National Clinical Programmes Model of Care Development Checklist Governance for Quality and Safety

1   Introduction

The Clinical Strategy and Programme Division (CSPD) and the Quality and Patient Safety Division (QPSD) have collaborated to develop this *Checklist for Quality and Safety Governance* as a guide to National Clinical Programme teams in the development of models of care.   This checklist replaces the *National Clinical Programmes Checklist for Clinical Governance* developed in August 2011.

2   What is Clinical Governance?

Clinical Governance means *corporate accountability for clinical performance*, built on the model of the CEO/GM/Area manager or equivalent working in partnership with the Clinical Director, Director of Nursing/Midwifery and service/professional leads. Clinical governance is about people receiving the right care, at the right time, from the right person in a safe, honest, open and caring environment. The term 'governance for quality and safety' is now being used in preference to the more traditional term 'clinical governance'.

Governance for quality and safety (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 (HSE, 2013).

Effective governance arrangements recognise the inter-dependencies between corporate, financial and clinical governance across the service and integrates them to deliver high quality, safe and reliable healthcare (see Appendix 1 for further guidance on governance for quality and safety).

2   What is the Checklist?

The checklist is a guide for quality and safety governance in the development of a model of care. A success of a model of care is dependent on incorporating sound quality and safety governance arrangements. The completion of this checklist will assist clinical leads in determining the structures and processes for quality and safety and can be used in conjunction with:

- Report of the Quality and Safety Clinical Governance Development Initiative: Sharing our Learning (2014) http://www.hse.ie/eng/about/Who/qualityandpatientsafety/Clinical_Governance/CG_docs/SharingOurLearningfinal.pdf
- Quality and Safety Committee(s): guidance and sample terms of reference (2013) http://www.hse.ie/eng/about/Who/qualityandpatientsafety/Clinical_Governance/CG_docs/Quality_and_Safety_Committees.html

3   Why use the Checklist?

The models of care developed by the National Clinical Programmes are central to the further development of governance for quality and safety.

When using the checklist you will be:
- embedding good governance for quality and safety across the continuum of care within the programme
- leading in the delivery of quality safe patient care
- contributing to the readiness to implement regulatory standards
- preparing for the introduction of a hospital licensing system committed to by the Government. HIQA (2011) have indicated that their standards will provide 'source material' for regulations that will underpin the licensing system.

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All models of care and pathways developed by national clinical programmes must provide clarity on governance and accountability for quality and safety to be authorised for publication by the HSE Leadership team. .

4   When to use the Checklist?

Please use the governance for quality and safety checklist to stimulate discussion within your working group and with other stakeholders such as service users. There are four possible uses of the checklist:
- to assist in developing your model of care
- to review the draft model of care
- to assist in planning how the model of care will be implemented, and
- to update your model of care (were the model of care has been previously authorised).

5   How to use the Checklist?

The checklist is a series of practical action points which guides how governance for quality and safety is incorporated into the model of care. It should be used with *The Clinical Strategy and Programmes Division, Model of Care Development Guidance Framework* (2013).

Each question should be discussed and answered at a working group meeting (this should take approximately one hour). For each section:
- A simple YES /NO answer is required
- Under 'Reference point in document' please indicate the relevant section number in your model of care
- If the answer is NO please indicate what actions to address the matter are being planned
- If the question is not relevant please indicate so in the 'Reference point in document' box
- A set of guiding principles for quality and safety are provided and will be of assistance in decision making when developing the model of care
- The final section of the checklist is provided to record the processes used for completing and reviewing the model from a good governance perspective.

A sample table of contents for a chapter/section within the model of care document is provided at Appendix 2.

6   Guiding Principles for Quality and Safety Governance Development

Ten guiding principles for quality and safety governance development, for the Irish health context, are provided with a title and descriptor. It is proposed that the principles inform each action and provide the guidance in choosing between options in the development of the model of care.

Figure 1: Guiding principles

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It is recommended that each decision (at every level) in relation to quality and safety be tested against the principles set out in Figure 1 and described in Table 1.

Table 1: Guiding principles descriptor

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 manger.
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 to 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 is 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 improvement is ongoing.

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Governance for Quality and Safety Checklist

Prompt Questions	Y	N	Ref point in document
Accountability and Governance			
1. Does the clinical lead (s) have accountability, responsibility and authority for the development of the model of care?			
2. Does the model of care take account of the HSE code of governance?			
3. Does the model of care clearly set out the clinical and managerial leadership roles for service delivery?			
4. Does the model of care set out the accountability arrangements for safe quality patient care?			
5. Does the model of care integrate governance for quality and safety within corporate governance arrangements?			
6. Does the model of care contain an organisational chart for the relevant model?			
7. Are the lines of responsibility, accountability and authority of the following personnel clearly identified and agreed in the model of care? ▪ HSE National Directors ▪ Area mangers ▪ CEO/GM (group/site specific) ▪ Clinical Directors (group /site specific) ▪ Director of Nursing/ Midwifery (group/site specific), and ▪ Members of the multidisciplinary team.			
8. Does the model of care provide for integration between: ▪ hospitals within hospital groups (HSE and voluntary)? ▪ hospital and community providers?			
9. Does the model of care outline: ▪ aims and objectives ▪ vision and core values ▪ description of services provided ▪ intended service user population ▪ location(s) or criteria for locations of service delivery, and ▪ access to services.			
10. Does the model of care contain service objectives and plans for the relevant service that take account of: ▪ existing structures and processes (e.g. committees) ▪ relevant national strategies, policies, standards and legislation ▪ current available evidence ▪ views of stakeholders (including staff, patients, public and professional/community organisations) ▪ the health and social care needs of the population served ▪ the need for ongoing staff training, development and education, and ▪ plans for the measurement of implementation.			
11. Does the model of care describe how the quality of clinical care is reported to the organisations' speciality/directorate, executive and/or board quality and safety committee?			
12. Will the model of care be publicly available and communicated to all stakeholders, in an accessible format?			

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Prompt Questions	Y	N	Ref point in document
Continuous Quality Improvement			
Quality and Performance Indicators			
13. Does the model of care identify a suite of quality of clinical care indicators which are recommended for monitoring within organisations and nationally?			
14. Does the model of care recommend the measurement of patient outcome and experience through direct patient feedback?			
15. Does the model of care recommend how the quality of clinical care is benchmarked within organisations, nationally and/or internationally?			
16. Does the model of care recommend public reporting of specific quality of clinical care indicators?			
Risk Management			

17. Does the model of care link with existing risk management processes in line with the HSE Code of Governance and national standards / legislation, HSE policy? E.g.
  ▪ risk identification, recording and reporting
  ▪ risk mitigation/risk reduction
  ▪ incident/adverse event reporting
  ▪ learning from mistakes
  ▪ applying learning from incidents to promote a culture of patient partnership
  ▪ promote a culture of openness and accountability			

18. Does the model of care provide a mechanism for any team member to raise concerns about the quality and safety of the service (for example Protected Disclosure, Trust in Care or Good Faith Reporting)?			
19. Where the model of care includes externally provided services is there assurance that the practices of corporate and quality and safety governance are clearly implemented by the provider (i.e. in service agreements were services are externally commissioned)?			
Clinical Effectiveness and Audit			
20. Does the model of care comply with relevant legislation[1], National Clinical Effectiveness Committee guidelines, standards and regulatory requirements?			
21. Have policies, procedures, protocols and guidelines (PPPG) that support the model of care been identified (in line with National Clinical Effectiveness Committee and existing HSE PPPG's (e.g. Code of Practice for Healthcare Records Management)?			
22. Does the model of care recommend a structured programme of clinical audit?			
Managing Performance			
23. Do clinical and managerial leads within services support the proposed model of care and its implementation?			
24. Does the model of care clarify for interdisciplinary team members their individual and collective responsibilities for performance standards?			
25. Does the model of care support a culture of performance management cycle?			

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[1] A listing of regulatory and compliance agencies is available on the Quality and Patient Safety Division web page at
http://www.hse.ie/eng/about/Who/qualityandpatientsafety/qpsfocuson/QPSlinks.html

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Planned Actions

Where 'NO' is answered to any of the checklist questions, please complete the plan below

Q	Action	Responsible	Date due	Status

Record of Completion Process

	Details
Name of National Clinical Programme	
Date(s) checklist considered by National Clinical Programme Working Group	
Check list completed by (please include names and titles)	
National Clinical Lead approval of completed checklist	**Signature:** **Date:**

When submitting the model of care for authorisation please include the completed checklist with the documentation

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Glossary of Terms

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), 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)	Is the systematic review and evaluation of clinical practice against reference based standards with a view to improving clinical care.
	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).
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	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).
	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 (Scally and Donaldson 1998; HIQA, 2010; adapted HSE, 2010).
	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

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Term	Descriptor
	Assurance, 2008).
	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).
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	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)

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Term	Descriptor
	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).
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	The term used to include: ■ people who use health and social care services as patients; ■ carers, parents and guardians; ■ organisations and communities that represent the interests of people who use health and social care services; ■ members of the public and communities who are potential users of health services and social care interventions. The term service user also takes account of the rich diversity of people in our society, whether defined by age, ethnicity or nationality, religion, disability, gender or sexual orientation, whom 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).
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,

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Term	Descriptor
	medical staff, government, insurers, industry, and the community (adapted from WHO, 2009).

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Appendix 1: Governance for Quality and Safety

Clinical governance is not a separate function but an integral component of governance arrangements (as illustrated in Figure 1). This is reflected in the aim for quality and safety governance development in creating an environment, where:

- staff **know** the purpose and function of clinical governance;
- staff **know** their responsibility, who they are accountable to and their level of authority;
- staff **understand** how the principles of clinical governance can be applied in their diverse practice;
- a **culture** of trust, openness, respect and caring is evident among managers, clinicians and staff;
- staff consistently demonstrate a **commitment** to the principles of clinical governance in decision making; and
- clinical governance is **embedded** within the overall governance arrangements for the HSEs statutory and voluntary health and social services in realising improved outcomes for patients.
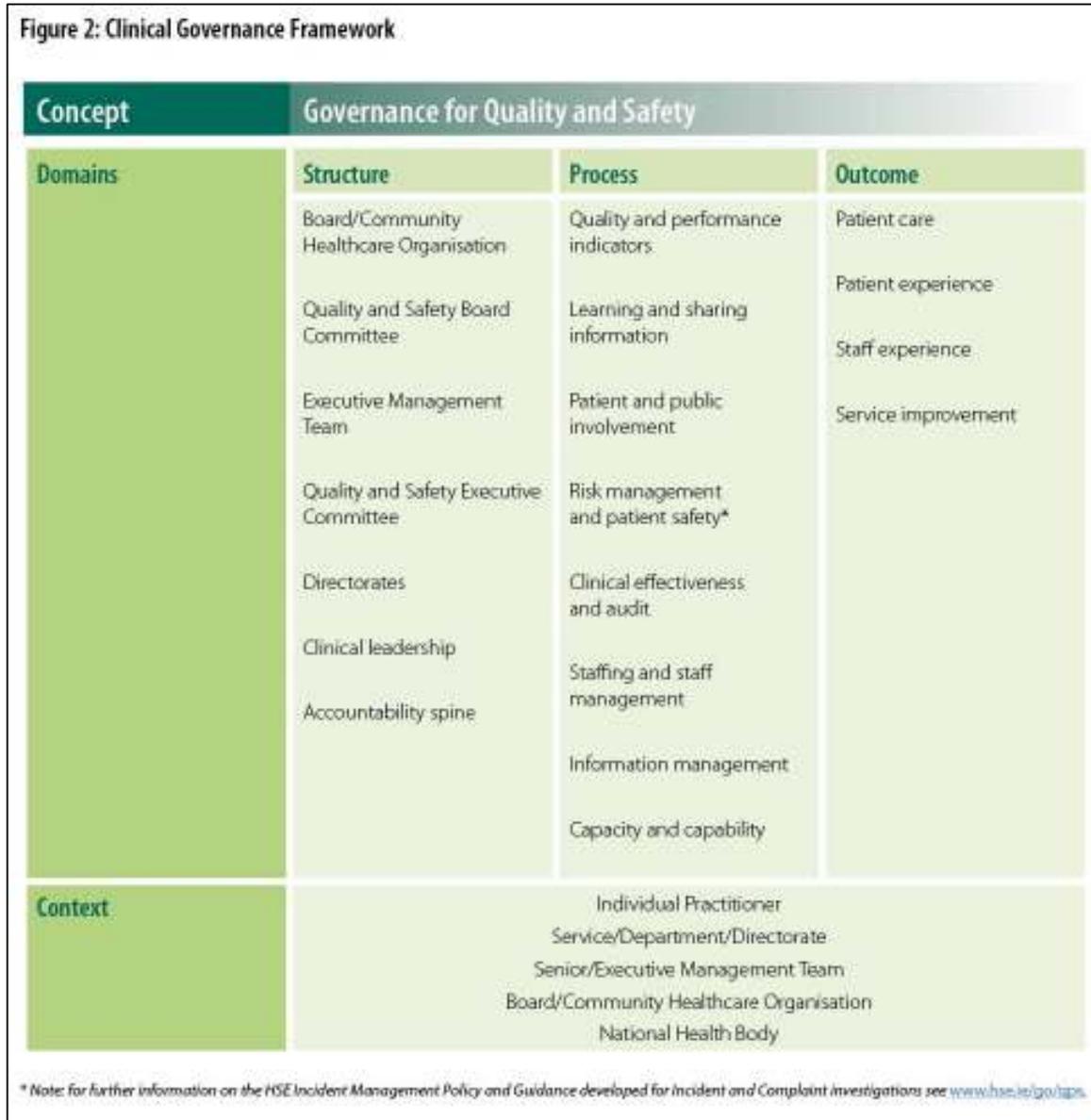
Clinical Governance is organised and delivered in accordance with the report of the Commission on Patient Safety and Quality Assurance (2008), Code of Governance of the Health Service Executive (2011), Standard 5 of the Health Information and Quality Authority National Standards for Safer Better Healthcare (2011) and Standard 8 of the Mental Health Commission Quality Framework (2007). Formalised governance arrangements ensure that everyone working in the service is aware of their responsibilities and accountability in this respect and work towards achieving this (see Figure 1).

Figure 1: Healthcare Governance
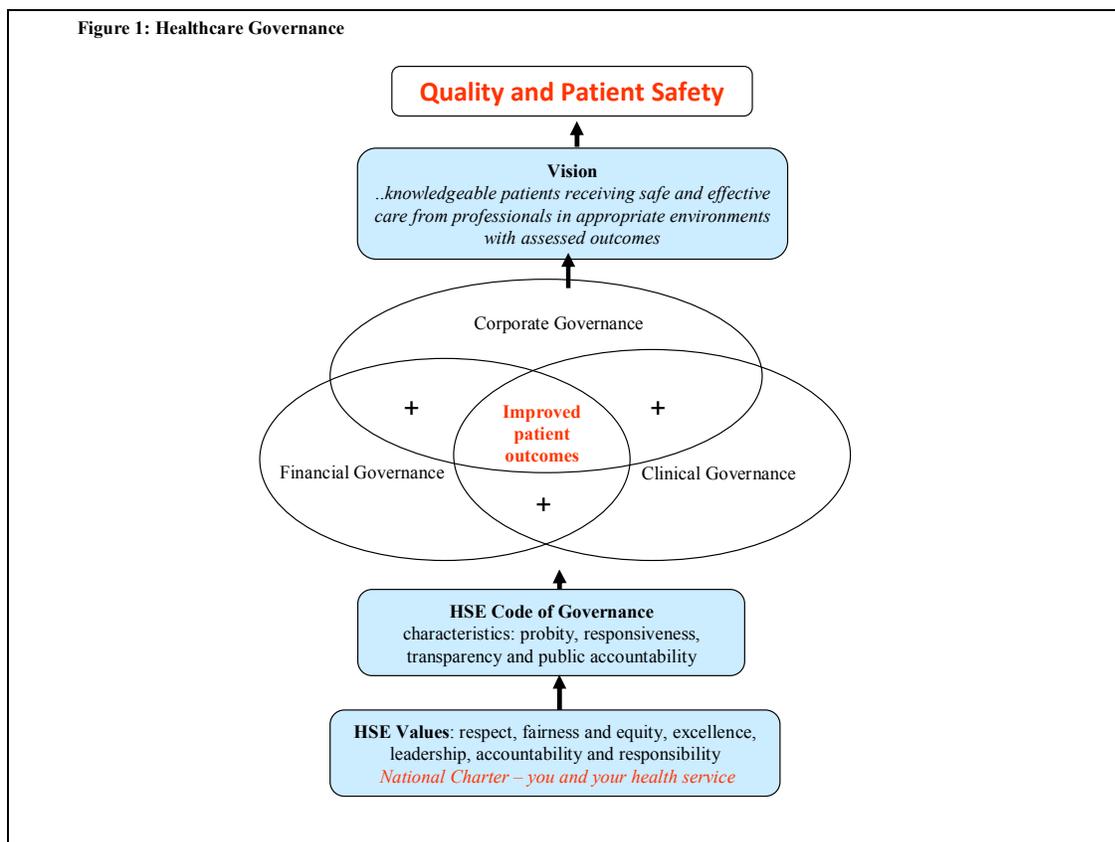
Source: HSE Working Group for Clinical Governance Development informed by the HSE Code of Governance (20011), the Standards of the Health Information and Quality Authority (2011) and the Mental Health Commission (2007).

A clinical governance framework based on Donabedian's (1966) classical approach to quality in healthcare (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

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clinical governance operates in specific contexts and at several levels (see Figure 2)..

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/tps.

Committees for quality and safety are part of the governance framework which help health services arrange lines of accountability, responsibility, authority and communications. Table 1 shows how information flows between quality and safety committees and integrates with the management structure.

Each committee has an opportunity to use formal and informal structures for seeking feedback from patient 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.

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Table 1: Committees for Quality and Safety

Management Structure	Committee Structure
Governance — **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.	**Committee** — **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). Non-executive directors provide independent scrutiny and constructive challenge of their executive colleagues and their organisations.
Operations — **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).	**Committee** — **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.
Delivery — **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.	**Committee** — **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.

In the development of the model of care it is important to appreciate the differences in the role and functions of: 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.

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Appendix 2:   Sample Table of Contents Quality and Safety Governance

This sample Table of Contents is a guide and may be amended to suit your model of care document

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