Feidhmeannacht na Seirbhíse Sláinte
Health Service Executive

An Roinn Sláinte
DEPARTMENT OF HEALTH

Tús Áite do Shábháilteacht Othar
Patient Safety First

Quality and Patient Safety

Clinical Governance Development…

…an assurance check for health service providers

We are all responsible… and how are we doing?

An initiative of the Quality and Patient Safety Directorate, Health Service Executive, February 2012 ©

Office of the Nursing & Midwifery Services Director
RCSI
Royal College of Physicians of Ireland
I.A.D.N.A.M. Founded 1904
HMI Health Management Institute of Ireland
Therapy Professions Committee
The College of Psychiatry of Ireland
Coláiste Síciatrachta na hÉireann

February 2012
ISBN 978-1-906218-50-8

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Introduction

The Quality and Patient Safety Directorate developed this document as a support for health service providers. The document is intended as a guide for clinical governance development across the continuum of care (statutory or voluntary hospital/network, mental health service, primary care services, area management etc). It is based on the relevant national standards and legislation (Health Information and Quality Authority, Mental Health Commission, Health and Safety Authority, etc). The achievement of a good clinical outcome for patients is dependent on good clinical governance arrangements (see appendix 1 and 2 for clinical governance principles and matrix).

What is clinical governance?

Clinical governance is a framework through which healthcare teams are accountable for the quality, safety and satisfaction of patients in the care they deliver. It is built on the model of the chief executive officer (CEO)/ general manager (GM) or equivalent working in partnership with the clinical director, director of nursing/midwifery and service/professional leads. A key characteristic of clincial governance is a culture and commitment to agreed service levels and quality of care to be provided.

What is the assurance check?

Every organisation should know its baseline for clinical governance. This assurance check is intended as a guide to reviewing the structures and processes used in achieving good clinical governance outcomes. The completion of the assurance check will assist CEO/GMs or equivalent (along with their senior management team/boards) in determining what clinical governance arrangements are in place. It is not intended as a reporting mechanism so there is no requirement for it to be returned centrally to the HSE or any other agency.

Why undertake the clinical governance development assurance check?

When undertaking the assurance check you will be:

- establishing the baseline for your organisation;
- embedding good clinical governance across the continuum of care;
- leading in the delivery of quality safe patient care;
- contributing to the readiness to implement regulatory standards; and
- preparing for the introduction of a licensing system committed to by the Government.

When to use the clinical governance assurance check?

There are four possible uses of the assurance check. It can be used to:

- confirm the clinical governance arrangements in place;
- develop an action plan for further development of the arrangements;
- assist in planning the implementation of new arrangements; or
- monitor progress in the further development of clinical governance arrangements.

The prompt statements can be used to stimulate discussion with the senior management team/board and other stakeholders such as service users.

How to use the clinical governance assurance check?

The series of practical statements are grouped in two parts:

- Part One: clinical governance structures
- Part Two: clinical governance processes
  - quality and performance indicators
  - learning and sharing information
  - patient and public community involvement
  - risk management and patient safety
  - clinical effectiveness and audit
  - staffing and staff management
  - information management
  - capacity and capability

Each statement should be discussed and answered at a board/senior management team meeting. In preparation for completing the check, reference should be made to the principles for clinical governance development and the matrix (see appendix 1 & 2) that underpin the clinical governance assurance check.

For each section:

- check the box for the most appropriate response from the three provided
- where a statement is checked as 'structure/process established and working effectively', the next question to be answered is:
  - 'how do we know', and
  - 'where is the evidence'

  that the structure/processes are in place and effective?
- where a statement is checked as 'structure/process under development… or no structure/process in place for this' the next step is to complete the action plan.

Part 1: Clinical Governance Structures

ACCOUNTABILITY AND CLINICAL GOVERNANCE

The board, CEO/GM or equivalent and leaders throughout the health service provider[1]…	EVIDENCE		ACTION PLAN				
	Structure in place and working effectively	What is your evidence that your structures are in place and effective	Structure under development	No structure in place	Actions	Responsible person	Due Date
1 Has documented and communicated to all staff that the CEO/general manager/ service lead has overall accountability, responsibility and authority for quality, patient safety and clinical outcomes.	☐		☐	☐			
2 Provides an organisational chart setting out the accountability arrangements and reporting relationships for all staff within the organisation.	☐		☐	☐			
3 Clearly sets out and integrates the roles of administrative and clinical staff in management/leadership posts, as they relate to service delivery.	☐		☐	☐			
4 Clearly identifies and agrees the lines of responsibility, accountability and authority of the following personnel: ■ CEO/GM/equivalent; ■ Executive Clinical Director; ■ Clinical Director(s); ■ Director of Nursing/ Midwifery; ■ Executive /Senior Management Team; ■ Service/professional leads.	☐		☐	☐			
5 Has established a joint meeting of senior hospital, primary care and community representatives to review and address how services are working together.	☐		☐	☐			

[1] *Statutory/voluntary hospital/network or primary care team, or mental health service or community care service.*

Part 1: Accountability and Clinical Governance Structures

ACCOUNTABILITY AND CLINICAL GOVERNANCE

The board, CEO/GM or equivalent and leaders throughout the health service provider…	EVIDENCE		ACTION PLAN				
	Structure in place and working effectively	What is your evidence that your structures are in place and effective	Structure under development	No structure in place	Actions	Responsible person	Due Date
6 Has established a multidisciplinary committee to review and address quality and safety issues and incidents e.g. clinical governance and/or quality, safety and risk management (QRSM) committee(s).	☐		☐	☐			
7 Provides clear reporting lines and escalation policies between committees on quality safety and risk management (QRSM) issues (where multiple committees exist).	☐		☐	☐			
8 Ensures an annual report (which is publicaly available and communicated to all stakeholders) is produced on: ■ service quality improvements completed; ■ evidence of performance indicators. showing improvement; ■ learning from incidents, complaints and risk management; ■ patient experience / service users views; and ■ practice/clinical audits undertaken.	☐		☐	☐			
9 Makes quality and safety a criterion against which financial or headcount resource decisions are made.	☐		☐	☐			

CONTINUOUS QUALITY IMPROVEMENT

The board, CEO/GM or equivalent and leaders throughout the health service provider…	EVIDENCE		ACTION PLAN				
	Process in place and working effectively	What is your evidence that your processes are in place and effective	Process under development	No process in place	Action	Responsible person	Due Date
Quality and Performance Indicators							
10 Has a suite of key performance/quality indicators in line with national priorities and standards.	☐		☐	☐			
11 Sets agenda items on management team/board meetings to monitor and review the indicators at defined intervals.	☐		☐	☐			
12 Benchmarks the health service providers performance locally, nationally and/or internationally.	☐		☐	☐			
13 Publicly reports the outcomes of the key performance / quality indicators.	☐		☐	☐			
Learning and Sharing Information							
14 Ensures that information systems are in place to support quality safety and risk management in identifying, monitoring and responding to risk and important aspects of care.	☐		☐	☐			
15 Has an effective flow of information on safety and quality matters to and from the board / executive/senior management team.	☐		☐	☐			
16 Has a procedure for responding to alerts from external bodies (for example from HIQA, IMB) that is documented and communicated to all staff.	☐		☐	☐			

Part 2: Clinical Governance Processes

CONTINUOUS QUALITY IMPROVEMENT

The board, CEO/GM or equivalent and leaders throughout the health service provider…	EVIDENCE		ACTION PLAN				
	Process in place and working effectively	What is your evidence that your processes are in place and effective	Process under development	No process in place	Action	Responsible person	Due Date
17 Has a process for systematic monitoring of, and learning from, safety incidents at local, regional and national levels.	☐		☐	☐			
Patient and Public Community Involvement							
18 Regularly seeks feedback on patient experience and integrates this into quality and safety improvement activities.	☐		☐	☐			
19 Reviews the response time and procedure for complaints from patients and the public.	☐		☐	☐			
20 Supports an open consistent approach to communicating with patients when things go wrong.	☐		☐	☐			
Risk Management and Patient Safety							
21 Has risk management processes in line with the HSE Code of Governance, national standards and policy e.g. ■ risk identification recording and reporting ■ risk mitigation / risk reduction ■ incident / adverse event reporting ■ incident investigation ■ openness and accountability.	☐		☐	☐			
22 Supports any member of the team who wishes to raise concerns about the quality and safety of the service.	☐		☐	☐			

CONTINUOUS QUALITY IMPROVEMENT

The board, CEO/GM or equivalent and leaders throughout the health service provider…	EVIDENCE		ACTION PLAN				
	Process in place and working effectively	What is your evidence that your processes are in place and effective	Process under development	No process in place	Action	Responsible person	Due Date
23 Where externally provided services are commissioned, the practice of corporate and clinical governance, are clearly implemented by the provider (in the service or grant aid agreement)	☐		☐	☐			
Clinical Effectiveness and Audit							
24 Ensures that services comply with relevant legislation[2] and regulatory requirements.	☐		☐	☐			
25 Has implemented and agreed national standards, guidelines and other policies, procedures, protocols for quality safe patient care (in line with the National Clinical Effectiveness Committee and other relevant national committees).	☐		☐	☐			
26 Has a structured programme of clinical audit that is monitored for appropriateness and effectiveness on an annual basis (including participation in national audits).	☐		☐	☐			
Staffing and Staff Management							
27 Has robust recruitment and selection procedures including professional credentialing and Garda vetting (where appropriate).	☐		☐	☐			

[2] *A compliance registry is currently under development by the Quality and Patient Safety Directorate, for further information please contact Ms. Ruth Maher email ruth.maher@hse.ie*

Part 2: Clinical Governance Processes

CONTINUOUS QUALITY IMPROVEMENT

The board, CEO/GM and leaders throughout the health service provider…	EVIDENCE		ACTION PLAN				
	Process in place and working effectively	Where have you gained evidence that your processes are in place and effective	Process under development	No process in place	Action	Responsible person	Due Date
28 Has a requirement that all new staff complete induction for their role and maintain their competence.	☐		☐	☐			
29 Clearly identifies and communicates the arrangements for evaluating individual performance including managing under performance.	☐		☐	☐			
30 Clearly identifies and communicates the arrangements for evaluating team performance including managing under performance.	☐		☐	☐			
31 Engages with staff around how clinical governance can influence their everyday behaviour and surveys the patient safety culture across the organisation.	☐		☐	☐			
Information Management							
32 Has a system to uniquely identify each patient.	☐		☐	☐			
33 Provides information systems, whether electronic or paper-based, which are integrated and interface with other systems to support high quality safe healthcare.	☐		☐	☐			
34 Ensures all information including personal information, is handled securely, efficiently, effectively and in-line with legislation.	☐		☐	☐			

Part 2: Clinical Governance Processes

CONTINUOUS QUALITY IMPROVEMENT							
	EVIDENCE		ACTION PLAN				
The board, CEO/GM and leaders throughout the health service provider…	Process in place and working effectively	Where have you gained evidence that your processes are in place and effective	Process under development	No process in place	Action	Responsible person	Due Date
Capacity and Capability							
35 Has developed and implemented plans for ongoing training, development and education on quality, safety, and risk management.							
36 Provides human, infrastructural and financial resources to implement effective quality, safety and risk management systems etc.							

Record of Completion Process

DETAILS	
Name of Health Service Provider	
Date(s) clinical governance arrangements considered by Executive/Senior Management Team	
Document completed by (please include names)	
CEO/GM or equivalent approval of document	**Signature:** **Date:**

Appendix 1: Principles for clinical governance development

To assist health services providers a suite of ten principles for good clinical governance, in the Irish health context, have been developed with a title and descriptor. The principles developed by the interdisciplinary working group were reviewed for clarity and usefulness by health managers, clinical directors, senior nurses and midwives, health and social care professionals and patient groups. The principles should inform all actions and provide the guide in choosing between options, when making decisions.

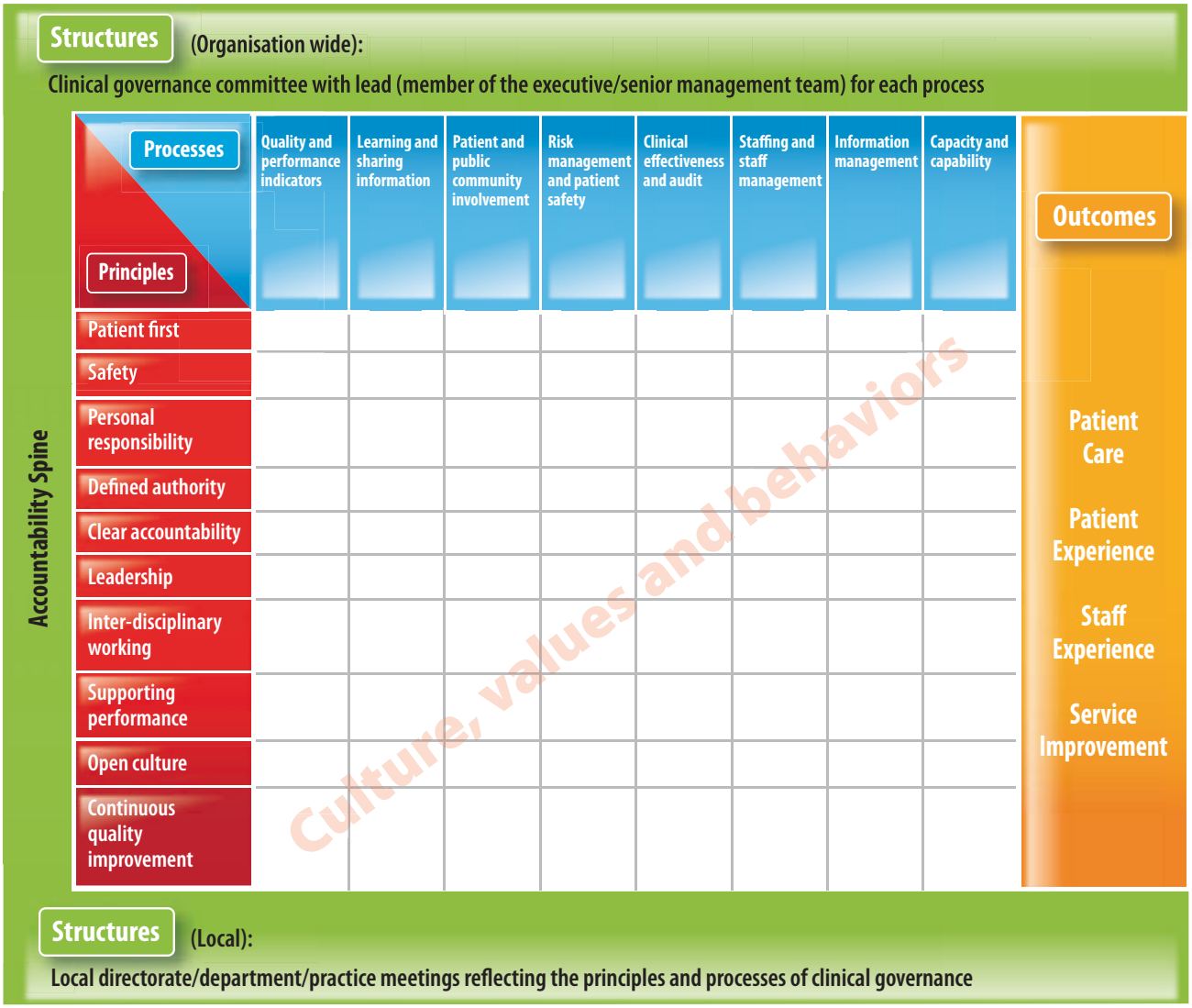
Figure 1: Guiding principles for clinical governance

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, whether members of healthcare teams, patients or members of the public, 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.
Inter-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	In a continuous process, managing performance in a supportive way, 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 and staff 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, 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 and 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 2: Clinical governance development matrix

The matrix is designed to assist discussions on clinical governance. It is based on the principles, required structures, process and anticipated outcomes of good clinical governance. The matrix is surrounded by the structures. Accross the top are the core processes (in blue) required to drive effective clinical governance. On the left side are the guiding principles (in red). On the right are the patient outcomes (in yellow) in terms of care, experience and service improvement. For each area discuss whether the principle is reflected in how the clinical governance structures and processes operate. It is not intended that you insert text in each cell of the matrix as this is a guide to discussion.



Source: Adapted from *Towards excellence in clinical governance: a framework for integrated quality, safety and risk management across HSE service providers* (HSE, 2009); *Achieving excellence in clinical governance: towards a culture of accountability* (HSE, 2010); *Better quality better healthcare* (Victorian Government Department of Health Services, 2005); *The Magic Matrix of Clinical Governance* (Lewis et al, 2002).

Glossary[3]

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.
Adverse event	An undesired patient outcome that may or may not be the result of an error.
Assurance	Confidence, based on sufficient evidence, that internal controls are in place, operating effectively and objectives are being achieved.
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.
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.
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.
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 lead quality improvement process that seeks to improve patient care and outcomes through systematic review of care against explicit criteria and acting to improve care, when standards are not met. The process involves the selection of aspects of the structure, processes and outcomes of care, which are then systematically evaluated against explicit criteria. If required improvements should be implemented at an individual, team or organisation level and then the care re-evaluated to confirm improvements.
Clinical governance	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.
	Is an umbrella term which encompasses a range of activities in which health care 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.
	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.
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.
Controls assurance	An 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.
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 in enhancing openness and transparency. To this end, the HSE has adopted a corporate governance regime in accordance with best practice.
External assurance	Assurances provided by reviewers, auditors and inspectors from outside the organisation, such as External Audit, HIQA, Mental Health Commission or Medical Colleges.
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.
Gap in assurance	Failure to gain sufficient evidence that policies, procedures, practices or organisational structures on which reliance is placed are operating effectively.

[3] *Descriptions adapted from the documents in the Bibliography.*

Guideline	A principle or criterion that guides or directs action.
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).
Independent Assurance	Assurances provided by (a) reviewers external to the organisation and (b) internal reviewers working to national standards, such as Internal Audit.
Internal Assurance	Assurances provided by reviewers, auditors and inspectors who are part of the organisation, such as Clinical Audit or management peer review.
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.
Leadership	Is getting people to do things, using intrinsic motivation, i.e. internal motivators such as knowing that the organisation (in the person of your manager) cares about you as a person; a sense of ownership of the work (whether individual or collective); of pride in something well done; of satisfaction in a challenge overcome; of meaning to what one does.
	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.
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.
Patient	A person who is a recipient of healthcare.
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.
Policy	Is a written statement that clearly indicates the position and values of the organisation on a given subject.
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.
Protocol	Operational instructions which regulate and direct activity.
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.
Risk management	Coordinated activities to direct and control an organisation with regards to risk.
	The culture, processes and structures that are directed towards realising potential opportunities whilst managing adverse effects.
Service users	Is 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, 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.
Stakeholders	A person, group, organisation, or system who affects or can be affected by an organisation's actions. Heath service provider's stakeholders, for example, include its patients, employees, medical staff, government, insurers, industry, and the community.

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