongly believes that full and effective implementation of all of the recommendations in this Report will prioritise patient safety to the extent necessary to ensure a significant and long-lasting effect throughout the Irish health system.

8.1 Options for implementation

The Commission considered a number of options in relation to the assignment of the new patient safety functions proposed throughout this Report.

The Commission looked at the possibility of amalgamating relevant functions of existing statutory agencies including HIQA, the Mental Health Commission and the Irish Medicines Board into a new statutory body with a wide patient safety remit. This new body could have a number of divisions with responsibilities as follows:
Standards, Inspections and Investigations Division

- Setting and monitoring standards for all healthcare services, public and private, excluding mental health services
- Instigating investigations into serious adverse events
- Undertaking health technology assessment
- Carrying out inspections and providing reports for the proposed new licensing regime for healthcare facilities and services.

Mental Health Services Division

- Setting and monitoring standards for all mental health services, public and private
- Ensuring the protection of detained persons
- Carrying out inspections and providing reports for the proposed new licensing regime for healthcare facilities and services.

Licensing Division

- Processing applications for licences to operate healthcare facilities and services in the public and private sectors.

Professional Regulatory Bodies Division

- Developing common code of standards and ethics to apply across all regulatory bodies
- Providing a central point of contact for complaints/reports regarding the conduct or competence of healthcare professionals
- Providing independent adjudication on disciplinary matters following investigations by the regulatory bodies
- Developing and maintaining a national credentialing database on healthcare professionals
- Advising on a system of privileging for the delivery of specialist clinical procedures and treatments and competence assurance for healthcare professionals.

Quality Improvement and Learning Division

- Developing national programmes and standards for clinical and other forms of patient safety audit
- Developing systems for adverse event reporting
- Promoting the use of evidence-based practice
- Disseminating information derived from these sources to facilitate learning.

Advocacy Division

- Establishing a national patient/advocate engagement framework
- Promoting a system of education and training that would include specific modules on patient safety
- Providing advice on other patient safety and quality matters.
It was felt that this model would provide clear national leadership on patient safety. It would also provide for the integration of bodies with similar functions within one statutory Authority with clear responsibility for patient safety. A single Patient Safety statutory agency would be likely to lead, in the medium to long term at least, to efficiency gains achieved through co-ordination and streamlining of complementary functions and processes with sharing and developing of expertise. This is supported by the 2007 OECD report which states:

‘The Irish Public Service now needs to become outward focused by better integrating and utilising the systems and processes it has developed. To become more integrated it needs to amend or revise existing accountability structures and ways of working, to allow for integrated system wide action where this is required. Moving towards a more integrated Public Service will allow a greater sharing of expertise and knowledge’.

The Commission also noted that the Joint Oireachtas Committee on Health and Children published a report in 2007 entitled ‘The Adverse Side Effects of Pharmaceuticals’ which recommended that:

‘A Patient Safety Agency would be the appropriate entity for the implementation of many of [its] recommendations… The Sub-Committee therefore recommends that such an entity should be set up. It hopes that the Patient Safety Commission, set up since the Sub-Committee started its work, will come to the same conclusion’.

However, the Commission felt that establishing a new State Agency of this kind at this time before taking any real substantive initiative might have the effect of losing the momentum already built up through the working of the Commission and the improvements in patient safety made to date by the existing regulatory bodies. Such an Agency would have a very broad remit necessitating major legislative, structural and organisational changes which would take some years to put in place, thereby delaying the effective implementation of the recommendations in this Report.

Also, the new Agency would have to absorb HIQA and the Mental Health Commission which have only been established in recent years and whose functions are therefore still evolving.

The Commission concluded that the same benefits could be achieved in a shorter timeframe through the establishment of expert sub-groups with clear reporting relationships to the Minister for Health and Children through an Implementation Steering Group (ISG) appointed by the Minister and representative of:

- Department of Health and Children
- HSE
- Independent hospitals
- HIQA
The ISG should be supported by a full-time executive team at senior level within the Department of Health and Children to focus exclusively on ensuring rapid progress in facilitating the implementation of this Report’s recommendations. The ISG should report every three months to the Minister on the progress in implementing the Commission’s Report and these progress reports should be published.

A number of sub-groups should be established with specific remits in relation to the implementation of specific sections of the Commission’s recommendations and with reporting obligations to the ISG. Each sub-group will also be supported by the full-time executive. The chairs and membership of the sub-groups will be approved by the Minister.
The role of the ISG will be to ensure that the proposals in the Report are implemented as effectively and efficiently as possible. It will bring together the different key interests to ensure that there is a co-ordinated approach to the implementation of the recommendations of the Commission. In addition, it will have a clear and detailed understanding of the progress being made in the areas within the remit of the proposed sub-groups which will be reporting to the ISG on a regular basis. The ISG will also have an important role in relation to the implementation of recommendations that have not been allocated to any of the proposed sub-groups. They may direct such recommendations to other bodies as appropriate e.g. the Education and Training recommendations may be directed to other bodies, such as the National Committee on Medical Education and Training and/or the Medical Council.

The ISG will advise the Minister on the progress or otherwise being made to implement all of the recommendations of the Commission and if there are difficulties in any particular area, will be expected to advise the Minister on how those difficulties are to be overcome. The ISG will also be kept updated by the Department of Health and Children on the progress of the licensing legislation and any other proposed legislative changes.

The remit of the proposed sub-groups of the ISG would be as follows:

1. **Credentialing sub-group**
   - To design the scope and implementation of a credentialing system for all healthcare professionals in Ireland
   - To recommend the means by which a credentialing database could be used as part of a privileging system for healthcare professionals
   - To develop and promote links within the EU on the development of an EU credentialing system
   - To plan a system of alert notices to be established for exchange of notices between healthcare employers in Ireland and adjacent jurisdictions.

   This sub-group should include representation from the HSE, independent hospitals, professional regulatory bodies, CIS and professional indemnity providers.

2. **Patient Safety Audit sub-group**
   - To develop national programmes of and standards for clinical and other forms of patient safety audit
   - To lead the development of educational programmes on audit and to promote their integration into all professional medical education and training curricula.

   This sub-group should include representation from the HSE, independent hospitals, HIQA, professional regulatory bodies, training bodies, the Higher Education Authority and patients.
3. Adverse event reporting sub-group

- To advise on the detailed implementation of the Commission’s recommendations on the development of a national mandatory reporting system across all public and private healthcare providers
- To agree on the most appropriate repository for the maintenance of a national database along the lines recommended by the Commission
- To recommend specific measures by which learning from adverse events should be disseminated throughout the system, including the facilitation of rapid alerts as necessary.

This sub-group should include representation from the HSE, independent hospitals, HIQA, professional regulatory bodies, CIS, patients, IMB, MHC and Irish Blood Transfusion Service (IBTS).

4. Professional regulatory bodies sub-group

- To identify and collaborate on shared professional interests, leading to the development of a common code of professional practice
- To develop plans for a single point of contact for patient concerns in relation to clinical care with referral to appropriate regulatory bodies as necessary
- To consider ways by which patients and the public may be enabled to access information relating to the maintenance of professional competence by healthcare professionals
- To audit disciplinary cases from all healthcare regulatory bodies with a view to developing a common framework for the investigation and preliminary handling of complaints
- To review current Fitness to Practise processes across the different regulatory bodies
- To devise a specific plan and timeframe for the implementation of the Commission’s recommendations in relation to the establishment of a single adjudicatory body for all complaints in relation to the conduct or competence of healthcare professionals.

This sub-group should include representation from all the professional regulatory bodies.

5. Advocacy sub-group

- To develop plans for the implementation of recommendations in Chapter Four in relation to advocacy and the management of service-user complaints
- To develop national standards for open communication/disclosure of adverse events
- To promote the inclusion of open communication principles, policies and standards in the education and training curricula of all healthcare professionals
- To develop specific training and supports on open communication for all healthcare professionals
- To develop mechanisms for the monitoring, evaluation and review of open communication standards based on patient and professional feedback.
This sub-group should include representation from the HSE, independent hospitals, HIQA, professional regulatory bodies and patients.

In the view of the Commission, the advantages of this model are that it immediately builds on the structures already in place, can deliver results quickly and would be less likely to be impeded by potential difficulties with existing bodies. The proposed structure will require strong leadership from all those bodies involved so that a new culture of cooperation is delivered. It is stressed that the full-time executive support and the publication of progress reports every three months will be the key drivers in ensuring that the ISG is delivering real and effective results.

8.2 Recommendations

The Commission recommends the following:

R8.1 The drafting of all the legislative changes necessary to implement the recommendations of this Report should begin as soon as possible.

R8.2 An Implementation Steering Group (ISG), with a clear reporting relationship to the Minister for Health and Children, should be established to oversee the implementation of all the recommendations in this Report.

R8.3 A number of specialised sub-groups should be established comprising service providers, regulators, education and training bodies, indemnity providers and patient advocacy representatives. These sub-groups should have clear and regular reporting relationships to the ISG.

8.3 Timeframe for implementation

The Commission suggests the following timeframe for implementation of the Report:

- **Licensing** – The Commission recognises that the drafting of legislation in relation to the introduction to the health system of a new licensing framework will be complex and time-consuming. However, the Commission is of the view that the Department of Health andChildren should begin work on this Bill immediately with a view to its publication in late 2009 at the latest, with passage through the Oireachtas in early 2010. This Bill should also provide for the other legislative changes recommended in this Report including the introduction of legal protection for healthcare staff in relation to data collected and analysed for purposes of audit, and legal exemption from disclosure in litigation for open communication following adverse events.

- **Establishment of ISG and sub-groups** – The ISG should be established within a month of approval of this Report. It should establish the proposed sub-groups as soon as
possible and set an appropriate timeframe for them to report, not later than twelve months after their establishment.

8.4 Benefits and costs of implementation

This Report sets out a roadmap for driving improvements in safety and quality across our health service. There is a considerable amount of excellent practice happening on a daily basis in the Irish health system but substantial changes are required to implement the improvements that are needed. The benefits for patients and staff realised by the implementation of the recommendations within this Report have been articulated throughout the various chapters. These benefits include:

- demonstrable and tangible change, for example improved access to information for patients about their care and the performance of the services provided
- more effective leadership, governance, accountability and management of services
- improved management information to drive a more efficient and effective approach to the organisation of services
- improved efficiency in the organisation and provision of health services through changing behaviour and work practices
- less adverse events as a result of improved culture, governance, management and learning at all levels in the provision of healthcare.

The international evidence of cost benefits resulting from implementing large scale change and improvements in safety and quality across a health system is sparse. However, one example of the cost benefit analysis of improvements in adverse event management involves the estimated avoidable costs to the US, in relation to adverse events. In 1999 these costs equated to between $17 and $29 billion per year. They were assimilated from a variety of different measures including the cost of 5 to 10% of hospital patients acquiring infections that resulted from excessive antibiotic prescribing.

In addition, in 2008 PricewaterhouseCoopers Health Research Institute published a report entitled ‘The Price of Excess’ identifying waste in US healthcare spending. Following a review of over 35 studies, interviews and surveys, the research found significant waste. Major areas of waste were: defensive medicine ($210 billion), described as redundant, inappropriate or unnecessary tests and procedures; medical errors ($17 billion); hospital acquired infections ($3 billion) and over-prescribing antibiotics ($1 billion).

Similarly, WHO suggests that up to half of complications and deaths arising from surgery are avoidable if basic standards are followed. Complications following surgery result in disability or prolonged hospital stay in up to one quarter of hospitalised patients, depending on the type of surgery and hospital setting. Given that in Ireland in 2007 there were an estimated 236,000 public hospital discharges which had at least one significant surgical procedure the financial waste arising in the Irish system is potentially significant.
It would be inappropriate for the Commission not to consider that there will be associated costs to the implementation of a number of the recommendations contained within this Report. However, the Commission believes that the outcome of the implementation of these recommendations will have significant benefits on the safety and quality of care received by patients, on the public health of the country and on reducing waste across the health system.
## Appendix A

### Glossary of Abbreviations

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<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>ABMS</td>
<td>American Board of Medical Specialists (United States)</td>
</tr>
<tr>
<td>ADE</td>
<td>Adverse Drug Event</td>
</tr>
<tr>
<td>AMR</td>
<td>Antimicrobial Resistance</td>
</tr>
<tr>
<td>APSF</td>
<td>Australian Patient Safety Foundation</td>
</tr>
<tr>
<td>ASRS</td>
<td>Aviation Safety Report System</td>
</tr>
<tr>
<td>CEMACH</td>
<td>Confidential Enquiry into Maternal and Child Health (United Kingdom)</td>
</tr>
<tr>
<td>CEO</td>
<td>Chief Executive Officer, or equivalent</td>
</tr>
<tr>
<td>CHRE</td>
<td>Council for Healthcare Regulatory Excellence (United Kingdom)</td>
</tr>
<tr>
<td>CIS</td>
<td>Clinical Indemnity Scheme</td>
</tr>
<tr>
<td>CME</td>
<td>Continuing Medical Education</td>
</tr>
<tr>
<td>CPD</td>
<td>Continued Professional Development</td>
</tr>
<tr>
<td>CQA</td>
<td>Continuing Quality Assurance</td>
</tr>
<tr>
<td>CT</td>
<td>Computed tomography</td>
</tr>
<tr>
<td>DOH</td>
<td>Department of Health (United Kingdom)</td>
</tr>
<tr>
<td>DoHC</td>
<td>Department of Health and Children</td>
</tr>
<tr>
<td>EEA</td>
<td>European Economic Area</td>
</tr>
<tr>
<td>EU</td>
<td>European Union</td>
</tr>
<tr>
<td>FAA</td>
<td>Federal Aviation Administration (United States)</td>
</tr>
<tr>
<td>FOI</td>
<td>Freedom of Information</td>
</tr>
<tr>
<td>FTP</td>
<td>Fitness to Practise</td>
</tr>
<tr>
<td>GMC</td>
<td>General Medical Council (United Kingdom)</td>
</tr>
<tr>
<td>GP</td>
<td>General Practitioner</td>
</tr>
<tr>
<td>HAZMAT</td>
<td>Hazardous Material</td>
</tr>
<tr>
<td>HCAI</td>
<td>Health Care Associated Infection</td>
</tr>
<tr>
<td>HDC</td>
<td>Health and Disability Commissioner (New Zealand)</td>
</tr>
<tr>
<td>HIPDB</td>
<td>Healthcare Integrity and Protection Data Bank (United States)</td>
</tr>
<tr>
<td>HIQA</td>
<td>Health Information and Quality Authority</td>
</tr>
<tr>
<td>HIT</td>
<td>Health Information Technology</td>
</tr>
<tr>
<td>HPSC</td>
<td>Health Protection Surveillance Centre</td>
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<tr>
<td>HRB</td>
<td>Health Research Board</td>
</tr>
<tr>
<td>HSE</td>
<td>Health Service Executive</td>
</tr>
<tr>
<td>IBTS</td>
<td>Irish Blood Transfusion Service</td>
</tr>
<tr>
<td>ICP</td>
<td>Integrated Care Pathway</td>
</tr>
<tr>
<td>ICT</td>
<td>Information Communication Technology</td>
</tr>
<tr>
<td>Abbreviation</td>
<td>Full Form</td>
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</tr>
<tr>
<td>IHI</td>
<td>Institute for Healthcare Improvement</td>
</tr>
<tr>
<td>IMB</td>
<td>Irish Medicines Board</td>
</tr>
<tr>
<td>IOM</td>
<td>Institute of Medicine (United States)</td>
</tr>
<tr>
<td>IPHA</td>
<td>Irish Pharmaceutical Healthcare Association</td>
</tr>
<tr>
<td>ISG</td>
<td>Implementation Steering Group</td>
</tr>
<tr>
<td>JCAHO</td>
<td>Joint Commission on Accreditation of Healthcare Organisations</td>
</tr>
<tr>
<td>MHC</td>
<td>Mental Health Commission</td>
</tr>
<tr>
<td>MRSA</td>
<td>Methicillin-Resistant Staphylococcus Aureus</td>
</tr>
<tr>
<td>NCEPOD</td>
<td>National Confidential Enquiry into Patient Outcome and Death (United Kingdom)</td>
</tr>
<tr>
<td>NCISH</td>
<td>National Confidential Inquiry into Suicide and Homicide by People with Mental Illness (United Kingdom)</td>
</tr>
<tr>
<td>NHIS</td>
<td>National Health Information Strategy</td>
</tr>
<tr>
<td>NHO</td>
<td>National Hospitals Office</td>
</tr>
<tr>
<td>NHS</td>
<td>National Health Service (UK)</td>
</tr>
<tr>
<td>NICE</td>
<td>National Institute of Clinical Excellence (United Kingdom)</td>
</tr>
<tr>
<td>NMC</td>
<td>Nursing and Midwifery Council (United Kingdom)</td>
</tr>
<tr>
<td>NPDB</td>
<td>National Practitioner Data Bank (United States)</td>
</tr>
<tr>
<td>NPSA</td>
<td>National Patient Safety Agency (United Kingdom)</td>
</tr>
<tr>
<td>NPSD</td>
<td>Network of Patient Safety Databases (United States)</td>
</tr>
<tr>
<td>NSFs</td>
<td>National Service Frameworks (United Kingdom)</td>
</tr>
<tr>
<td>OECD</td>
<td>Organisation for Economic Co-operation and Development</td>
</tr>
<tr>
<td>OHPA</td>
<td>Office of Health Professionals Adjudicator (United Kingdom)</td>
</tr>
<tr>
<td>PACS</td>
<td>Picture Archiving and Communication System</td>
</tr>
<tr>
<td>PCCC</td>
<td>Primary Community and Continuing Care</td>
</tr>
<tr>
<td>PGTB</td>
<td>Post Graduate Training Body</td>
</tr>
<tr>
<td>PSEP</td>
<td>Patient Safety Education Project</td>
</tr>
<tr>
<td>QA</td>
<td>Quality Assurance</td>
</tr>
<tr>
<td>RCA</td>
<td>Root Cause Analysis</td>
</tr>
<tr>
<td>SARI</td>
<td>Strategy for the control of Antimicrobial Resistance in Ireland</td>
</tr>
<tr>
<td>SASM</td>
<td>Scottish Audit of Surgical Mortality</td>
</tr>
<tr>
<td>SSI</td>
<td>Social Services Inspectorate</td>
</tr>
<tr>
<td>UK</td>
<td>United Kingdom</td>
</tr>
<tr>
<td>US</td>
<td>United States</td>
</tr>
<tr>
<td>WHO</td>
<td>World Health Organisation</td>
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# Appendix B

## Glossary of Terms

<table>
<thead>
<tr>
<th>Term</th>
<th>Definition</th>
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<tbody>
<tr>
<td>Acute hospital</td>
<td>A hospital providing medical and surgical treatment of relatively short duration</td>
</tr>
<tr>
<td>Advocate</td>
<td>Someone who represents or defends the views, needs and rights of an individual who is not in a position or does not feel able to do this for him or her self</td>
</tr>
<tr>
<td>Alternative medicine</td>
<td>A broad range of healing resources encompassing health systems and practices, that are seen as alternative to conventional medicine or healthcare</td>
</tr>
<tr>
<td>Clinical Audit</td>
<td>The systematic, critical analysis of the quality of care, including procedures used for diagnosis and treatment, use of resources and resulting outcome and quality of life for the patient</td>
</tr>
<tr>
<td>Clinician</td>
<td>Intended to refer to all clinical healthcare professionals involved in clinical work</td>
</tr>
<tr>
<td>eHealth</td>
<td>The provision of healthcare supported by electronic processes and communication</td>
</tr>
<tr>
<td>Evidence-based practice</td>
<td>Practice which incorporates the use of best available and appropriate evidence arising from research and other sources</td>
</tr>
<tr>
<td>Governance</td>
<td>In the context of this report, means a framework composed of many elements that combine to drive a culture of continuous improvement in the safety and quality of services for all service-users, service providers and the wider community</td>
</tr>
<tr>
<td>Multi-disciplinary</td>
<td>Professionals from more than one discipline working together in a co-ordinated way</td>
</tr>
<tr>
<td>Patient</td>
<td>Intended to include all people who use health and social care services</td>
</tr>
<tr>
<td>Primary care</td>
<td>An approach to care that includes a range of services designed to keep people well, from promotion of health and screening for disease to assessment, diagnosis, treatment and rehabilitation as well as personal social services; the services provide first-level contact that is fully accessible by self-referral and have strong emphasis on working with communities and individuals to improve their health and social well-being</td>
</tr>
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<tr>
<td>Risk management</td>
<td>The prevention and containment of liability by careful and objective determination, investigation, monitoring and management of risks</td>
</tr>
<tr>
<td>Self-regulation</td>
<td>A system of non-statutory rules by which organisations agree to be bound</td>
</tr>
</tbody>
</table>
Appendix C

Select Bibliography

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Health Information and Quality Authority (2008). *Report of the investigation into the circumstances surrounding the provision of care to Rebecca O’Malley in relation to her symptomatic breast disease, the pathology services at Cork University Hospital and Symptomatic Breast Disease Service at the Mid Western Regional Hospital, Limerick*.


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Royal College of Surgeons in Ireland (2004). *Good Surgical Practice*.


**International**


Books, papers and articles:


Appendix D

Acknowledgement of Submissions

Academy of Medical Laboratory Science  
BreastCheck  
Competition Authority  
Consumers’ Association of Ireland  
Daughters of Charity Service for Persons with Intellectual Disability  
Dr. Edgar Mocanu  
Dr. Ambrose McLoughlin  
Dr. John Hillery  
Dr. J. McAdoo  
Global Standards 1 (Ireland) Limited  
Health Information and Quality Authority  
Hospital Pharmacist Association, Ireland  
Independent Hospitals Association of Ireland  
International School of Healthcare Management, Royal College of Surgeons in Ireland  
Irish Association of Plastic Surgeons  
Irish Healthcare Risk Management Association  
Irish Medical Organisation  
Irish Medicines Board  
Irish Patients’ Association  
Irish Pharmaceutical Union  
Irish Rural Link  
Irish Society for Quality and Safety in Healthcare  
Joint Commission International  
Medical Council  
Mental Health Commission  
Mid-Western Regional Hospital, Ennis  
Mid-Western Regional Hospital, Nenagh  
Mr. Jonathan M. Oakes, Chief 1 Pharmacist, Waterford Regional Hospital  
Mr. Michael Corcoran  
Ms. Ann Callinan  
Ms. Ann Kennedy  
Ms. Rebecca O’Malley
Ms. Teresa Lee CNM3, Our Lady’s Hospital, Navan, Co. Meath
Ms. Theresa O’Leary MPSI
Naas General Hospital
National Federation of Voluntary Bodies
National Haemovigilance Office, Irish Blood Transfusion Service
National Hospital Office, HSE
National Treatment Purchase Fund
Office of the Nursing Services, HSE
Office of the Ombudsman
Patient Focus
Pfizer Healthcare Ireland
Royal College of Physicians of Ireland
School of Medicine and Medical Science, University College Dublin
Ms. Siobhan McCarthy, Prof. Hannah McGee & Prof. Ciarán O’Boyle, Department of Psychology, Division of Population Health Sciences, Royal College of Surgeons of Ireland
South Infirmary-Victoria University Hospital, Cork
St. Vincent’s Healthcare Group
The Adelaide & Meath Hospital, Dublin incorporating The National Children’s Hospital, Tallaght
The Biomedical Engineering Division of Engineers Ireland
The Biomedical/Clinical Engineering Association of Ireland
The Clinical Engineering Voluntary Registration Board
The Irish Hospice Foundation
The Irish Nurses Organisation
The Pharmaceutical Society of Ireland
The Psychiatric Nurses Association
The Women’s Health Council
VHI
VIVAS