

Report of the Quality and Safety Clinical Governance Development Initiative

Sharing our learning

**We are all responsible...and together
we are creating a safer healthcare system**

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Note: The words 'service', 'health service provider', 'organisation', 'health care facility' are used in a broad sense inclusive of all health care e.g. acute, maternity, children's, mental health, palliative care, primary care, intellectual disability and residential care for older persons.

Foreword

This report presents an overview of the quality and safety clinical governance development initiative. The main purpose is to consolidate the learning and make core recommendations for health service providers, policy makers and commissioners to inform their own specific actions plans.

The Quality and Patient Safety Division of the Health Services Directorate intends that all health service providers place quality and safety at the top of every agenda. The ingredients that enable an organisation to achieve quality are (i) a commitment to quality starting with the board and senior management (ii) a strategically defined role for quality (iii) a model upon which to guide quality improvement programmes (iv) education and training for all staff on quality and (v) a mechanism for measuring quality. This can be achieved using leadership and management structures to support proactive performance management while supporting front line staff to do their jobs. What this means is that quality and safety is a priority and considered in all decision making. The CEO or equivalent of the health care facility is accountable and responsible for both corporate and clinical governance and works in partnership with their clinical director and director of nursing/midwifery and service professional leads.

The clinical governance development initiative involved three phases (i) developing resources for practice (ii) implementing resources in practice; and (iii) evaluation and sharing learning.

- (i) **Resources for practice** - eight resource documents were developed and tested in use. A wide range of advice was also provided to services, associations and interest groups on incorporating the principles for quality and safety within structures, process policies procedures and guidelines.
- (ii) **Implementation in practice** - focused projects - five hospital action projects and two primary care teams (primary care projects in progress). Detailed support was provided in these demonstration sites to embed the governance of care quality and patient safety in their management processes.
- (iii) **Evaluation and sharing learning** - a thematic analysis of the data gathered for the evaluation was used to identify the learning and inform the development of key recommendations.

Quality does not happen by accident – across this initiative there was tremendous learning which is captured in this report. Some of our important insights are:

- We often find that the lack of clarity and shifting of responsibility for care quality and safety is an issue in our delivery system therefore the focus throughout was on ‘we are all responsible...and together we can create a safer health care system’.
- We also found some confusion around the term ‘clinical governance’ therefore, we are using the term quality and safety and specifically ‘governance for quality and safety’.
- We are convinced of the importance of listening and engaging with patients and staff. Understanding the experience of patients and what motivates staff is central in creating a quality culture.
- Real time information prompts wise decisions which lead to the need for good quality measurement and transparency.

I commend the report to you and urge each management team to carefully consider the recommendations and apply them within your own service, when you are commissioning services or in policy making.

Finally I would like to acknowledge the considerable commitment of the many participants who are listed in the appendix to this report. I would like to especially thank the working group, steering group, international reference panel, the five hospital project teams, the two primary care services and many staff that contributed by sharing their experience and learning in strengthening quality and safety structures and process.



Dr Philip Crowley

National Director of Quality and Patient Safety

Key Learning Points

The following twelve points provide an outline of the key learning throughout the Clinical Governance Development initiative. Additional learning outcomes are located in section 6 of this report.

- 1 The integration of corporate and clinical governance is of utmost importance for all health system changes.
- 2 The importance of quality and safety being a priority agenda item at every meeting.
- 3 The importance of board members and executives hearing directly from patients, members of the public and staff of their experiences.
- 4 The value of board members and executives having direct observation through walk-rounds of the quality and safety of care and treatment provided.
- 5 Real change in improving quality and safety requires total executive management team buy-in (inclusive of finance, human resource, information technology, management and clinical directors).
- 6 In all matters there must be clarity so that staff members know and understand their personal and team role and responsibilities at all times.
- 7 Along with leadership and accountability clinical governance is about having the right structures and processes in place to achieve quality and safety of services.
- 8 Investment in achieving a critical mass of managers, clinicians and staff with expertise in quality improvement methodologies improves patient safety.
- 9 The term clinical governance can be confusing for staff as it comprises a mixture of activities relating to governance, management and practice.
- 10 Staff lead and respond well to focused quality and safety support at a time when there are a lot of demands (measurement and scrutiny).
- 11 Understanding the quality and safety of our health service requires a comprehensive approach to collecting, analysing and discussing data.
- 12 Sharing information and experiences among health service providers leads to and supports a learning environment.

“...People struggle with the phrase clinical governance, but really it’s about having a framework in place throughout the organisation, that supports you to be explicit about the standard of care delivered, about how you protect patients from harm, about how you listen to patients and about how you plan and measure improvement”

(Project Manager, Acute Hospital).

Recommendations

The single most important obligation for any health system is patient safety and improving the quality of care. During the Clinical Governance development initiative practical experience was gained of the structures and processes which are a prerequisite to delivering quality and safety. The recommendations below are provided to guide and support (i) health service providers and (ii) policy makers and commissioners in improving care provided across the healthcare system. Providers, policy makers and commissioners should use these recommendations to inform their own specific action plans.

Recommendations for: Health Service Providers

- | | | | |
|----------|--|-----------|---|
| 1 | Establish a Quality and Safety committee of the Board or Community Healthcare Organisation with responsibility for overseeing and seeking assurance (through clear data analysis), on the quality and safety of services provided. | 2 | Establish a Quality and Safety Executive Committee with responsibility for implementing quality and safety arrangements on behalf of the Executive Management Team. |
| 3 | Make quality and safety a standing item on Board/Community Healthcare Organisation and all Executive Management Team agendas where clinical outcomes data and the profile of quality of care are examined. ¹ | 4 | Develop a mechanism for the Board or Community Healthcare Organisation to hear directly about patient and staff experiences. |
| 5 | Value, listen, and engage with patients in identifying and acting on suggestions to improve their experience of care as well as overall service improvements. | 6 | Value, listen, and engage with staff in identifying and acting on suggestions for quality improvement including improving their work experience. |
| 7 | Ensure senior management job descriptions include accountability for quality and safety for staff and patients. | 8 | Invest time to support clinicians and managers as a team in understanding and enacting their leadership role for quality and safety. |
| 9 | Make local quality and safety data transparent to staff and members of the public. | 10 | Provide ICT infrastructure including an integrated quality management system for document control and retrieval (e.g. policy, procedures, protocols and guidelines) which are easily accessible by staff. |

Next steps

The recommendations above should now be taken and used by health service providers to review their own quality and safety arrangements and develop quality improvement programmes with identified lead responsibilities and defined time lines.

¹ focused on a balanced set of metrics: quality and safety; access; flow; cost and revenue; and human resource management

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1 Introduction

Effective governance arrangements recognise the inter-dependencies between corporate, financial and clinical governance across the service and integrate them to produce high quality, safe and reliable healthcare. Over recent years the health service has placed an important emphasis on quality and patient safety by developing an infrastructure for integrated quality, safety and risk management. The Quality and Patient Safety Directorate (QPSD) renewed its focus within the organisation on clinical governance development in 2011. A steering group and working group for clinical governance development was established under the direction of the National Director for Quality and Patient Safety (see Appendix 1 for terms of reference and Appendix 2 for membership). A national lead and project manager were appointed and an international reference panel established, with strong engagement of a wide range of stakeholders across the health service. This report presents an overview of the initiative and the recommendations arising from the learning over the timeframe (Q3 2011 – Q4 2013).

1.1 Clinical governance development initiative

The purpose of this quality and safety initiative was to foster and grow the capability of staff to improve the quality and safety processes at work. It is built on the model of the chief executive officer/general manager or equivalent working in partnership with the clinical director, director of nursing/midwifery and service/professional leads³ in all matters related to the quality and safety of services provided. At the outset a descriptor of clinical governance for the Irish health system was agreed.

Clinical governance is:

- The system through which healthcare teams are accountable for the quality, safety and experience of patients in the care they have delivered.

For health care staff this means:

- Specifying the clinical standards you are going to deliver and showing everyone the measurements you have made to demonstrate that you have done what you set out to do.

The steering group met on a quarterly basis to provide guidance and direction to the working group which met monthly. Quarterly progress reports were presented to the steering group and biannual reports presented to the Health Service Executive (HSE) Chief Executive Officer (CEO). A detailed action plan was agreed.

Aim of Clinical Governance Development Initiative:

- Creating a culture where quality and safety is everybody's primary goal.

Objective of Clinical Governance Development Initiative:

- Every clinical and social care action is aligned within a clinical governance framework.

Priorities of Clinical Governance Development Initiative are:

- Developing cultures supportive of clinical governance
- Building leadership capacity
- Focusing on systems and methodologies of clinical governance.

In September 2012 the steering group agreed to expand their original role, to provide strategic direction and advice to the acute care collaboration on supports for the implementation of the National Standards for Safer Better Healthcare (2012).

1.2 Strategy for change

A clinical governance framework for quality in healthcare was developed to clearly articulate the fundamentals of clinical governance. Following feedback from stakeholders, consultation and testing within clinical services a series of resource documents targeted to be inclusive of all levels of the health system from patient to board were prepared. Five hospitals and two primary care teams were nominated to work with the resources. Each site established a multidisciplinary project team led by the clinical director, with a project manager and agreed terms of reference. Each team used the resources to undertake a gap analysis; the findings of which helped them prioritise and plan quality improvement actions for eight to twelve month projects.

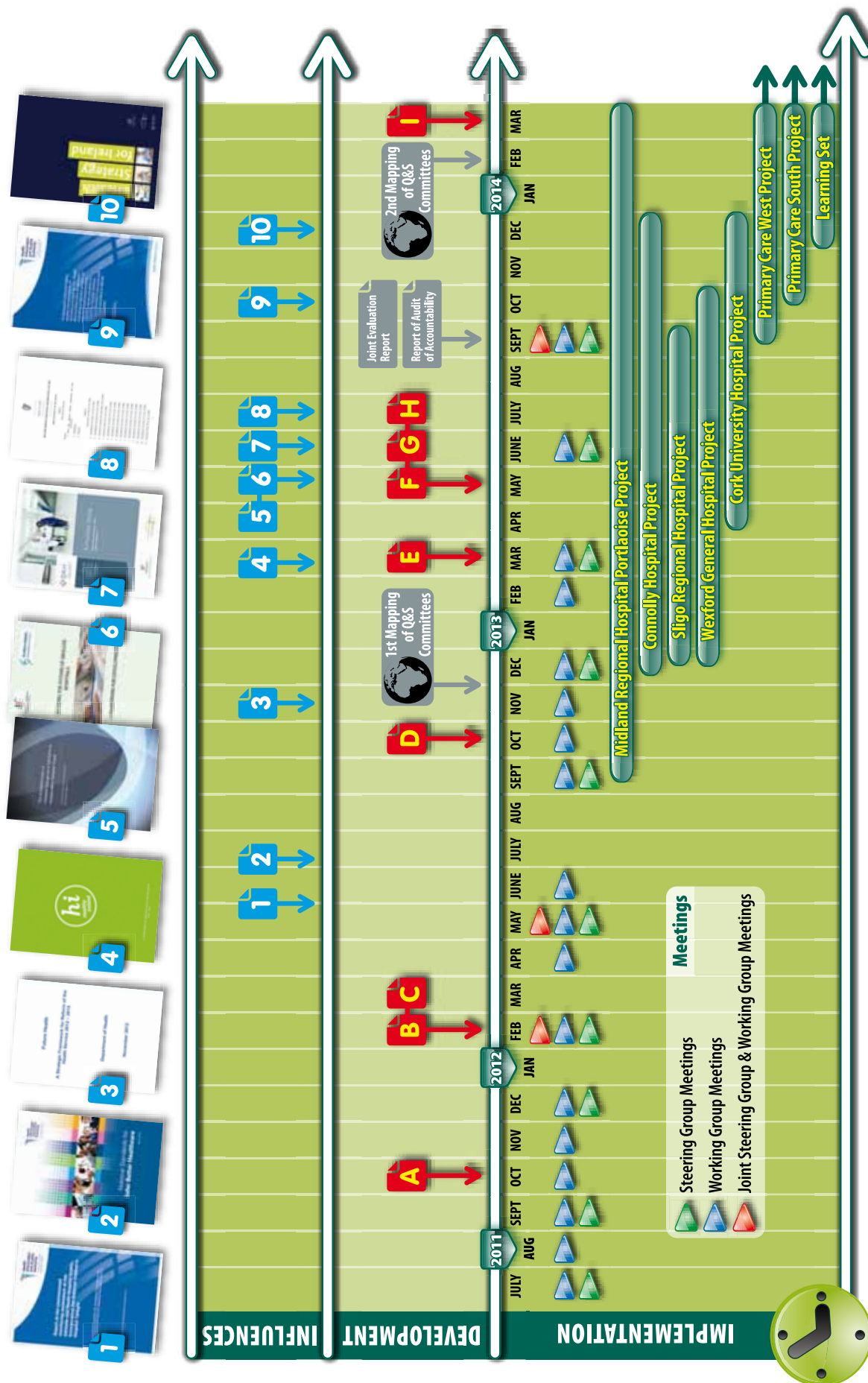
“...leadership and accountability for quality and safety is realised at the point of contact with patients and members of the public”

(Steering Group member).

1.3 Project plan

A project plan of activities for the initiative was agreed. Set out below is a time line for the initiative including key national developments (see Figure 1). It involved consultation and communication with key stakeholders. These included Department of Health, professional and service regulators, the Clinical Indemnity Scheme, National Clinical Programmes, the Special Delivery Unit and regional quality and safety managers. Formative evaluation of process and outcome was planned (see Appendix 3). This report gives details of the activities achieved in the project.

Figure 1: Clinical Governance Development Initiative Timeline



Note: see appendix 4 for details of publications presented

2 Developing resources for practice

2.1 Clinical governance framework

A clinical governance framework based on Donabedian's (1966) classical approach to quality in healthcare (see Figure 2), was developed to clearly articulate the fundamentals of clinical governance. The framework consists of three domains (structure, processes and outcomes) required in the achievement of good quality outcomes in terms of patient care, patient and staff experiences and service improvement. The framework also acknowledges that clinical governance operates in specific contexts and at several levels.

Figure 2: Clinical Governance Framework

Concept	Governance for Quality and Safety		
Domains	Structure	Process	Outcome
	Board/Community Healthcare Organisation	Quality and performance indicators	Patient care
	Quality and Safety Board Committee	Learning and sharing information	Patient experience
	Executive Management Team	Patient and public involvement	Staff experience
	Quality and Safety Executive Committee	Risk management and patient safety*	Service improvement
	Directorates	Clinical effectiveness and audit	
	Clinical leadership	Staffing and staff management	
	Accountability spine	Information management	
		Capacity and capability	
Context	Individual Practitioner Service/Department/Directorate Senior/Executive Management Team Board/Community Healthcare Organisation National Health Body		

* Note: for further information on the HSE Incident Management Policy and Guidance developed for Incident and Complaint investigations see www.hse.ie/go/qps.

To assist health services providers and staff a suite of ten guiding principles for quality and safety underpin the framework (see Figure 3 and Appendix 5). It is proposed that each decision (at every level) in relation to clinical governance development should be tested against the principles which are: (i) patient first; (ii) safety; (iii) personal responsibility; (iv) defined authority; (v) clear accountability; (vi) leadership; (vii) interdisciplinary working; (viii) supporting performance; (ix) open culture; and (x) continuous quality improvement.

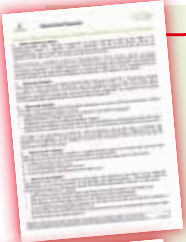



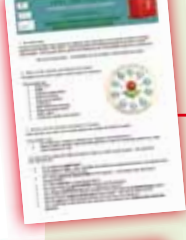

Figure 3: Guiding principles for quality and safety



“...it will require a culture firmly rooted in continual improvement. Rules, standards, regulations and enforcement have a place in the pursuit of quality, but they pale in potential compared to the power of pervasive and constant learning” (Berwick, 2013: 5).

2.2 Quality and safety resources

Following feedback from stakeholders, consultation and testing within clinical services the following documents were launched and endorsed by the Minister for Health, Dr. James Reilly, TD at the second National Patient Safety Conference in February 2012 and third National Patient Safety Conference in May 2013. The endorsement of the colleges and stakeholder groups for each publication is demonstrated by the inclusion of their logos on the front cover (see Appendix 2 for details).

-  **A** *National Clinical Programmes: Clinical governance checklist*. The document is intended as a guide for clinical governance development, across the continuum of care, in each national clinical programme. The completion of the Checklist (issued in October 2011) assists leads in ensuring that clinical governance arrangements are incorporated in the model /pathways of care and is a requirement prior to authorisation of the model/pathway by the National Director. At the time of writing this report a review of the checklist is being undertaken for 2nd edition purposes.
-  **B** *A Quality and Patient Safety: Clinical Governance Information Leaflet* (February, 2012). This leaflet provides a succinct overview of quality and safety clinical governance descriptor vision, principles and matrix. The document is designed to be easily accessible and provide a summary for all staff in understanding that we are all responsible in creating a safer healthcare system.
-  **C** *A Quality and Patient Safety: Clinical Governance Development assurance check for health service providers* (February, 2012). This document provides a series of practical statements which are grouped into two parts i) clinical governance structures and ii) clinical governance processes. The completion of the assurance check assists Boards/CEO/GMs or equivalent in determining what clinical governance arrangements are in place. It is designed as a development tool and is not intended as a reporting mechanism. Review of the statements in the assurance check assists in preparation for meeting theme 5 leadership governance and management of the National Standards for Safer Better Healthcare (2012).
-  **D** *Quality and safety prompts for multidisciplinary teams* (October, 2012). This is an easily accessible, practical guide, for local multidisciplinary teams to use in discussing quality and safety at regular team meetings. The approach was tested with over twenty teams, is based on the principles for good clinical governance and aligned with the themes of the National Standards for Safer Better Healthcare (2012).
-  **E** *Toolbox talks for QPS DNE* (March, 2013). This Dublin North East regional initiative incorporates some of the national resources (as above) in addition to a 'talk' applying the principles of quality and patient safety to the workplace.
-  **F** *Quality and Safety Committee(s): Guidance and Sample Terms of Reference* (May, 2013). This document provides guidance and sample terms of reference for organisations to use in the establishment of both i) Quality and Safety Board Committees and ii) Quality and Safety Executive Committees. This guidance contains a standard meeting agenda aligned with the themes of the National Standards for Safer Better Healthcare (2012) and can be adapted to suit particular context and environments.



G *Quality and Safety Walk-rounds: Toolkit* (May, 2013). In a systematic review leadership walk rounds and multi-faceted unit-based strategies are the two strategies with some stronger evidence to support a positive impact on patient safety culture in hospitals (Morello et al. 2012). This toolkit provides a structured process to bring senior managers and front line staff together to have conversations about quality and safety to prevent, detect and mitigate patient/staff harm. The walk-round can be focused on any location or service that may affect patient care and safety.



H *The Safety Pause: Information Sheet* (May, 2013). This guide is based on a practical, why, who, when and how approach to the Safety Pause which heightens safety awareness and assists teams in being proactive about the challenges they face in providing safe high quality care for patients. It centres on one question 'what patient safety issues do we need to be aware of today' resulting in immediate actions.

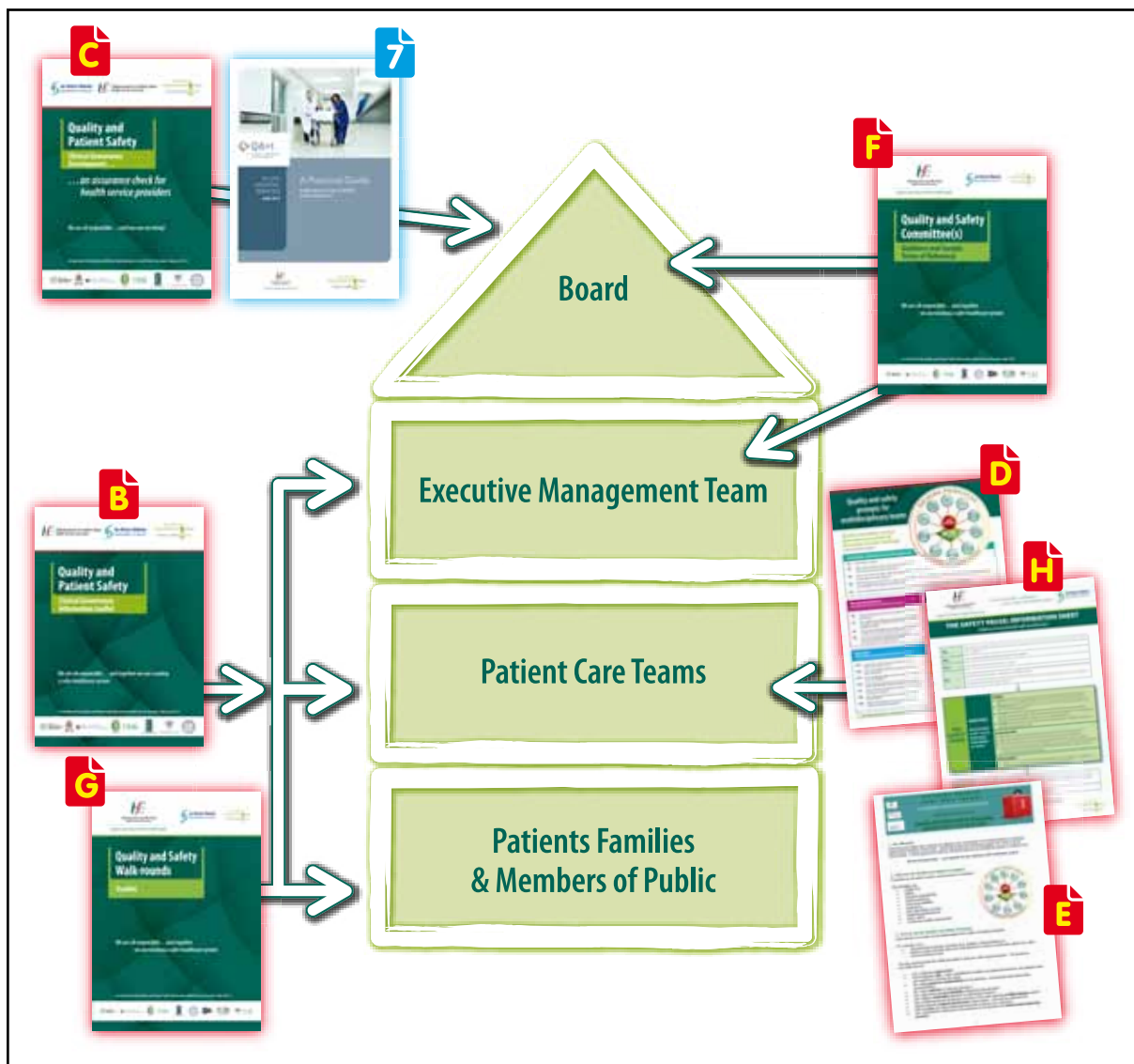
The documents above can be located at www.hse.ie/go/clinicalgovernance

Communication of the new resources to staff occurred through HSE media channels (website, Health Matters, newsletters, workshops to the (previous) HSE Board and key staff groups, etc). In addition, widespread dissemination occurred through conference presentations, educational programmes, guest publication in stakeholder newsletters and peer reviewed journal. Leadership education programmes were especially targeted for dissemination purposes.

“...for the first time we have short easy to read resources that can guide use in putting quality and safety at the top of all our agendas” (Working Group member).

The resources developed were targeted to be inclusive of all levels of the health system from patient to board (as outlined in Figure 4).

Figure 4: Clinical Governance Resources

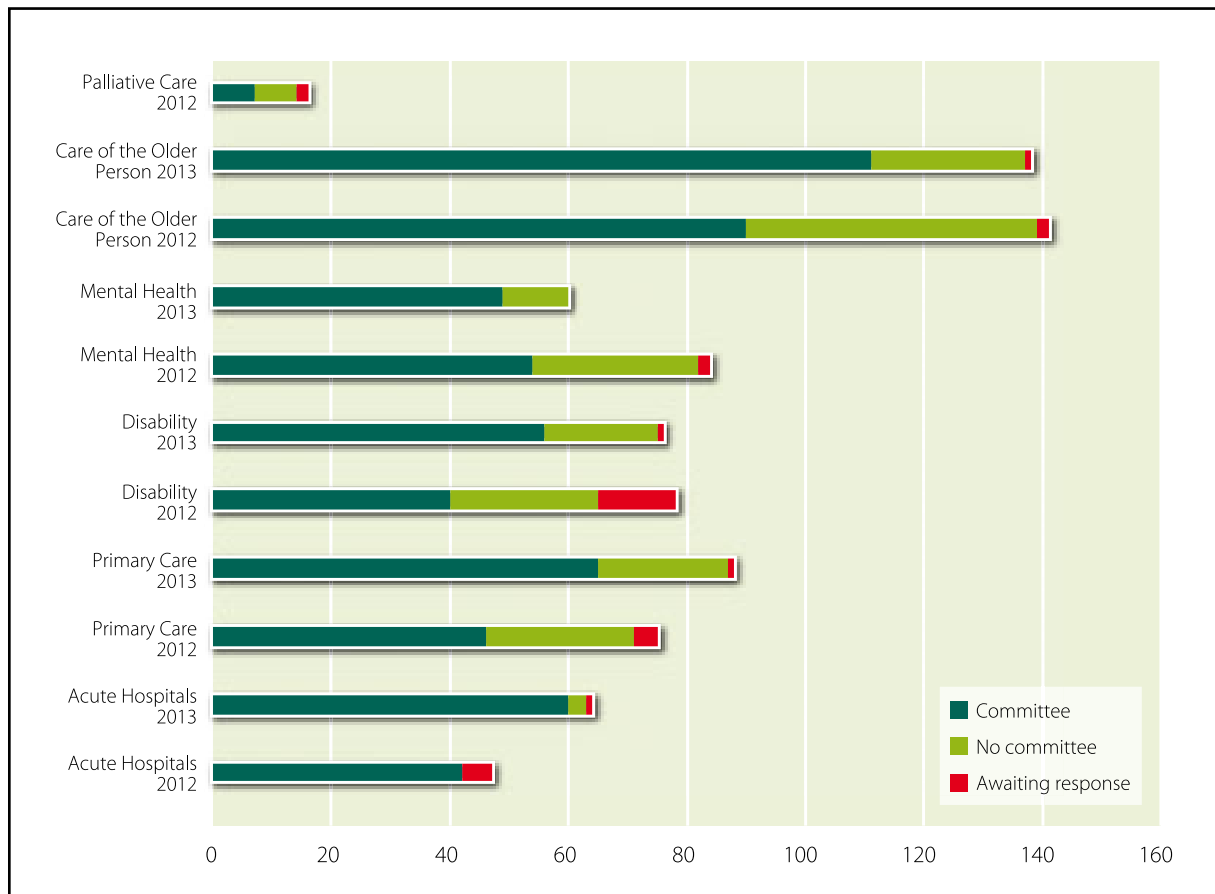


“...patient safety is the keystone dimension of quality. The pursuit of continually improving safety should permeate every action and level”
(Berwick, 2013).

2.3 Committees for quality and safety

As hospital groups and community healthcare organisations seek to drive quality and safety, boards have an opportunity to develop effective roles and committees structure for quality and safety at board, executive and directorate/specialty levels. During the initiative the first mapping of quality and safety executive committees in each HSE region was completed and submitted to the HSE Board Risk Committee in November 2012. In total 441 agencies were included in the mapping. Of this 273 (62%) reported having a committee structure, 132 (30%) reported no formal structure and a response was awaited from 36 (8%) of agencies. A baseline report of the mapping was provided to each Regional Director of Operations, in December 2012, highlighting the areas where there were gaps. Follow up mapping for end 2013 showed significant developments with 68 additional committees reported (see figure 5). Of the 426 agencies (small decrease in number arising from clarifications and reconfiguration) 341 (80%) reported having a committee structure, 81 (19%) reported no formal structure and a response was awaited from 4(1%) of agencies. A quality and patient safety audit of quality and safety committees is planned for 2014.

Figure 5: Quality and Safety Committee 2012 and 2013



Note: palliative care included with acute hospital response for 2013

Committees for quality and safety are part of the governance framework which help health services arrange lines of accountability, responsibility, authority and communications. Table one shows how information flows between quality and safety committees and integrates with the management structure.

Table 1: Committees for Quality and Safety

Management Structure		Committee Structure	
Governance	<p>Board for the hospital group/community healthcare organisation: the board governance role involves seeking assurance that the necessary actions are being taken throughout the service and that reporting and monitoring are carried out and performance targets reached.</p>	Committee	<p>Quality and safety board committee: oversees quality and safety on behalf of the board. The committee is chaired by a member of the board (non-executive director).</p> <p>Non-executive directors provide independent scrutiny and constructive challenge of their executive colleagues and their organisations.</p>
Operations	<p>Executive management team: led by the CEO with directors (operations, clinical, nursing/midwifery, service professional, human resources, finance, and ICT). The CEO is the named accountable person for quality and safety (reporting to the board/community healthcare organisation).</p>	Committee	<p>Quality and safety-executive committee: manages quality and safety on behalf of the executive management team. The committee is normally chaired by the lead clinical director reporting to the CEO/executive management team. The committee reports on the implementation of quality and safety arrangements.</p>
Delivery	<p>Directorates/community management structure: implement and deliver safe quality care and treatment based on an accountability spine with a single point of accountability. Directorate structures (working across the group) are led by clinical directors with clear roles, responsibilities, authority, and accountability for the quality and safety of services.</p>	Committee	<p>Quality and safety directorate/specialty committee: leads on the implementation of quality and safety standards, plans clinical audit and reviews outcomes and actions required. The multi-disciplinary committee chaired by the clinical director/specialty lead determines, agrees reviews and monitors key performance and quality indicators for the directorate/specialty. The committee reports to the quality and safety executive committee.</p>

Each committee has an opportunity to use formal and informal structures for seeking feedback from patients, advocacy groups and the public and interfacing with other service providers (particularly primary care). The Quality and Safety Committee(s): Guidance and Sample Terms of Reference (2013) provides useful guidance to use in reviewing structures for quality and safety.

In the development of hospital group boards /community healthcare organisations it is important that the new arrangements rigorously distinguish between the role and functions in the: i) board members - governance of quality and safety; ii) executives - leadership and management of daily operations and iii) clinicians - leadership and delivery of clinical practice.

3 Implementing in practice

Following the design of the resources an implementation plan was developed. This incorporated development projects, audits of existing arrangements and mapping of the committees for quality and safety. It was agreed that five hospitals would be identified and supported by the national lead to develop new clinical governance structures and processes using the national resources.

“...Participating in the Clinical Governance Development Project gave us the design we needed to ensure quality and safety in our hospital – the implementation phase is about making it real, so that outcomes are improved for all” (Project Manager, Acute Hospital).

3.1 Quality and safety clinical governance development projects

The five hospitals nominated by the Regional Director of Operations to participate in the quality and patient safety (clinical governance) development projects were:

- Sligo Regional Hospital in HSE West;
- Midland Regional Hospital Portlaoise in HSE Dublin Mid Leinster;
- Connolly Hospital in HSE Dublin North East;
- Wexford General Hospital, in HSE South; and
- Cork University Hospital in HSE South.

Each site established a multidisciplinary project team led by the clinical director with a project manager and agreed terms of reference. Each team used the *Assurance Check for Health Services Providers* to undertake a gap analysis; the findings helped them prioritise and plan quality improvement actions for eight to twelve month projects.

The quality improvement actions focused on strengthening quality and safety structures and processes, by:

- defining accountability arrangements for quality and safety;
- clarifying governance and reporting relationships set out in organisational charts;
- reviewing terms of reference for executive management teams;
- supporting the establishment and development of directorates;
- identifying clinical specialty groupings with clinical leadership;
- establishing/reviewing the terms of reference for clinical governance committees;
- mapping the reporting relationships of all quality and safety committees;
- using standard meeting agendas focused on the themes of the national standards;
- forming patient partnership groups;
- focusing on open disclosure;
- reviewing the organisations' approach to clinical audit;
- involving staff through the use of staff briefing sessions, newsletters, invitations to provide suggestions for quality and safety developments; and
- arranging formal launch events at the conclusion of the project.

“... The governance structures at [the hospital] have been immeasurably facilitated and strengthened as a result of the Hospital’s participation in the Clinical Governance Development Project” (Clinical Director, Lead for Hospital Quality and Safety Clinical Governance Development Project).

Learning from each hospital was achieved through:

- completion of standardised (interim and final) progress reports which included summary of learning from the project (at the time);
- presentation by a project group member from each site of the progress and learning at the joint evaluation meeting (using a standard presentation format);
- participation in round table discussions at the joint evaluation meeting; and
- completion of a structured evaluation survey at the end of the joint meeting.

Following on from the initiative acute hospitals are now using the Quality Assessment and Improvement Tool (QA+I) developed to support hospitals in assessing against the *National Standards for Safer Better Healthcare* (2012). It is anticipated that the resources and learning from the clinical governance initiative will support them to meet theme 5 (leadership, governance and management). It is expected that activities from this initiative, alongside new and emerging actions will be incorporated into local quality improvement plans.

“... The challenge now will be to ensure that all staff embrace the initiatives that have emerged from the improved quality and safety structures. This will contribute hugely to a patient centred focus and ensure that nothing less than best practice in all disciplines is the consistent goal” (Clinical Director, Lead for Hospital Quality and Safety Clinical Governance Development Project).

Whilst working with the quality and safety projects there was tremendous learning and benefits (which are further described in section 5 of this report). A follow on quality and safety learning set has been established to support and sustain improvements across project sites.

In consultation with the National Primary Care Steering Group two primary care areas were identified to commence (six to eight month) projects for quality and safety development (one in HSE West and one in HSE South). These projects commenced in autumn 2013 with a similar approach.

3.2 Audit of accountability arrangements for quality and safety of patients in acute hospitals

Clear accountability is one of the ten guiding principles for clinical governance (see Appendix 5) and is an essential element identified in the Quality Assessment and Improvement (QA+I) Resource (Standard 5.1) for the *National Standards for Safer Better Healthcare* (2012).

The steering group commissioned an audit through the Quality and Patient Safety Audit function (QPSA). The purpose of the audit was to provide assurance as regards the accountability arrangements in place for quality and patient safety in a sample of four acute hospitals (voluntary and statutory).

The audit concluded that current accountability arrangements for quality and patient safety within hospitals are evolving and expanding with the development of the clinical directorates and new hospital groups. Reasonable evidence was provided to the audit team to demonstrate that:

- the CEO/GM and senior management team in each hospital are fully informed of all key areas of quality and patient safety in their hospital;
- hospitals have documented arrangements in place for monitoring quality and patient safety; and
- processes and systems are in place to ensure that quality and patient safety is a priority for senior managers.

Audit reports were provided to each of the participating hospitals, with local recommendations pertinent to each hospital, as well as a final audit report which collated the evidence from all four hospitals and provided national recommendations (see Appendix 6). A report of the audit was provided to the National Directors for Acute Services, Quality and Patient Safety, Human Resources and the Regional Director of Operations, along with presentation at the joint steering group and working group evaluation meeting September 2013, and is available at www.hse.ie/go/qps.

4 Integrating clinical governance

Leadership (both formal and informal) at all levels is required to make the case and to achieve sustainable change. Creating linkages, integration and synergy with other developments is a focus for this clinical governance initiative. Below are examples of how clinical governance has been incorporated within some existing programmes and systems.

4.1 Patient and staff experience

Patient and service user experience is central to clinical governance. The National Healthcare Charter – You and Your Health Service describes what is important to patients (HSE, 2012). Through the initiative we have worked closely with staff of the National Advocacy Unit, who have developed a series of guides and tools to support services in measuring patient experience at local level and in using this information to improve healthcare services (see details at www.hse.ie/go/qps).

The relationship between front line managers and their team is central in supporting staff to deliver safe quality care.

“... Ward, unit, clinic and service managers exert the greatest influence on organisational performance and patient outcomes... having awareness of service objectives, being clinically excellent, putting the patient first and staff second” (Steering Group member).

A ‘quality and safety culture’ ensures that quality and safety is important to every person working within that service. This culture supports and values learning, and promotes effective governance and accountability. The Quality and Patient Safety Division in collaboration with the Regional Managers for Quality and Patient Safety, are undertaking a National Patient Safety Culture Survey of Staff working in all acute hospitals. The survey tool being used was developed by the Agency for Healthcare Research and Quality in the USA adapted for use in the Irish Health System (following pilot in 2012). It includes questions pertaining to Open Disclosure and Clinical Governance. The Clinical Governance questions (9 items) are adapted from the Clinical Governance Development Index (CGDI), developed in New Zealand (Gauld et al, 2011). This will provide a baseline for staffs’ perception of clinical governance development within their service, along with providing information on areas of strength and areas for further quality improvements.

“...the quality of the engagement between line manager and staff, and not structural or technical devices, is the key to achieving better patient outcomes” (Steering Group member).

4.2 Open disclosure

Open disclosure is central to any clinical governance system. The open disclosure process integrates and supports other clinical governance processes including clinical incident reporting procedures, systems analysis reviews, complaints management and privacy and confidentiality procedures. The HSE, in conjunction with the State Claims Agency, piloted an open disclosure programme for two years in two acute hospitals, the Mater Misericordiae University Hospital, Dublin and Cork University Hospital. The aim of the project was the creation and support of an “open” approach in relation to the management of patients/service users and their carers following adverse events where harm has occurred as a result of healthcare and to develop a standardised approach in relation to the management of open disclosure across all health and social care services.

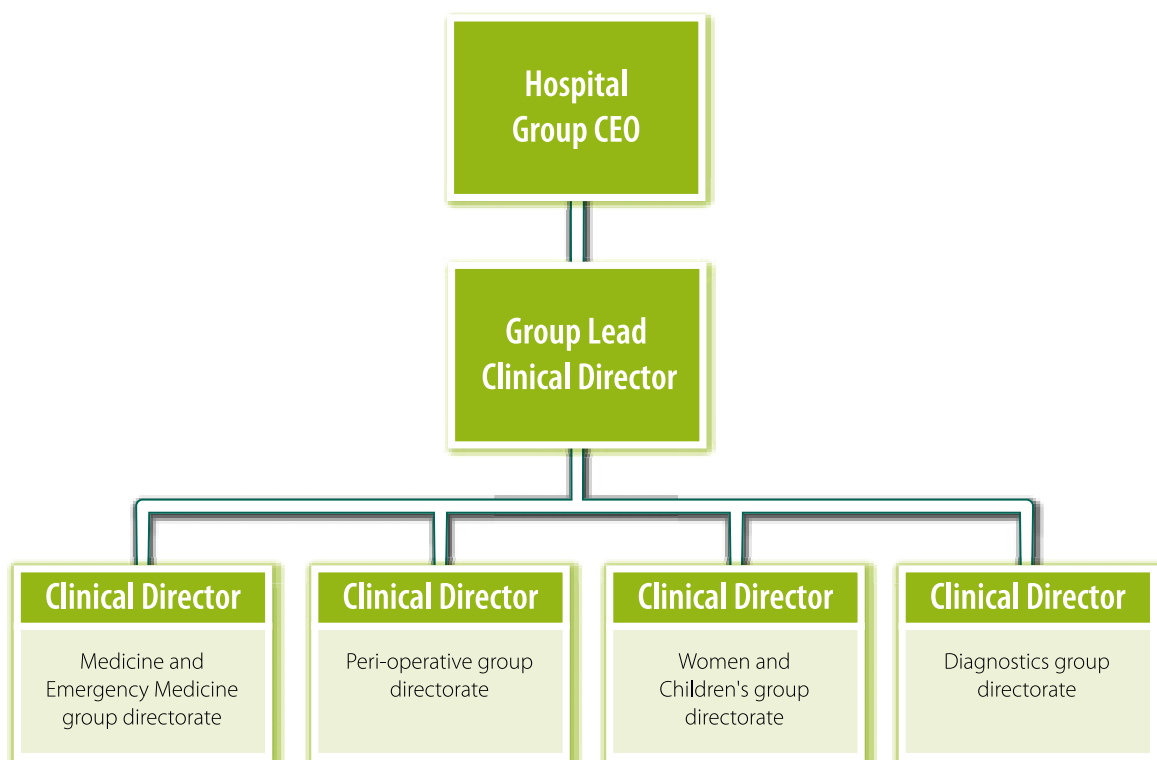
The HSE and State Claims Agency launched a national policy and national guidelines on Open Disclosure on 12th November 2013. Three further supporting documents were also launched including a staff support booklet, patient information leaflet and staff briefing guide. These documents can be accessed at www.hse.ie/opendisclosure.

4.3 Clinical director/directorates

The clinical directorate model, incorporating the appointment of clinical directors with formal authority to lead, is central to clinical governance. The underlying principle of the clinical director model is that of a single point of accountability with an accordant level of responsibility and authority. Within each hospital group there will be a group lead clinical director (or chief clinical director as it is named in the Hospital Groups report) and four specialty clinical directorates. The group lead clinical director will report to the group CEO and be a member of the Group Executive (see Figure 6). All consultants in the group will report to the clinical director for their own specialty grouping. Each Model III hospital in the group will have a Clinical Lead in each of the four specialties (if specialties exist in hospital) reporting through to the corresponding group clinical director. Throughout the initiative we worked closely with the HSE lead for clinical directors /directorate (appointed September 2013) in supporting clinical directors in chairing the quality and safety executive committee for their service.

“...a good clinician will make consistently good clinical decision, but having a system of effective clinical governance means there is a structure to ensure that this is not by chance, but follows from good recruitment, continuing professional education and clinical audit. Such a system will enable good performance to be sustainable and to be spread across the organisation” (Owens, 2005).

Figure 6: Clinical Director Hospital Group Model



4.4 Leadership and quality in health care

Leadership both formal and informal provides the foundations for good governance for quality and safety of services. Building clinical leadership and accountability for quality and safety is in development through a number of different programmes described below. During the initiative presentations/workshops and the resources on clinical governance have been incorporated within the various education/programmes for leadership. The following paragraphs provide a brief summary of what each programmes delivers.

National clinical programmes

The national clinical programmes are providing multidisciplinary, clinical leadership for the standardisation of service provision in terms of quality, access and value for money. The output from the national clinical programmes - evidence based, models of care/pathways for each programme, are central to clinical governance. Completion of the *National Clinical Programmes: Clinical governance checklist* assists leads in ensuring that clinical governance arrangements are incorporated in the model /pathways of care and is a requirement prior to authorisation of the model/pathway by the National Director.

Diploma in leadership and quality in healthcare

To support the development of leadership capacity the HSE has funded and collaborated with the Royal College of Physicians of Ireland (RCPI) in a number of initiatives focused on leadership for quality improvement. The Diploma in Leadership and Quality in Healthcare (launched in September 2011) aims to provide training specifically in patient safety and quality improvement recognising the importance of clinical leadership to change clinical systems. The programme is inclusive of all disciplines, including doctors, nurses and midwives, pharmacists, health and social care professional and managers. Part of the curriculum includes sessions on the value of clinical governance and how this is a central requirement which supports leaders in delivering quality and safety.

Leadership and innovation for nursing and midwifery

The Office of the Nursing and Midwifery Services Director, National Leadership and Innovation Centre (NLIC) in collaboration with the Royal College of Surgeons in Ireland (RCSI) Institute of Leadership are providing a national leadership development programme for directors and assistant directors of nursing and midwifery. There are 75 directors and assistant directors of nursing and midwifery participating in the programme. In addition to personal and professional leadership development, directors are working together on strategic organisational development projects that align with the reconfiguration of the hospital groups and the health system.

Leadership and management development for health and social care professionals

The Health and Social Care Professions (HSCP) Education and Development Unit of the HSE in collaboration with the National HR Directorate designed a multidisciplinary leadership programme for HSCP - *Beginning a New Leadership Journey*. The pilot programme is designed to enhance the performance of HSCP managers in their current and possible future roles recognising the need for strong leadership at all levels in the professions. Learning methodologies include project work, seminars, action learning sets, coaching, reflective log, pre and post programme 360 degree assessment and development of a post programme personal leadership development plan (designed and delivered on a collaborative basis with the RCSI Institute of Leadership).

Leadership and succession management programme

The HSE *Leadership and Succession Management Strategy and implementation programme* was developed in response to a loss of corporate memory and experience through early retirement schemes and restrictions on recruitment. In the short term the focus is on identifying and developing successors for key senior roles (i.e. senior management teams). Development approaches include: assessment centres, projects, leading new service developments, action learning sets, coaching and specific skills development.

Fellowships with Scottish Patient Safety Programme

In March 2012 arrangements were put in place to facilitate clinicians from the Republic of Ireland to undertake the year long Scottish Patient Safety Programme Fellowship (SPSP) (part-time). The SPSP fellowship programme aims to develop and strengthen clinical leadership and improvement capability and contribute to the development of a long-term quality improvement and patient safety culture. Two fellows from Ireland have been supported by the National Leadership and Innovation Centre, Office of the Nursing and Midwifery Services Director and the Quality and Patient Safety Division to undertake this programme in 2012 and four in 2013 which will strengthen capacity and capability within the Irish health system.

4.5 Assurance for quality and safety

A number of assurance mechanisms for quality and safety of service provision are in place. Working closely with lead personnel the principles for quality and safety (good clinical governance) were incorporated in (i) service agreements (ii) supports for national standards; and (iii) the HSE annual controls assurance processes.

Service agreements

As part of a HSE wide initiative to improve governance arrangements for the funding of non-statutory agencies, a national framework for service agreement has been developed, to ensure a consistent approach. This seeks to provide a level of governance, that will link funding provided to a quantum of service, and allows for these services to be linked to quality standards, with continuous monitoring to ensure equity, efficiency and effective use of available resources. Template service agreements for section 38 (acute and non-acute service) section 39 and section 10 services are provided. In the review of the documentation for 2012 and 2013 the principles, structures and processes for quality and safety clinical governance were further integrated within the approach. For details see http://www.hse.ie/eng/services/Publications/Non_Statutory_Sector/Section_38_Documentation.html

National standards

The National Standards for Safer Better Healthcare were launched in June 2012 for most health services, the *Quality Framework for Mental Health Service in Ireland* (2005) provides this guidance for the mental health services. Standards are central in that they allow service providers to clearly articulate on behalf of their staff the standards of care they are committed to providing to their patients and families. The HSE Quality and Patient Safety Division formed a national standards implementation team to plan and lead this process by developing support mechanisms to enable successful implementation. The learning from the clinical governance development initiative was incorporated into the development of the support materials in order to ensure alignment and consistency in approach.

“...Planning to implement the National Standards has been made easier following our participation in the Quality and Safety Clinical Governance Development Project” (Project Manager, Acute Hospital).

HSE annual controls assurance processes

The annual controls assurance processes incorporates a formal review of the effectiveness of the system of internal control within HSE. It contributes to the integration of corporate and clinical governance arrangements. This review provides assurance to the Director General that the Health Services Directorate has effective controls in place and that weaknesses are addressed where they exist. The structures and process for quality and safety clinical governance development were incorporated in the review of the Management Controls handbook for 2012 and 2013 including the extension of the process to all senior clinicians (at grade VIII or equivalent pay grade). See management controls handbook and further details at

http://hsenet.hse.ie/finance_Transformation_Projects/Internal%20Control%20Reviews/Managementersion5.pdf

5 Evaluation of the initiative

An evaluation framework was developed as part of the project plan and initiative outputs were aligned against targets (see Appendix 3 for more detail). In addition, a joint evaluation event (18th September 2013) was held for the steering, working groups and invited guests.⁴ Learning was identified through:

- circulation of final progress reports from each hospital project (including summary of learning in advance of the meeting);
- presentation by a member of each project group of progress and learning during the meeting (using a template presentation);
- presentation of a summary of the audit of accountability arrangements for quality and safety of patients in four acute hospitals (one in each HSE region);
- participation in round table discussions focused on four questions (i) what worked well during the two year initiative; (ii) what did not work so well during the two year initiative; (iii) if starting again what would you do differently; and (iv) what are your three suggestions for further quality and safety governance development; and
- completion of a structured evaluation survey at the end of the joint meeting.

At this early stage an evaluation of the full impact of the initiative is premature.

Progress demonstrated included:

- structures for leadership and accountability for quality and safety have been clarified through the development of organisational charts;
- an integrated approach to corporate and clinical governance is emerging;
- in the main, clinical leads are now in place and a cohort of local clinical governance champions has developed;
- quality and patient safety processes, such as open disclosure and patient partnership have been strengthened;
- the national Quality and Patient Safety Division resources provided important tools for this developmental work; and
- all sites reported an increased awareness of clinical governance.

A thematic analysis was conducted by an external evaluation officer through attendance at the joint meeting; reading the site specific progress reports and presentations, output from the round table discussions and individual evaluation forms.

“...The project finally produced structure to the groups in relation to nurse management. It enabled all staff to be engaged with care programmes, clinical directorates and governance. It helped align the hospital with the National Standards”

(Director of Nursing and Midwifery, acute hospital project team member)

⁴ These included the regional General Managers for Quality and Patient Safety, national leads from Quality and Patient Safety Division, the primary care teams due to commence quality and safety clinical governance development projects, the Quality and Patient Safety Audit auditors and the external evaluation guide.

Theme 1: Continually sustaining and refining the vision:

- A focus on quality and safety through clinical governance is evident across projects and other hospitals but has best occurred where there is dedicated resource.⁵ The starting point, journey and pace of changes varies across sites and requires organisational ownership.
- There is a strong sense that this initiative is timely with focus on learning from the Mid-Staffordshire Inquiry (Francis, 2013), National Standards for Safer Better Healthcare (2013) and changing of previous structures such as earlier hospital organisational divisions.
- Use of the Clinical Governance Development Assurance Check for Health Service Providers (2012) assisted with a clear plan of action and further next steps have been identified in the project sites.
- Clinical Leads and local clinical governance champions are now in place.

Theme 2: Clarity, especially in complex systems

- A starting point for services has been top down e.g. focus on structures; identification of clinical leadership; and integration of clinical governance within the role and function of the Executive Management Team (EMT). There has been some streamlining of functions (for example merging and reporting arrangements for committees).
- Quality and patient safety needs to be standing items on EMT agendas and be positioned above finance and HR. Of note, the important enabler of performance management had limited reference within site reports and clarity is required on the role of Medical Boards.
- In the absence of a document management system there are challenges in identifying, accessing and reviewing policies procedures and guidelines.

Theme 3: Don't underestimate the role of culture

- There is diversity in the system on the use of terminology and a desire for simpler clearer language, both for staff and patient/family engagement e.g. 'governance for quality and safety' preferred to the term clinical governance.
- Culture change requires long investment and so sites require 'bite size' chunks of development in order to sustain motivation and achievement.

Theme 4: Incorporating the Patient and Family Voice (at every level)

- Patient involvement is challenging; some sites used mixed methods e.g. focus groups, survey and patient representation on committees. Further consideration of how best to get this at all levels is required. Of note, most development sites could not articulate well what has changed for patients, during the project, but this should be read cautiously considering the focus on the top-down approach and the timeframe involved.

Theme 5: Staff need to be involved

- Staff need to be included, valued and invited to give their suggestions for quality improvement including improving their work experience. The organisation's support for staff particularly during investigations is paramount.
- There is a sense that engagement with front line staff has commenced. The level of feedback to staff on quality and safety is unclear, although some has occurred e.g. newsletters, patient safety culture survey results.

Theme 6: Future challenges

- There is a benefit of being a development site and having national support for guidance and advice.
- Planning is required on the future approach to sharing the learning using applied examples with other sites.
- It is too early to measure the impact of the initiative. Whilst quality improvement plans have been designed, there has been varying degrees of implementation at this stage.
- ICT supports (e.g. Quality Dashboard, 'QPulse') require an increase in development and/or procurement pace.

5 Where there is a Risk Manager, a Quality Manager and a designated project manager in post and clearly identified clinical leadership.

Overall, the evaluation showed the success of the initiative in driving the development of clinical governance. At this stage of the process some learning outcomes have emerged and are detailed in key learning points at the start of the report and additional learning outcomes below (see Table 2). Development is dynamic (not a static process) and so these should not be assumed to be the totality of learning achieved.

Table 2: Additional learning outcomes

1	Leadership is central to holding the vision. A longer timeframe is required to sustain the gains of the initiative and allow for culture change.
2	Key to the enthusiastic response to the initiative was its timeliness in relation to other drivers (local ownership, project managers, clinical directorate development, hospital groups, National Standards for Safer Better Healthcare).
3	In some projects the ownership and accountability for quality and safety has been confirmed but there remains difference of opinion in others. In addition, the audit showed that clinical governance is not explicit in senior management job descriptions.
4	Greater focus is required for collecting and analysing multiple sources of quality and safety data (measures). Driving quality improvement means being able to measure existing quality levels as well as being able to demonstrate the impact of quality improvement plans. This allows data driven decisions to be made, including potential impact on patient outcomes. A key issue is transparency of data to staff and the public alike.
5	Some projects recognise that they have made tentative steps in relation to patient and/or staff engagement during the project initiative. More data will become available in relation to staff engagement and understanding of clinical governance once the patient safety culture survey reports and additional data will become available in relation to patient experience through the work of the Quality and Patient Safety Advocacy Unit.
6	Staff well-being requires a focus in services when investigations are occurring (the HSE published a critical incident stress debriefing policy in 2012 to be implemented to support staff throughout the process of managing and investigating incidents).
7	The resources produced during the initiative were reported to be practical and user friendly.
8	The central support for implementation was acknowledged. There is now a need to identify other types of support mechanisms for future spread e.g. peer to peer.

The focus on meeting the National Standards for Safer Better Healthcare and the establishment of implementation teams within all services provides a mechanism and opportunity to incorporate the learning and recommendations arising from this initiative.

“...the project presented an excellent opportunity for colleagues in acute hospitals to ‘put practice into theory’” (Working Group Member).

6 Conclusion

Arising from the initiative a focus on quality and safety through clinical governance development has emerged. The three priorities (cultures, leadership and systems and methodologies) set for the initiative provided a good mechanism for the project and its implementation. The term clinical governance comprises a mixture of activities relating to governance, management and practice which can be confusing for those expected to execute these roles. Promoting the use of the term 'governance for quality and safety' assisted in gaining an understanding of 'clinical governance'.

The clinical governance framework developed during the initiative provides guidance on the appropriate quality and safety structures (committees) and processes. The learning has shown the importance of hearing directly from patients, members of the public and staff when striving to deliver a safe quality service. A culture of quality and safety can be created by: (i) board member and executive walk-rounds (ii) putting quality and safety on every agenda (iii) using multidisciplinary team prompts; (iv) introducing safety pauses; and (v) targeted quality improvement programmes.

Across the health system there is a focus and interest in leadership and management development including quality improvement methodologies. In this report we have highlighted a number of programmes building leadership capacity. A greater focus on interdisciplinary leadership development in the workplace where teams learn together and are supported in leading quality safety and improvement programmes could be achieved. Investment by providing on the job coaching for clinicians and managers (with a focus on developing the whole team not just the leader) to understand and enact their leadership role provides real benefits for quality and safety along with using opportunities to share experiences and learn from other services and industries (i.e. high reliability organisations).

In all systems and methodologies the integration of corporate and clinical governance is of utmost importance. These must provide mechanisms where clinical outcomes data and the profile of quality of care can be examined focused on a balanced set of metrics: quality and safety; access; flow; cost and revenue; and human resource management. Making quality and safety data transparent to staff and members of the public (for example by publishing the data in an accessible format) reinforces the culture of quality and safety.

At a time when there are a lot of demands (measurement and scrutiny) the health services lead and respond well to focused support as they improve the quality and safety of services. This initiative set the aim of creating a culture where quality and safety is everybody's primary goal, every aspect of the development was focused on improving patient safety, delivering quality compassionate care and achieving good clinical outcomes. The learning and resources described in this report provide an opportunity for all health service providers, policy makers and commissioners to use the recommendations to inform their own specific action plans. The implementation of the *National Standards for Safer Better Healthcare and the Quality Framework for Mental Health Services in Ireland* provide the mechanism to bring the work forward and further integrate governance for quality and safety.

References

- Brennan, N. and Flynn, M (2013), 'Differentiating clinical governance, clinical management and clinical practice.' *Clinical Governance: an International Journal*, 18(2):114-131.
- Concise Oxford Dictionary*. (1995), Oxford: Oxford University Press.
- Department of Health and Children (2008). *Building a Culture of Patient Safety – Report of the Commission on Patient Safety and Quality Assurance*, Stationery Office, Dublin.
- Donabedian, A. (1966), 'Evaluating the quality of medical care.' *Milbank Memorial Fund Quarterly*, 44(3): 166-206.
- Gauld, R., Horsburg, S. and Brown, J. (2011), The clinical governance development index: results from a New Zealand study. *British Medical Journal Quality and Safety*, 20(11): 947-952.
- Health Information and Quality Authority (2006), Hygiene Services Assessment Scheme. Dublin: Health Information and Quality Authority.
- Health Service Executive (2009). *Framework Document Towards Excellence in Clinical Governance – a framework for integrated quality, safety and risk management across the HSE Service Providers*. Dublin: Health Service Executive.
- Health Service Executive (2009), *Integrated Risk Management Policy Document 2.4 V3*. Dublin: Health Service Executive.
- Health Service Executive (2009), *Quality and Risk Taxonomy Governance Group Report On Glossary of Quality and Risk Terms and Definitions*. Dublin: Health Service Executive.
- Health Service Executive (2010), 'Leadership', Dublin: HSE, Leadership Hub, accessed at <https://www.hseland.ie/leadership/> on 17th February 2014.
- Health Service Executive (2010), *Achieving Excellence in Clinical Governance Towards a Culture of Accountability*. Dublin: Health Service Executive.
- Health Service Executive (2011), *Code of Governance*. Dublin: Health Service Executive.
- Health Service Executive (2012), *HSE Procedure for Developing Policies, Procedures, Protocols and Guidelines*. Dublin: Health Service Executive.
- Health Service Executive (2012), *Policy for Preventing and Managing Critical Incident Stress*. Dublin: Health Service Executive.
- Health Service Executive (2012), *The National Healthcare Charter – you and your health service*. Dublin: Health Service Executive.
- Health Service Executive (2013), *Management Controls Handbook*. Dublin: Health Service Executive.
- Health Service Executive (2013), *National Service Plan 2014*. Dublin: Health Service Executive.
- Health Service Executive (2013), *National Open Disclosure Policy*. Dublin: Health Service Executive and State Claims Agency.
- Martin, A. (2007), 'Everyday Leadership'. Centre for Creative Leadership accessed at <http://www.ccl.org/leadership/pdf/research/EverydayLeadership.pdf> (18th February 2014).
- Mental Health Commission (2005), *Quality Framework for Mental Health Services in Ireland*. Dublin: Mental Health Commission.

Mental Health Commission (2007). *Quality Framework for Mental Health Services Draft Audit Toolkit*. Dublin: Mental Health Commission.

Morello, R., Lowthian, J., Barker, A., McGinnes, R., Dunt, D., and Brand, C. (2012), 'Strategies for improving patient safety culture in hospitals: a systematic review.' *British Medical Journal Quality and Safety*, on line published on 21st July 2012 as 10.1136/bmjqs-2011-000582.

National Advisory Group on the Safety of Patients in England (2013), *'A promise to learn – a commitment to act – improving the safety of patients in England'* (the Berwick Report). London: National Advisory Group on the Safety of Patients in England.

National Health Service Scotland (2005), *Clinical Governance and Risk Management: Achieving Safe Effective Patient Focused Care and Services*. Edinburgh: NHS Quality Improvement Scotland.

Scally, G. and Donaldson, L. (1998), 'Clinical governance and the drive for quality improvement in the new NHS in England'. *British Medical Journal* 317, 61-65.

Special Delivery Unit (2013), *Introducing Demand and Capacity Planning: technical guidance*. Dublin: Health Service Executive.

The Australian Commission on Safety and Quality in Health Care (2003), *Open Disclosure Healthcare Professionals Handbook*. Sydney: the Australian Commission on Safety and Quality in Health Care.

World Health Organisation (2009), *The Conceptual Framework for the International Classification for Patient Safety*. Geneva: World Health Organisation.

Bibliography

- AS/NZS Standards Australia/Standards New Zealand (2004), *Standard for Risk Management AS/NZS 4360:2004*, New South Wales.
- Balding, C. (2005), 'Strengthening clinical governance through cultivating the line management role.' *Australian Health Review*, 29(3), 353-359.
- Balding, C. (2008), 'From quality assurance to clinical governance.' *Australian Health Review*, 32(2): 383-391.
- Braithwaite, J. and Travaglia, J. (2008), 'An overview of clinical governance policies, practices and initiatives' *Australian Health Review* 32(1): 10-22.
- Campbell, S., Sheaff, R, Sibald, B., Marshall, M., Pickard, S., Gask., L., Halliwell, S., Rogers, A., and Roland, M. (2002), 'Implementing clinical governance in English primary care groups/trusts: reconciling quality improvement and quality assurance', *BMJ Quality Safety in Health Care* 11: 9-14.
- Clinical Leaders Association of New Zealand (2000), *Clinical Governance: A CLANZ overview paper*. Auckland: Clinical Leaders Association of New Zealand.
- Crowley, P. and Flynn, M. (2012), 'Leadership and accountability for quality and safety.' *Clinical Indemnity Scheme Newsletter*. Dublin: State Claims Agency.
- Crowley, P. and Flynn, M. (2012), 'Supporting Clinical Governance Development.' *eHospital Official Journal of European Association of Hospital Managers*, 14(1): 14-15.
- Crowley, P., Flynn, M., and Burgess, T., (2012), 'Quality and Safety Prompts', *Health Matters*, 8(4):58.
- Crowley, P., Flynn, M., and Burgess, T., (2013), 'Prompts for Safety', *World of Irish Nursing and Midwifery*, 21(1):20-23.
- Crowley, P., Flynn, M., and Burgess, T., (2013), 'Quality and Safety: Key Improvement Resources', *Health Matters*, 2(9): 31.
- Degeling, P., Maxwell, S., Iedema, R., and Hunter, D. (2004), 'Making clinical governance work', *British Medical Journal*, 329: 679-682.
- Department of Health (1999), *Clinical governance: quality in the new NHS*. Health Service Circular 1999/065. London: NHS Executive.
- Department of Health (2001), *Clinical governance standards for Western Australian health services*. Perth: Department of Health Government of Western Australia.
- Donaldson, L. (1998), 'Clinical governance: a statutory duty for quality improvement', *Journal of Epidemiology and Community Health*, ;52:73-74.
- Flynn, M. (2013), 'Quality and Safety Column – introducing the safety pause', *World of Ireland Nursing and Midwifery*, 21(8): 17.
- Flynn, M. (2014), 'Developing a culture of quality and safety'. *Forum*, 31(2): 16-17.
- Flynn, R. (2002), 'Clinical Governance and Governmentality'. *Health Risk and Society*, 4(2): 155-173.
- Flynn, R. (2004), 'Soft bureaucracy', governmentality and clinical governance: theoretical approaches to emergent policy', in Gray, A. and Harrison, S., *Governing medicine: theory and practice*. Maidenhead: Open University Press.
- Francis, R. (2013), *Report of the Mid Staffordshire NHS Foundation Trust Public Inquiry*. London: The Stationary Office.
- Freedman, D.B. (2004), 'Clinical governance: the implications for point-of-care testing in hospitals: a UK perspective', in Price, C.P., St John, A. and Hicks, J.M. (eds), *Point-of-care Testing* (2nd edition), AACC Press, Washington DC.
- Freeman, T. (2003), 'Measuring progress in clinical governance: assessing the reliability and validity of the clinical governance climate questionnaire'. *Health Services Management Research*, 16: 234-250.

- Freeman, T. and Walsh, K. (2004), 'Achieving progress through clinical governance? A national study of health care managers' perceptions in the NHS in England', *British Medical Journal Quality and Safety*, 13: 335-343.
- Galbraith, S. (1998), Clinical Governance, NHS Scotland Management Executive Letter (MEL) 1998/75. The Scottish Office, Department of Health, Edinburgh (available at http://www.sehd.scot.nhs.uk/mels/1998_75.htm).
- Greenfield, D., Nugus, P., Fairbrother, G., Milne, J., and Debono, D. (2011), 'Applying and developing health service theory: an empirical study into clinical governance', *Clinical Governance: an International Journal*, 16 (1): 8-19.
- Hackett, M. (1999), 'Implementing clinical governance in trusts', *International Journal of Health Care Quality Assurance*, 12(5): 210-213.
- Halligan, A. (2006), 'Clinical Governance: assuring the sacred duty of trust to patients'. *Clinical Governance: an International Journal* 11(1), 5-7.
- Halligan, A. and Donaldson, L. (2001), 'Implementing clinical governance: turning vision into reality'. *British Medical Journal*, 322: 1413-17.
- Health Service Executive (2007), *Quality and Risk Management Standard*. Dublin: Health Service Executive.
- Healthcare Improvement Scotland (2011), *Draft healthcare quality standard: assuring person-centred, safe and effective care: clinical governance and risk management*. Edinburgh: Healthcare Improvement Scotland.
- Kelleher, J. and McAuliffe, E. (2012), 'Developing clinical governance in a service for people with intellectual disabilities: an action research approach', *Clinical Governance: an International Journal*, 17(4): 287-296.
- Khayat-zadeh-Mahani, A., Nekoel-Monghadam, M., Esfandiari, A, Ramezani, F. and Parva, S. (2013), 'Clinical governance implementation: a developing country perspective', *Clinical Governance: An International Journal*, in press.
- Koneth, F., Mannion, R., and Davies, H. (2008), 'Clinical governance views on culture and quality improvement', *Clinical Governance: an International Journal*, 13(3): 200-2007.
- Kumar Singh, R. (2008), 'Clinical governance in operation – everybody's business: a proposed framework'. *Clinical Governance: an International Journal* 14(3), 189-197.
- Lewis, S., Sanders, N., and Fenton, K. (2002), 'The magic matrix of clinical governance'. *British Journal of Clinical Governance*, 7(3): 150-153.
- Lugon, M. and Secker-Walker, J. (1999), *Clinical governance: making it happen*. London: Royal Society of Medicine Press Pl.
- Machell, M. (1999), 'Implementing clinical governance in trusts', *International Journal of Health Care Quality Assurance*, 12(5): 210-2013.
- Maynard, A. (1999), 'Clinical Governance – an economic perspective'. *British Journal of Clinical Governance*. 4: 4-6.
- McSherry, R. and Pearce, P. (2011), *Clinical governance: a guide to implementation for healthcare professionals*. 3rd edn. Oxford: Wiley Blackwell Publishing Ltd.
- Mental Health Commission (2007), *Quality Framework Mental Health Services in Ireland*. Dublin: Mental Health Commission.
- Ministerial Task Group on Clinical Leadership (2009), *In good hands transforming clinical governance in New Zealand*. Wellington: Ministerial Task Group on Clinical Leadership.
- National Health Service Executive (1999), *Clinical governance in the new NHS*. London: Department of Health Circular of 16 March 1999.
- NHS, North Thames Region (1998), *Clinical Governance in North Thames*. NHS Executive, Leeds.

- O'Connor, N. and Paton, M. (2008), 'Governance of' and 'Governance by': implementing a clinical governance framework in an area mental health service.' *Australian Psychiatry* 16(2): 69-73.
- Office of Safety and Quality in Health Care (2001), *Introduction to Clinical Governance: A Background Paper*. Western Australia Department of Health, Perth.
- Onion, C. (2000), 'Principles to govern clinical practice,' *Journal of Evaluation in Clinical Practice*, 6(4): 405-412.
- Peak, M., Burke, R., Ryan, S., Wratten, K., Turnock, R., and Vellenoweth, C. (2005), 'Clinical governance – the turn of continuous improvement,' *Clinical Governance: an International Journal*, 10(2): 98-105.
- Penny, A. (2000), 'Clinical governance in Britain defined.' *Healthcare Review Online (now known as Health Care and Informatics Review Online)*, 4(9).
- Perkins, R., Pelkowitz, A. and Seddon M. (2006), 'Quality improvement in New Zealand healthcare. Part 7: Clinical governance – an attempt to bring quality into reality,' *Journal of the New Zealand Medical Association*, 119 (1243).
- Phillips, C.B., Pearce, C.M., Hall, S., Travaglia, J. de Lusignan, S., Love, T. and Kljakovic, M. (2010), 'Can clinical governance deliver quality improvements in Australian general practice and primary care? A systematic review of the evidence,' *Medical Journal of Australia*, 193(10): 602-607.
- Queensland Health (2007), *Clinical governance Implementation Standard, Clinical Governance Operational Plans*. Brisbane: Queensland Health.
- Robinson, M. (2008), 'An overview of clinical governance policies, practices and initiatives.' *Australian Health Review* 32(3): 381-2.
- Royal College of Nursing (1998), *RCN Information: Guidance for Nurses on Clinical Governance*. Royal College of Nursing, London.
- Scally, G. and Donaldson, L. (1998), 'Clinical governance and the drive for quality improvement in the new NHS in England,' *British Medical Journal*, 317: 61-5.
- Scotland, A. (1998), 'Clinical governance in the new NHS: an agenda for personal and organisational development.' *Clinicians in Management*, Vol. 7, pp. 138-141.
- Shekelle, P., Pronovost, P., Wachter, R., McDonald, K., Schoelles, K., Dy, S., Shojania, K., Reston, J., Adams, A., Angood, B., Bates, D., Bickman, L., Caryon, P., Donaldson, L., Duan, N., O Farley, D., Greenhalgh, T., Huaughton, J., Lake, E., Lilford, R., Lohr, K., Meyer, G., Miller, M., Neuhauser, D., Ryan, G., Saint, S., Shortell, S., Stevens, D., and Walshe, K. (2013), 'The top patient safety strategies that can be encouraged for adoption now,' *Annals of Internal Medicine* 158(5): 365-368.
- Singh, R. (2009), 'Clinical governance in operation – everyone's business: a proposed framework.' *Clinical Governance: an International Journal*, 14(3): 189-197.
- Som, C. (2004), 'Clinical governance: a fresh look at its definition.' *Clinical Governance: an International Journal*, 9(2): 87-90.
- Som, C. (2009), 'Sense making of clinical governance at different levels in NHS hospital trusts.' *Clinical Governance: an International Journal*, 14(2): 98-112.
- Spark, J.I. and Rowe, S. (2004), 'Clinical governance: its effect on surgery and the surgeon.' *ANZ Journal Surgery*, 74(3): 167-170.
- Specchia, M., LaTorre, G., Sliquini, R., Capizzi, S., Valerio, L., Nardella, P. Campana, A, and Ricciardi, W. (2010), 'OPTIGOV – a new methodology for evaluating clinical governance implementation by health providers.' *BioMed Central Health Services Research*, 10, 174; 1-15.

- Staniland, K. (2009), 'A sociological ethnographic study of clinical governance implementation in one NHS Hospital Trust,' *Clinical Governance: an International Journal*, 14(4): 271-280.
- Stanton, P. (2006), 'The role of an NHS Board in assuring the quality of clinically governed care and the duty of trust to patients,' *Clinical Governance: an International Journal* 11(1): 39-49.
- Swage, T. (2000), *Clinical Governance in Health Care Practice*. Oxford: Butterworth-Heinemann.
- Travaglia, J., Debono, D., Spigelman, A., Braithwaite, J. (2011), 'Clinical governance: a review of key concepts in the literature,' *Clinical Governance: an International Journal*, 16(1): 62-77.
- Trong Tuan, L. (2012), 'Clinical governance: a lever for change in Nhan Dan Gia Dinh hospital in Vietnam,' *Clinical Governance: an International Journal*, 17(3): 223-247.
- Vanu Som, C. (2004), Clinical Governance: a fresh look at its definition. *Clinical Governance* 9(2), 87-90.
- Victorian Healthcare Association (2009), 'Clinical Leadership in Action' available from: <http://www.vha.org.au/uploads/Clinical%20Leadership%20in%20Action%20-%20Model%20and%20recommendations%20V6.pdf>.
- Wall, D., Dickinson, K., Kilbane, J., Cummings, D. (2006), 'Developing large group working in clinical governance,' *Clinical Governance: an International Journal*, 11(1): 50-57.
- Walshe, K. (1998), 'Clinical governance what does it really mean?' *Health Services Management Centre Newsletter*, 4 (2): 1-2.
- Winter, M. (1999), 'Clinical governance – getting beyond a new management mantra?,' *Healthcare Quality*, 4 (3): 26-29.
- Wright, L., Barnett, P., and Hendry, C. (2001). *Clinical Leadership and Clinical Governance: a Review of Developments in New Zealand and Internationally*. Auckland: Clinical Leaders Association of New Zealand.

Glossary

Term	Descriptor
Accountability	Staff have a defined responsibility within an organisation and are accountable for that. Accountability describes the mechanism by which progress and success are recognised, remedial action is initiated or whereby sanctions (warnings, suspension, deregistration, etc) are imposed (HSE, 2010).
Adverse event	An undesired patient outcome that may or may not be the result of an error (WHO, 2009).
Assurance	Confidence, based on sufficient evidence that internal controls are in place, operating effectively and objectives are being achieved (HSE, 2009).
Assurance framework	A structure within which boards identify the principal risks to the organisation meeting its principal objectives and map out both the key controls in place to manage them and also how they have gained sufficient assurance about their effectiveness (HSE, 2009).
Authority	Is associated with your role, which is linked to the responsibilities you were given. Authority is the power given to you to carry out your responsibilities (HSE, 2010).
Benchmarking	A system whereby health care assessment undertakes to measure its performance against "best practice" standards. Best practice standards can reflect (1) evidence-based medical practice (this is practice supported by current investigative studies of like patient populations), and (2) knowledge-based systems. Explicit in benchmarking is movement away from anecdotal and single-practitioner experience-based practice (WHO, 2009).
Clinical audit (can also be described as practice audit)	<p>Is the systematic review and evaluation of clinical practice against reference based standards with a view to improving clinical care.</p> <p>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 (Commission on Patient Safety and Quality Assurance, 2008).</p>
Clinical effectiveness	Encompasses clinical audit and evidence-based practice. A structured programme, or programmes, should be in place to systematically monitor and improve the quality of clinical care provided across all services. This should include, systems to monitor clinical effectiveness activity (including clinical audit); mechanisms to assess and implement relevant clinical guidelines; systems to disseminate relevant information; and use of supporting information systems (HSE, 2009).
Clinical governance	<p>Structures, systems, and standards applying to create a culture, and direct and control clinical activities. Clinical accountability and responsibility, a sub-set of clinical governance, involves the monitoring and oversight of clinical activities, including regulation, audit, assurance and compliance by governors (such as boards of directors), regulators (such as governments and professional bodies), internal auditors and external auditors (Brennan and Flynn, 2013).</p> <p>Is a system through which service providers are accountable for continuously improving the quality of their clinical practice and safeguarding high standards of care by creating an environment in which excellence in clinical care will flourish (Sally and Donaldson 1998; HIQA, 2010; adapted HSE, 2010).</p> <p>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 (Commission on Patient Safety and Quality Assurance, 2008).</p> <p>Is an umbrella term which encompasses a range of activities in which healthcare staff should become involved in order to maintain and improve the quality of care they provide to patients and to ensure full accountability of the system to patients. Traditionally it has been described using seven key pillars: clinical effectiveness and research; audit; risk management; education and training; patient and public involvement; using information and information technology; and staffing and staff management (NHS, 2005).</p>

Term	Descriptor
Clinical management	Processes and procedures, including resourcing clinical staff, by managers to efficiently, effectively and systematically deliver high quality, safe clinical care (Brennan and Flynn, 2013).
Clinical practice	Delivery by clinicians of high quality, safe clinical care in compliance with clinical policies and performance standards, in the interests of patients (Brennan and Flynn, 2013).
Controls assurance	A holistic concept based on best governance practice. It is a process designed to provide evidence that organisations are doing their 'reasonable best' to manage themselves so as to meet their objectives and protect patients, staff, the public and other stakeholders against risks of all kinds (HSE, 2009).
Corporate governance	Is the systems and procedures by which organisations direct and control their functions and relate to their stakeholders in order to manage their business, achieve their missions and objectives and meet the necessary standards of accountability, integrity and propriety. It is a key element in improving efficiency and accountability as well as enhancing openness and transparency. To this end, the HSE has adopted a corporate governance regime in accordance with best practice (HSE, 2011).
External assurance	Assurances provided by reviewers, auditors and inspectors from outside the organisation, such as External Audit, HIQA, Mental Health Commission or Medical Colleges (HSE, 2009).
Financial governance	Is concerned with specific internal financial and operational control and accountability procedures. These include a wide range of written policies, procedures, guidelines, codes, audits, standards applicable to all HSE employees and are essential to ensure that governance in the HSE is robust and effective (adapted HSE, 2011).
Gap in assurance	Failure to gain sufficient evidence that policies, procedures, practices or organisational structures on which reliance is placed are operating effectively (HSE, 2009).
Guideline	A principle or criterion that guides or directs action (Concise Oxford Dictionary 1995).
Healthcare	Services of health care professionals and their agents that are addressed at (1) health promotion; (2) prevention of illness and injury; (3) monitoring of health; (4) maintenance of health; and (5) treatment of diseases, disorders, and injuries in order to obtain cure or, failing that, optimum comfort and function (quality of life) (WHO, 2009).
High Reliability Organisation	An organisation that has succeeded in avoiding catastrophes in an environment where normal accidents can be expected due to risk factors and complexity.
Independent Assurance	Assurances provided by (a) reviewers external to the organisation and (b) internal reviewers working to national standards, such as Internal Audit (HSE, 2009).
Internal Assurance	Assurances provided by reviewers, auditors and inspectors who are part of the organisation, such as clinical audit or management peer review (HSE, 2009).
Internal Control	The ongoing policies, procedures, practices and organisational structures designed to provide reasonable assurance that objectives will be achieved and that undesired events will be prevented or detected and corrected (HSE, 2009).
Leadership	<p>Leadership is the ability to create a vision for positive change, help focus resources on right solutions, inspire and motivate others, and provide opportunities for growth and learning (Martin, 2007). Clinical leadership extends the concept of leadership to add the responsibilities for the care and safety of clients and the monitoring of both service and individual outcomes (Victorian Healthcare Association, 2009)</p> <p>Leadership represents a key lever for successful transformation towards integrated service delivery. It influences the performance of all professions and grades in providing services for users. Health services require dispersed and collective forms of leadership, alongside active followership, core management practices and organisational direction (HSE leadership hub, 2010).</p>

Term	Descriptor
Open disclosure	An open, consistent approach to communicating with patients when things go wrong in healthcare. This includes expressing regret for what has happened, keeping the patient informed, providing feedback on investigations and the steps taken to prevent a recurrence of the adverse event (Australian Commission on Safety and Quality in Health Care, 2003).
Patient	A person who is a recipient of healthcare (WHO, 2009).
Performance management	Is not just a process; it is, more importantly, a mindset and a way of behaving which influences organisational outcomes. It is primarily a process which establishes a shared understanding about what is to be achieved, why it needs to be achieved and how it is to be achieved, the acceptance of personal responsibility and accountability and an approach to managing outcomes and people that increases the probability of achieving success (HSE, 2011).
Policy	Is a written statement that clearly indicates the position and values of the organisation on a given subject (HIQA 2006).
Positive assurance	Evidence that shows risks are being reasonably managed and objectives are being achieved (HSE, 2009).
Procedure	Is a written set of instructions that describe the approved and recommended steps for a particular act or sequence of events (HIQA, 2006).
Protocol	Operational instructions which regulate and direct activity (NHS Scotland 2005).
Quality profile	A detailed report of the organisation which describes the quality of healthcare provided.
Responsibility	Is a set of tasks or functions performed to a required standard that your employer can legitimately demand from you and which you are qualified and competent to exercise. Your responsibilities are defined by a contract of employment, which usually includes a job description describing responsibilities in detail (HSE, 2010).
Risk management	Coordinated activities to direct and control an organisation with regards to risk (HSE, 2011). The culture, processes and structures that are directed towards realising potential opportunities whilst managing adverse effects (AS/NZS 4360:2004, HSE 2009).
Service users	Is the term used to include: <ul style="list-style-type: none"> ■ 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 users of health services and social care interventions. <p>The term service user also takes account of the rich diversity of people in our society, whether defined by age, colour, race, ethnicity or nationality, religion, disability, gender or sexual orientation, who may have different needs and concerns. The term service user is used in general, but 'patients and the public' is also used where appropriate (Department of Health and Children, 2008).</p>
Stakeholders	A person, group, organisation, or system who affects or can be affected by an organisation's actions. Health service provider's stakeholders, for example, include its patients, employees, medical staff, government, insurers, industry, and the community (adapted from WHO, 2009).

Appendix 1: Extract from terms of reference

Role of the Quality and Safety Steering Group

The role of the steering group is to provide advice on the further development and implementation of clinical governance, across all health and social services. The responsibilities of the steering group are as follows:

- Set the strategic direction for clinical governance development so that it becomes embedded within the overall governance arrangements for the HSE's statutory and voluntary services.
- Oversee the development of a HSE statement for clinical governance based on a vision and the HSE values which sets out the principles, elements and a framework for clinical governance.
- Guide and approve the development of material and checklists for clinical governance to be used at various levels (national, regional and local) of the organisation.
- Review and recommend strategies and processes to the National Directors of Integrated Services, Clinical Strategy and Programmes and Quality and Patient Safety Directorates.
- Advise and guide the implementation of clinical governance within the National Clinical Programmes.
- Provide advice and guidance with the development of the Executive Clinical Directors/ Clinical Directors roles and Directorates in terms of clinical governance.
- Provide advice and guidance for the implementation of clinical governance in collaboration with existing and future processes for the assessment, implementation and monitoring of compliance against national and regulatory standards and legislation (for example theme 5 Leadership, Governance and Management (HIQA, 2012) and Mental Health Commission (2005, 2007)).
- Sign off on an evaluation framework to review the effectiveness of clinical governance development and implementation.
- Provide advice and guidance to the working group and make recommendations regarding the project plan.

Additional terms of reference agreed on the 19th September 2012

- Provide strategic direction, advice and guidance to the Safer Better Healthcare – acute, primary care and ambulance service collaboratives in implementing the *National Standards for Safer Better Healthcare*.
- Receive and make recommendations on quarterly reports from each of the collaboratives on their respective work.

Role of the Quality and Safety Clinical Governance Development Working Group

The role of the working group is to develop the clinical governance development material and implementation mechanisms. The responsibilities of the clinical governance working group are, to:

- Agree a definition of 'clinical governance' and develop a HSE Statement for Clinical Governance.
- Develop a project plan for the further development and implementation of clinical governance within all HSE statutory and voluntary healthcare settings.
- Develop standardised clinical governance checklists and supporting material for use by each national clinical programme in the development of the model of care.

- Develop educational and supporting material to guide and assist the following in the further implementation of clinical governance:
 - HSE CEO and management team
 - Regional Director of Operations and Health Area Management Teams
 - CEO/General Managers of health service providers
 - Clinical Directors/Directorates
 - Multidisciplinary Teams
- Ensure regular communication and progress reports to the steering group and key stakeholders.
- Identify and work with personnel from specialist services (for example, mental health, public health, primary care etc) for certain aspects of the material development.
- Provide advice and guidance in support to personnel reviewing and developing clinical governance arrangements.
- Develop an evaluation framework to review the effectiveness of clinical governance development and implementation at various levels.
- Establishing strong links with the primary care collaborative to support discussions, sharing of learning and partnership working on areas such as improving the safety and experience of care for patients when moving between primary and secondary care.

Appendix 2: Acknowledgements

Quality and Safety Clinical Governance Development Steering Group Members

Emma Benton	Therapy Professions Advisor
Dr. Mary Boyd	Strategic Lead in Bed Management and Discharge Planning, Special Delivery Unit (until May 2013)
Dr. Mary Browne	Consultant in Public Health Medicine, Quality and Patient Safety Division, HSE
Dr. Aine Carroll	National Director Clinical Strategy and Programmes Division, HSE
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Fergus Clancy	Chief Executive, Mater Private Hospital, Independent Hospitals Association
Dr. Joe Clarke	Primary Care Lead, Health Services Executive
Dr. Eibhlin Connolly	Deputy Chief Medical Officer, Department of Health
Dr. Philip Crowley	National Director of Quality and Patient Safety (Chair)
Paddy Duggan	Performance Management and Management Information, National Human Resource Division, HSE
Maria Lordan Dunphy	Assistant National Director, Quality and Patient Safety Division, HSE
Maureen Flynn	National Lead for Quality and Safety Governance Development, Office of the Nursing and Midwifery Service Director, Quality and Patient Safety Division HSE (Project Lead)
Eilish Hardiman	Chief Executive Officer, Tallaght Hospital
Dr. Cate Hartigan	Assistant National Director, Care Group Lead for Disabilities, HSE
Dr. Colm Henry	National Lead for Clinical Directors / Directorates, Quality and Patient Safety Division, HSE
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Eileen Kelly	Director of Nursing, St Joseph's Intellectual Service, Portrane, Mental Health Nurse Managers Ireland
Paddy McGowan	Patient representative nominee, HSE Patient Advocacy
Dr. Deirdre Murray	Consultant in Public Health Medicine, National Cancer Control Programme, HSE
Gerry O'Neill	Area Manager, HSE, Dublin Mid Leinster
Dr. Liam Plant	Clinical Director, Cork University Hospital, HSE South
Kieran Ryan	Chief Executive Officer, Irish College of General Practitioners
Dr. Michael Shannon	Nursing and Midwifery Services Director, HSE

Quality and Safety Clinical Governance Development Working Group Members

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Margaret Brennan	Quality and Risk Manager Quality and Patient Safety Division, HSE (until April 2012)
Dr Mary Browne	Consultant in Public Health Medicine, Quality and Patient Safety Division, HSE
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Elaine Dobell	Head of Physiotherapy Services, Galway University Hospital
Rose Doyle	General Manager, Acute Services Division, HSE
Mary Duff	Director of Nursing, St. Vincent's University Hospital
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Winifred Ryan	Head of Specification, Quality and Patient Safety Division, HSE (until April 2012)
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Quality and Safety Clinical Governance Development Reference Panel Members

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Dr. Frances Elliot	Healthcare Improvement Scotland, Scotland
Dr. Robin Gauld	University of Otago, New Zealand
Professor John Øvretveit	Karolinska Institutet, Sweden
Dr. Simon Walford	Independent Health Adviser, UK

Colleges and Associations

College of Anaesthetists of Ireland

Heads of Psychology Services Ireland

Health Management Institute Ireland

Irish Association of Directors of Nursing and Midwifery

Irish College of General Practitioners

Colleges and Associations

Irish Medication Safety Network

Mental Health Nurse Managers Ireland

Office of the Nursing and Midwifery Services Director

Royal College of Physicians of Ireland

Royal College of Surgeons in Ireland

The College of Psychiatry of Ireland

Therapy Professions Committee

Quality and Safety Clinical Governance Development Project Group Members

Connolly Hospital

Dr. Eamon Dolan	Consultant in Medicine for the Elderly
Professor Trevor Duffy	Clinical Director (Chair)
Dr. Peter Kavanagh	Administrative Lead in Radiology
Dr. Eamon Leen	Consultant Pathologist
Mairead Lyons	Director of Nursing
Stephanie Manahan	Director of Allied Health, recently appointed Assistant Hospital Manager
Dr. John McDermott	Consultant Endocrinologist
Doreen Powell	A/Risk Manager (Project Manager)
Mary Walshe	Hospital Manager

Cork University Hospital

Celia Cronin	Clinical Governance Manager
Dr. Julie McCarthy	Clinical Director and Chair of Quality and Safety Executive Committee

Midland Regional Hospital Portlaoise

Dr. John Connaughton	Clinical Director (Chair)
James Conway	Assistant National Director, Midland Hospitals
Mary Fitzpatrick	Assistant Hospital Manager (Project Manager)
Jacqueline McNulty	Hospital Manager
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Sligo Regional Hospital

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John McElhinney	Risk Advisor
Domhnall McLoughlin	Assistant General Manager
Mr. Paul Mullaney	Clinical Director (Chair)
Karen Reynolds	Accreditation/Quality Coordinator (Project Manager)

Quality and Safety Clinical Governance Development Project Group Members

Wexford General Hospital

Anne Bursnell	Assistant Director of Nursing
Lily Byrnes	General Manager
Geraldine Crean	Chief Medical Scientist, Health and Social Care Representative
Margaret Curran	Director of Nursing and Midwifery
Mary Doyle	Administrative Support
Patricia Hackett	Services Manager
Michael Kehoe	Finance Manager
Siobhan Lynch	Clinical Risk Manager
Linda O'Leary	Deputy General Manager
Dr. Colm Quigley	Clinical Director (Chair)
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Additional Acknowledgements

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Ann Gilmartin	Quality and Patient Safety Auditor, HSE
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Joseph Reeves	Quality and Patient Safety Division
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Cornelia Stuart	Regional General Manager, Quality and Safety, HSE Dublin North East
Angela Tysall	Project Officer, National Advocacy Unit, Quality and Patient Safety Division, HSE

Appendix 3: Evaluation framework

Introduction

The evaluation framework focuses on formative evaluation⁶ (see Table 1 and 2) of the support materials developed during the initiative, at the following levels:

- National (through the national clinical programmes)
- Regional (through RDOs and the GMs for Quality and Safety)
- Local (in five hospitals and four audit hospitals)

Overview of evaluation

- Process evaluation was incorporated into the project design and some outcome evaluation was incorporated from within HSE structures.
- Summative evaluation⁷ will be through organisations own evaluation of how they are meeting theme 5 (leadership governance and management) of the national standards for safer better healthcare. This will be validated by HIQA during monitoring visits. Two QPSA (level 2) audits are also being undertaken in 2014.
- Impact evaluation⁸ is outside the scope of this framework, due to the need to: allow for clinical governance to be rooted across the system; the potential resource implications of commissioning external evaluation; and the compounding factors such as the changing governance arrangements for the HSE.

Table 1: Formative Evaluation of Process⁹

Evaluation Focus	Method	Status
1.1 Working group Steering group	– Monitoring the completion of the action plan for clinical governance development	Complete
	– Quarterly reports to the steering group (N=8 reports submitted to the Steering Group)	Complete
	– Biannual reports to the HSE CEO/DG (N=3), January 2012, October 2012, October 2013	Complete
	– Producing a risk register for the clinical governance development initiative (Risk register Feb 2012 updated and reviewed Feb 2013)	Complete
	– Annual evaluation by the working group of the work processes Jan 2012 and Feb 2013	Complete
	– Completion of terms of reference for the two year initiative	Sept 2013

⁶ Formative evaluation is designed to assess the strengths and weaknesses including pre-testing of administrative and organisational processes or materials or strategies before implementation. Messages or products are tested by a small group before they are implemented on a large scale. This type of evaluation permits necessary revisions before the full effort goes forward.

⁷ Summative evaluation: any combination measurements and judgments that permit conclusions to be drawn about impact, outcome, or benefits of a programme or method.

⁸ Impact evaluation: the most comprehensive of the evaluation types. It is desirable because it focuses on the long-range results of the programme and changes or improvements. However, impact evaluations are rarely possible because they are frequently costly and involve extended commitment. Also, the results often cannot be directly related to the effects of an activity or programme because of other (external) influences on the target audience, which occur over time.

⁹ Process evaluation: examines the procedures and tasks involved in implementing a programme. This type of evaluation also can look at the administrative and organisational aspects. Process evaluation monitors the programme to ensure feedback during the course of the programme.

Evaluation Focus	Method	Status
<p>1.2 Acute services: nominated clinical governance development sites (n= 5)</p>	<ul style="list-style-type: none"> - Learning from the participation in the clinical governance initiative (18th September 2013) - Completion of terms of reference for each hospital project - - Sites self evaluation 	<p>Complete</p> <p>Progress reported</p> <p>Complete</p>
<p>1.3 Primary Care Teams: nominated (n=2) by the National Primary Care Steering Group</p>	<p>Completion of assessment of clinical governance structures and process for quality and safety (by PCT and associated Management Team) with report to the national primary care steering group</p>	<p>In progress due to complete Q2 2014</p>
<p>1.4 Quality and Patient Safety Clinical Governance Information Leaflet</p>	<ul style="list-style-type: none"> - Principles identified by rounds of Delphi review - Endorsement of colleges and associations (x 7) - - Published Feb 2012 - Report to the steering group and HSE CEO 	<p>Complete</p>
<p>1.5 Quality and Patient Safety Clinical Governance Development: assurance check for health service providers</p>	<ul style="list-style-type: none"> - Rounds of review by WG, SG and QPS Directorate - Endorsement of colleges and associations (x 7) - - Published Feb 2012 - Report to the steering group and HSE CEO 	<p>Complete</p>
<p>1.6 Quality and Safety Prompts for Multidisciplinary Teams</p>	<p>Assessment of the use of the draft Quality and Safety Prompts document prior to publication.</p> <ul style="list-style-type: none"> - Desk top review completed by working group members - QPS Directorate - Regional GMs Quality and Safety - MDTs (n=20) - International reference panel <p>Endorsement of colleges and associations (x 11) -</p> <p>Published Nov 2012</p> <p>Report to the steering group and HSE CEO</p>	<p>Complete</p>
<p>1.7 Quality and Safety Walk-round: toolkit</p>	<p>Desk top assessment of the draft document prior to publication.</p> <ul style="list-style-type: none"> - Working group members - QPS Directorate - Regional GM Quality and Safety - Sligo Community Care Services - Tallaght Hospital - Cork University Hospital - International reference panel <p>Endorsement of colleges and associations (x 9)</p> <p>Published May 2013</p> <p>Report to the steering group and HSE SMT</p>	<p>Complete</p>

Evaluation Focus	Method	Status
1.8 Quality and Safety Committee(s): guidance and sample terms of reference	Prepared by sub group Desk top assessment of the draft document <ul style="list-style-type: none"> – Working group members – QPS Directorate – Regional GMs Quality and Safety – Tallaght Hospital – International reference panel Endorsement of colleges and associations (x 9) Published May 2013 Report to the steering group and HSE SMT	Complete
1.9 The Safety Pause: information sheet	Desk top assessment of the draft Information Sheet <ul style="list-style-type: none"> – Working group members – Emergency medicine national clinical programme – QPS Directorate – Regional GMs Quality and Safety – International reference panel Included in the DNE Toolbox talks launched March 2013 Published May 2013 Report to the steering group and HSE SMT	Complete

Table 2: Formative Evaluation of Outcome¹⁰

Evaluation Focus	Method	Status
2.1 Quality and Safety Committees	Completion of first mapping of quality and safety committee(s) to set the baseline (Report submitted to HSE Board Risk Committee (Nov 2012) and circulated to each RDOs (Dec 2012) Repeat mapping after an agreed timeframe	Complete In progress
2.2 Quality and Safety Committees outputs	Verification of the first mapping and further audit of function of quality and safety committee(s) in a sample of services across the four HSE regions by QPSA	Requested for 2014
2.3 National Standards for Safer Better Healthcare (Theme 5)	<ul style="list-style-type: none"> – Briefing sessions (included clinical governance) for all acute hospitals – Workshops for National Ambulance Service – Evaluation of the self assessment using QA+I to determine how their services meet the standards within Theme 5 of the National Standards for Safer Better Healthcare 	Complete Complete Anticipated Q2 2014
2.4 Accountability arrangements for Theme 5 of the National Standards	Audit of accountability arrangements in a sample of services across the four HSE regions by QPSA Auditors	Complete

¹⁰ Outcome evaluation: used to obtain descriptive data on a project and to document short-term results. Task-focused results are those that describe the output of the activity (e.g., the number of public inquiries received as a result of a public service announcement). Short-term results describe the immediate effects of the project on the target audience.

Evaluation Focus	Method	Status
<p>2.5 HIQA Tallaght Hospital report recommendations pertaining to clinical governance</p>	<ul style="list-style-type: none"> - Representation at the HSE HIQA Tallaght Hospital Report Implementation Group - Assessments undertaken by hospitals for the HIQA Tallaght Hospital Report Recommendations implementation (Draft one of review submitted to ND ISD Feb 2013, HSE SMT April 2013) 	<p>Complete</p> <p>Complete</p>
<p>2.6 HSE annual controls assurance process</p>	<ul style="list-style-type: none"> - Alignment and incorporation of clinical governance within the HSE annual controls assurances processes - Numbers completing and returning a Controls Assurance Statement (CEOs, GMs, CDs, DONMs, and Therapy Professional Leads) 	<p>Complete</p>
<p>2.7 Support for health service providers and staff</p>	<p>Development of materials</p> <p>Information leaflet</p> <p>Assurance check for health service providers</p> <p>Quality and safety prompts</p> <p>Quality and safety walk-rounds, and</p> <p>Quality and safety committee(s)</p> <p>Safety Pause Information Sheet</p> <p>Numbers of hits on the www.hse.ie/go/clinicalgovernance</p>	<p>Complete</p> <p>Jan 2012 - 2014 (18,741 page views)</p>
<p>2.8 Staff perceptions</p>	<ul style="list-style-type: none"> - CGDI score for five hospitals participating in the pilot in the Patient Safety Culture Survey. - Extend to all hospitals and repeat after an agreed timeframe 	<p>Complete</p> <p>Phased roll out under way</p>
<p>2.9 Incorporation of clinical governance within educational programmes and curricula.</p>	<p>Inclusion of clinical governance materials in:</p> <ul style="list-style-type: none"> - First time managers programme - Leading in challenging times programme - Future nurse leaders programme for DON/Ms - Competency 5 Development Framework for nursing and midwifery, 'developing and shaping a culture of quality and safety' <p>Meeting with regulators and the forum of health and social care regulators.</p>	<p>Complete</p> <p>Complete</p> <p>Complete</p> <p>Complete</p>
<p>2.10 National Clinical Programmes</p>	<p>Number of models of care/pathways that incorporate the principles for quality and safety and structures /processes for clinical governance</p>	<p>Ongoing – four completed checklists received (EMP, Surgery and AMP, Critical Care)</p>

Appendix 4: Resources published and national documents (figure 1)

HSE Quality and Safety Resource published during the clinical governance development initiative

- a) *National Clinical Programmes: Clinical governance checklist* (issued in October 2011)
- b) *A Quality and Patient Safety: Clinical Governance Information Leaflet* (February, 2012).
- c) *A Quality and Patient Safety: Clinical Governance Development assurance check for health service providers* (February, 2012).
- d) *Quality and safety prompts for multidisciplinary teams* (November, 2012).
- e) *Toolbox talks for QPS DNE* (March, 2013).
- f) *Quality and Safety Committee(s): Guidance and Sample Terms of Reference* (May, 2013).
- g) *Quality and Safety Walk-rounds: Toolkit* (May, 2013).
- h) *The Safety Pause: Information Sheet* (May, 2013).
- i) *Report of the Quality and Safety Clinical Governance Development Initiative: Sharing our learning* (March, 2014).

Documents and reports published during the clinical governance development initiative influencing the direction.

1. Health Information and Quality Authority (2012), *Report of the investigation into the quality and safety and governance of the care provided by the Adelaide and Meath Hospital, Dublin incorporating the National Children's Hospital (AMNCH) for patients who require acute admission*. Dublin: Health Information and Quality Authority.
2. Health Information and Quality Authority (2012), *National Standards for Safer Better Healthcare*. Dublin: Health Information and Quality Authority.
3. Department of Health (2012), *Future Health: A Strategic Framework for Reform of the Health Service 2012 – 2015*. Dublin: Department of Health.
4. Department of Health (2013), *Healthy Ireland*. Dublin: Department of Health.
5. Department of Health (2013), *The Establishment of Hospital Groups as a transition to Independent Hospital Trusts [Higgins Report]*. Dublin: Department of Health.
6. Department of Health (2013), *The Framework for Development – Securing the Future of Smaller Hospitals*. Dublin: Department of Health.
7. The HSE (Governance) Act 2013.
8. Health Service Executive (2013), *Quality Assessment and Improvement Resources*. Dublin: Health Service Executive.
9. Health Information and Quality Authority (2013), *Patient Safety Investigation report into services at University Hospital Galway (UHG) and as reflected in the care provided to Savita Halappanavar*. Dublin: Health Information and Quality Authority.
10. Department of Health (2013), *eHealth Strategy for Ireland*. Dublin: Department of Health.

Appendix 5: Quality and safety principles

It is recommended that each decision (at every level) in relation to clinical governance development be tested against the principles described in Table 1.

Table 1: Guiding principles for quality and safety

Principle	Descriptor
Patient First	Based on a partnership of care between patients, families, carers and healthcare providers in achieving safe, easily accessible, timely and high quality service across the continuum of care.
Safety	Identification and control of risks to achieve effective efficient and positive outcomes for patients and staff.
Personal responsibility	Where individuals as members of healthcare teams, patients and members of the population take personal responsibility for their own and others health needs. Where each employee has a current job-description setting out the purpose, responsibilities, accountabilities and standards required in their role.
Defined authority	The scope given to staff at each level of the organisation to carry out their responsibilities. The individual's authority to act, the resources available and the boundaries of the role are confirmed by their direct line manager.
Clear accountability	A system whereby individuals, functions or committees agree accountability to a single individual.
Leadership	Motivating people towards a common goal and driving sustainable change to ensure safe high quality delivery of clinical and social care.
Multi-disciplinary working	Work processes that respect and support the unique contribution of each individual member of a team in the provision of clinical and social care. Inter-disciplinary working focuses on the interdependence between individuals and groups in delivering services. This requires proactive collaboration between all members.
Supporting performance	Managing performance in a supportive way, in a continuous process, taking account of clinical professionalism and autonomy in the organisational setting. Supporting a director/manager in managing the service and employees thereby contributing to the capability and the capacity of the individual and organisation. Measurement of the patients experience being central in performance measurement (as set out in the National Charter, 2010).
Open culture	A culture of trust, openness, respect and caring where achievements are recognised. Open discussion of adverse events are embedded in everyday practice and communicated openly to patients. Staff willingly report adverse events and errors, so there can be a focus on learning, research and improvement, and appropriate action taken where there have been failings in the delivery of care.
Continuous quality improvement	A learning environment and system that seeks to improve the provision of services with an emphasis on maintaining quality in the future not just controlling processes. Once specific expectations and the means to measure them have been established, implementation aims at preventing future failures and involves the setting of goals, education, and the measurement of results so that the improvement is ongoing.

Appendix 6: Audit of accountability arrangements

The steering group commissioned the audit through the Quality and Patient Safety Audit service (QPSA). The purpose of the audit was to provide assurance as regards the accountability arrangements in place for quality and patient safety in a sample of four acute hospitals (voluntary and statutory). The audit was to determine:

- the current accountability arrangements for quality and patient safety established in the hospitals;
- if the accountability arrangements demonstrate that the CEO/General Manager (GM) and senior management team are fully informed of all key areas of quality and patient safety in the hospital;
- if the processes and systems in place demonstrate that quality and patient safety is a priority for the CEO/GM and senior management team.

The audit concluded that current accountability arrangements for quality and patient safety within hospitals are evolving and expanding with the development of the clinical directorates and new hospital trusts. Reasonable evidence was provided to the audit team to demonstrate that:

- the CEO/GM and senior management team in each hospital are fully informed of all key areas of quality and patient safety in their hospital
- hospitals have documented arrangements in place for monitoring quality and patient safety and
- processes and systems are in place to ensure that quality and patient safety is a priority for senior managers.

Audit recommendations

- QPSD to work with the National Director Acute Services to ensure that quality and patient safety features as a standing agenda item at hospital management team meetings. All issues relating to cost containment measures must consider the impact of quality and patient safety, and be clearly documented;
- QPSD to work with ND Acute Services in the development of national guidance to address best practice relating to hospital management structures, including terms of references for management committees and accountability practices for recording meeting minutes;
- QPSD to further disseminate and provide guidance in the use of the HSE's Quality and Safety Committee(s): Guidance and Sample Terms of Reference document published in May 2013;
- QPSD to work with the National Director Acute Services and National Director HR to ensure that job descriptions for acute services senior management clearly document that the post holder is accountable, responsible and has authority for delivering a quality service and ensuring patient safety; and
- QPSD to support and work with Finance in the Controls Assurance process to clearly define hospital CEO/GMs' accountability and responsibility for clinical outcomes.



Notes

“...Clinical governance is a process – indeed, more than a process. It’s an organising principle, a state of mind, the day-by-day, flesh-and-blood embodiment of how we practise – acting together across the traditional boundaries of our different roles and responsibilities; concentrating our will to care, the skills we have acquired, and the resources at our disposal – in order to give our patients – all of them, whatever their means, wherever they are – the best and safest care that a good health service can deliver”

“...Clinical governance is about our organisational conscience, our DNA, the things we do when we’re not being supervised; it’s about remembering whom and what we first came here for. It’s about asking ourselves, as clinicians: How would I be feeling if I were the patient in front of me? What more would I need? What more would possibly help me?” (Sir Liam Donaldson speaking on the subject ‘Making quality count in today’s NHS’ 12 December 2003).

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