Health Information and Quality Authority

An tÚdarás Um Fhaisnéis agus Cáilíocht Sláinte

Monitoring and Regulation of Healthcare Services

Guide to the Assessment Judgment Framework for monitoring healthcare services against the *National Standards for Safer Better Healthcare*

April 2022

Safer Better Care

About the Health Information and Quality Authority

The Health Information and Quality Authority (HIQA) is an independent statutory authority established to promote safety and quality in the provision of health and social care services for the benefit of the health and welfare of the public.

HIQA's mandate to date extends across a wide range of public, private and voluntary sector services. Reporting to the Minister for Health and engaging with the Minister for Children, Equality, Disability, Integration and Youth, HIQA has responsibility for the following:

- **Setting standards for health and social care services** — Developing person-centred standards and guidance, based on evidence and international best practice, for health and social care services in Ireland.
- **Regulating social care services** — The Chief Inspector within HIQA is responsible for registering and inspecting residential services for older people and people with a disability, and children's special care units.
- **Regulating health services —** Regulating medical exposure to ionising radiation.
- **Monitoring services** — Monitoring the safety and quality of health services and children's social services, and investigating as necessary serious concerns about the health and welfare of people who use these services.
- **Health technology assessment** — Evaluating the clinical and cost-effectiveness of health programmes, policies, medicines, medical equipment, diagnostic and surgical techniques, health promotion and protection activities, and providing advice to enable the best use of resources and the best outcomes for people who use our health service.
- **Health information** — Advising on the efficient and secure collection and sharing of health information, setting standards, evaluating information resources and publishing information on the delivery and performance of Ireland's health and social care services.
- **National Care Experience Programme** — Carrying out national service-user experience surveys across a range of health services, in conjunction with the Department of Health and the HSE.

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1. Introduction to the guidance

The Health Information and Quality Authority (HIQA) is responsible for assessing compliance with the *National Standards for Safer Better Healthcare* in healthcare services. HIQA has published this guidance to support compliance with the standards.

In order to consistently carry out its functions as required by the Health Act 2007 (as amended), HIQA has adopted what it terms a common 'Authority Monitoring Approach' (AMA). All HIQA inspection staff adhere to this approach and to any associated procedures and protocols.

The aim of HIQA's Authority Monitoring Approach is to ensure:

- a consistent and timely assessment when monitoring compliance with national standards
- a responsive and consistent approach to the assessment of risk within healthcare services
- a focus on improving the service being inspected through the application of the inspection process.

This monitoring approach gives HIQA inspectors a range of steps, approaches and tools to assist them in carrying out their functions and does not replace their professional judgment.

When HIQA inspectors conduct an inspection, they check to confirm that each healthcare provider being inspected has put in place different measures which would indicate compliance with the *National Standards for Safer Better Healthcare*. In order to do this fairly and consistently, inspectors use what is known as an assessment-judgment framework, as a tool to aid each inspection. An assessment-judgement framework is used to ensure the assessment of compliance against the national standards is timely, consistent and responsive to any risks identified within the services.

This guidance document aims to explain how HIQA might apply its assessment-judgment framework in assessing the *National Standards for Safer Better Healthcare*. This document has been published to provide transparency for service providers and the public on how HIQA assesses and makes judgments about compliance and non-compliance against national standards. This guidance should be used as a tool for providers, particularly in preparing services for inspection. Given the broad scope and nature of these national standards, HIQA will use this assessment-judgement framework to assess compliance with a number of standards on each inspection, as explained in section 2 of this document.

A glossary of key terms used throughout this guidance document is available for use by the reader in Appendix 6.

1.1 Scope of this guidance

The *National Standards for Safer Better Healthcare*, published by HIQA in 2012, are relevant to all publicly-funded healthcare services in Ireland, including inpatient, outpatient and community healthcare services.

The scope of this guidance refers to what compliance with the national standards looks like in healthcare services provided by publicly-funded acute hospitals and rehabilitation and community inpatient care services.

HIQA inspection staff will apply the assessment-judgment framework in conjunction with the Health Act 2007 (as amended) and the following standards published by HIQA in recent years:

- *National Standards for the prevention and control of healthcare-associated infections in acute healthcare services*
- *National Standards for infection prevention and control in community services*
- *National Standards for Safer Better Maternity Services*
- *National Standards for the Conduct of Reviews of Patient Safety Incidents.*[¥]

1.2 Purpose of the guidance

This guidance document should be used by service providers to self-assess the compliance of their own services against the *National Standards for Safer Better Healthcare*. It also supports HIQA inspectors to gather information and evidence when they are monitoring a healthcare service, and when assessing and making judgments on compliance.

The guidance aims to guide inspectors on reviewing each standard and sets out the lines of enquiry (the questions) to be explored by inspectors in order to assess compliance with the standards. The guidance gives greater detail on how inspectors may assess compliance and what they may review during HIQA fieldwork planning and inspection.

Furthermore, this guidance facilitates a consistent approach to conducting inspections by:

- providing direction to providers on what evidence of compliance with national standards looks like
- supporting inspectors to make consistent judgments of what compliance looks like against national standards.

[¥] These standards were jointly developed and published by HIQA and the Mental Health Commission.

HIQA inspects against two overarching elements of care which it terms the 'dimensions' of:

- Capacity and capability
- Quality and safety.

Capacity and capability checks the provider's ability to sustainably deliver the service, and be aware of what is going on in the service. Quality and safety reviews the day-to-day experiences of people receiving services and is a check on whether this a caring and safe service. In the national standards, a coloured chart (see Figure 1) shows both dimensions. In each dimension are 'themes', or aspects of care, such as 'Governance, Leadership and Management'. In this guidance, we have explained in broad terms, under each theme, what providers have to demonstrate in order to show they are complying with the standards.

Figure 1. The themes of the national standards

Dimension of Quality and safety

Dimension of Capacity and capability

Throughout this guidance, the examples given under each theme — in the sections entitled *What compliance with this standard looks like* — of services striving for compliance are not intended to be an exhaustive list of how to comply with the national standards.

HIQA recognises that given the wide range of services and complexity of acute care, service providers can use these and any other appropriate measures to ensure compliance with the relevant standard for the benefit of the people who use services.

2. Assessing compliance

2.1 Inspection

HIQA carries out inspections in order to assess compliance with the national standards. Before an inspection, HIQA reviews information on the service to inform what needs to be examined during the inspection. Throughout inspections, the views of people who use the service are sought.

As part of this monitoring programme and in order to make judgments about compliance, HIQA may:

- communicate with people who use the service, whenever it is appropriate, to find out about their views and experience of the service
- talk with staff and management to find out how they plan and deliver care and services; these conversations may concentrate on:
  - the structures and processes in place
  - how care is delivered
  - other aspects of their role, such as their experience and training
- observe practice to see if it reflects what is outlined in relevant documents, such as national guidelines and local policies
- review documents to see if appropriate records are being kept which reflect practice and what people have stated.

While an inspection can in some cases be disruptive, changes to the normal routine of staff and of people using services are not expected to happen. Every effort will be made by HIQA inspectors to minimise any potential disruption to staff and people using services.

At the beginning of the inspection, HIQA inspectors will introduce themselves and present their official 'certificate of appointment / authorisation and personal identification' to the person they meet and outline the purpose and duration of the inspection to the service or hospital manager.

Staff should always ask to see this identification document (which is in the style of a passport and is passport sized) before letting the HIQA inspector enter the premises. Inspectors will always carry this identification document with them while on inspection.

While inspectors have powers of entry and inspection, these will be exercised respectfully and with an awareness of people's dignity and rights at all times. Inspectors' observations will be unobtrusive, discreet, and will respect the services being provided.

Further details on the approach to inspection is available in the HIQA publication; *HIQA's monitoring approach against the National Standards for Safer Better Healthcare.*

2.2 How will inspections be carried out?

HIQA uses a risk-based approach to monitoring compliance against the national standards. This means that monitoring activities are prioritised and that resources relating to inspection are organised based on an assessment of regulatory risk.

This risk-based approach informs how frequently HIQA will inspect any service, and the focus and type of inspection carried out. In addition, this approach ensures that HIQA can tailor its monitoring activities so they are responsive and proportionate to regulatory risk.

HIQA will carry out one or more of the following types of inspection:

1. Monitoring – announced or unannounced
2. Targeted – for risk
3. Thematic

Announced inspection: An announced inspection will generally take place **once in every three years**. It can be expected to take place over one to two days, dependent on the size of the healthcare facility, types of services provided and inspection findings on the day.

An announced inspection will involve monitoring compliance against a selection of the *National Standards for Safer Better Healthcare* through what is known as a core assessment. Details of what a core assessment will involve is contained in the companion document to this guide; *HIQA's monitoring approach against the National Standards for Safer Better Healthcare.* While the approach to the core assessment may evolve over time, any change to that methodology will be underpinned by HIQA's assessment-judgment framework which – as outlined in this document – will remain unchanged. Furthermore, any future change to the Core Assessment will be outlined in updated published documentation as changes occur.

Unannounced inspection: This type of inspection will also generally take place **once in every three years**, or more often if determined necessary by HIQA. With unannounced inspections, healthcare service managers will not be notified by HIQA in advance of the inspection. The inspectors will turn up at the healthcare facility to carry out the inspection. This inspection will usually be of shorter duration and take place over one day, lasting for six to eight hours. The purpose of each unannounced inspection will be to follow-up and review progress made in relation to any areas

that were not in compliance with national standards during the announced inspection. It also allows HIQA inspectors to evaluate progress with the implementation of compliance plans following announced inspections.

Targeted inspection in response to regulatory risk:* If HIQA becomes aware of specific risk within a service, a targeted inspection may be carried out in response. These inspections are in addition to the two routine-type inspections described above.

As they will be responsive to risk, these inspections will be individually designed to align to the risk issue to be investigated. This will be done by applying HIQA's assessment-judgment framework in selecting one or more of any of the 45 national standards, and applying relevant lines of enquiry as required by the nature of the risk issue to be explored on inspection. These type of inspections will generally be unannounced. However they may also be short-notice announced inspections, where 48 hours' notice will typically be given in order to facilitate meeting with key hospital or service personnel.

2.3 Judgments on compliance with standards

Once inspectors have gathered information, they make a judgment about the level of compliance against each standard reviewed. Inspectors will judge whether the provider has been found to be compliant, substantially compliant, partially compliant or non-compliant with the standards as outlined in the assessment-judgment framework.

The level to which services have complied with the standards has an impact on outcomes for people using the service. In order to improve outcomes for people using the service, compliance with the standards are risk-rated (see Appendix 1 for HIQA's Risk Rating Matrix).

* Regulatory risk is about identifying and evaluating risk caused by non-compliance with legislation, regulations, and national standards by hospital/healthcare service providers.

The compliance descriptors are defined as follows:

Compliant: A judgment of compliant means that the service is in compliance with the relevant national standard.
Substantially compliant: A judgment of substantially compliant means that the service meets most of the requirements of the relevant national standard, but some action is required to be fully compliant.
Partially compliant: A judgment of partially compliant means that the service meets some of the requirements of the relevant national standard while other requirements are not met. These deficiencies, while not currently presenting significant risks, may present moderate risks which could lead to significant risks for people using the service over time if not addressed.
Non-compliant: A judgment of non-compliant means that one or more findings indicate that the relevant national standard is not being met, and that this deficiency is such that it represents a significant risk to people using the service.

When a judgment of partial compliance or non-compliance is made, inspectors will assess the risk of the non-compliance to the people using the service. Risk-rating will include determination of the severity of impact on people using the service and the likelihood of occurrence or reoccurrence.

A judgment of partial compliance is where non-compliance with some requirements of the national standards presents moderate risks to the safety, health and welfare of people using the service but these deficiencies could lead to significant risks for people using the service over time if not addressed. The provider must take action within a reasonable time frame to come into compliance.

A judgment of non-compliance means the provider has not complied with a standard and that considerable action is required to come into compliance. It also means the non-compliance and or continued non-compliance poses a significant risk to the safety, health and welfare of people using the service.

If an inspector identifies a specific issue that may present an immediate and or potential serious risk to the health or welfare of people using the service, then, in line with HIQA policy, these risks will be assessed using HIQA's Risk Rating Matrix by the lead inspector and their regional manager. These risks will be escalated to the relevant manager during the inspection fieldwork and or following completion of the

inspection fieldwork to the General Manager/Chief Executive Officer/Clinical Director/Master, or hospital group Chief Executive Officer if deemed appropriate.

In addition, continued non-compliance resulting from a failure by a service to put appropriate measures in place to address the areas of risk previously identified by HIQA inspectors may result in escalation to the relevant accountable person in line with HIQA policy.

2.4 Reporting the findings of inspections

The inspector will give feedback to the service or hospital manager or their delegate on the preliminary[†] findings from the inspection on completion of the on-site inspection.

The inspector will then write up an inspection report to summarise the findings. In order to summarise these findings, the standards are grouped in the inspection report under the two overarching elements of care which HIQA terms the 'dimensions' of:

- Capacity and capability
- Quality and safety.

Capacity and capability of the provider to deliver a safe quality service

This section of the inspection report describes the governance, leadership and management arrangements in place in the service. It considers how effective they are in ensuring that a good quality and safe service is being sustainably provided. It outlines how people who work in the service are recruited and supported through education and training, and whether there are appropriate systems in place to underpin the safe delivery and oversight of the service.

Quality and safety of the service

This section of the inspection report describes the experiences, care and support people receive on a day-to-day basis. It is a check on whether this is a good quality and caring service which ensures people are safe. It includes information about the environment where care is provided for people.

Both the *capacity and capability* and *quality and safety* dimensions described here are intrinsically linked.

[†] Preliminary feedback does not include a full evaluation of the findings of an inspection.

2.5 Applying the assessment-judgment framework to other types of monitoring work HIQA may conduct in healthcare settings

In addition to the types of inspection described in Section 2.2 of this guidance document, HIQA may also conduct other types of monitoring activities in healthcare settings, in accordance with our legal remit under the Health Act 2007 (as amended).

Specifically HIQA may seek to conduct a more detailed evaluation of a services approach to ensuring compliance with the standards under Section 8 of the Act through, for example, the conduct of a regulatory governance review. Such reviews may take a number of months to conclude. Furthermore, and should the necessary threshold of concern related to the potential health and welfare of patients be met, HIQA may also initiate a statutory investigation into services in accordance with Section 9 of the Health Act 2007 (as amended).

Whenever HIQA initiates such review or investigation, a specific guidance document outlining the terms of reference for the review or investigation will be published. Within such a document, details of the national standards to be assessed will also be included. The approach to monitoring against the national standards selected will again relate back to HIQA's assessment-judgment framework which is explained within this document.

3. Structure of the guidance on each standard

In this guidance, the national standards are listed under each dimension of care, either Capacity and capability or Quality and safety, and associated theme. The standard associated with each of the themes is then presented.

Each standard is presented as follows:

- a numbered standard statement taken from the national standards
- the scope of that particular standard
- a list of other related national standards
- statements illustrating what compliance with the standard looks like
- examples of the information and evidence HIQA may review to assess compliance with that individual standard.

Scope of standard

This section outlines the key areas included in the scope of the standard and also lists related national standards that may overlap with this standard or are related to this standard.

What compliance with this standard looks like

This part of the guidance outlines examples of what is expected of a service that is striving for compliance with the relevant standard. Details on 'what compliance with this standard looks like' are described and aligned with the lines of enquiry (questions to be asked to assist with checking compliance) as set out in the assessment-judgment framework.

HIQA recognises that service providers may be seeking out other ways to improve the quality of their services and outcomes for people using the service. However, compliance with the standards is the overall responsibility of the service provider. It is expected that healthcare services continually review and self-assess their services against the national standards and put measures in place to comply with the standards.

Examples of the information and evidence that may be reviewed and how this may be done

This part of the guidance gives examples of information and evidence that inspectors may review to assist with assessing compliance. The examples are listed under the headings of:

- observation
- communication
- documentation.

These examples will support HIQA inspectors to plan an inspection, gather information before, during and after an inspection and make judgments about compliance. They also inform providers of what to expect during the inspection and help them to ensure they have all the required information to hand.

The types of information reviewed will be determined by the service's history of compliance, specific areas of risk identified and the outcome of inspection planning.

4. Guidance

4.1 Guidance on the assessment-judgment framework for the *National Standards for Safer Better Healthcare* related to capacity and capability

This section describes the themes and standards relevant to the dimension of capacity and capability. They outline standards related to the leadership governance and management of healthcare services and how effective they are in ensuring that high-quality and safe service is being provided. It also includes the standards related to workforce, use of resources and use of information.

Theme 5: Leadership, governance and management

This section describes the standards associated with the leadership, governance and management arrangements of a healthcare service. Good leadership, governance and management, in keeping with the size and complexity of the services provided, are fundamental starting points for sustainably delivering safe, effective person-centred care and support.

A key function of effective governance is specifying the accountability and reporting structures in the service. A service that is well governed is clear about what it does, how it does it, and is accountable to its stakeholders and other interested parties. It is clear about who is in charge and who has overall executive accountability for the quality and safety of the services delivered. In addition, formalised systems of governance ensure that there are clear lines of accountability at individual, team and service levels. Therefore, healthcare professionals, managerial staff and everyone working in the service are aware of their responsibilities and accountability.

Effective governance in healthcare integrates corporate and clinical governance to achieve safe, high-quality care for people using the service.

Healthcare services with good governance structures promote transparency and responsiveness by accurately describing, in a published statement of purpose, its aims and objectives, and the services provided. This information includes how and where they are provided. The statement of purpose is accessible through different media; for example, a service's website or in leaflets in different languages and accessible formats where necessary.

Service providers need to set a clear direction for delivering high-quality, safe and reliable healthcare through its objectives and plans. This includes setting out their short, medium and long-term goals, addressing the competing demands on the service and taking the needs of the population into consideration. The service

provider's governance systems assures itself that the delivery of services is only within the scope of what it can do safely, effectively and sustainably.

Services should have effective management arrangements in place to ensure they have the capacity and capability to effectively support and promote the delivery of high-quality, safe and reliable healthcare services. Effective management arrangements take account of the input and expertise of clinical staff in decision-making.

Managing delivery of healthcare services requires an understanding of the numerous and complex factors that affect the increases and decreases in demand for healthcare in the short and long term. Services providers should have the necessary arrangements in place to manage increases and decreases in service demand, service change and transition to ensure the delivery of safe and reliable care. In addition, service providers should have effective management arrangements in place to respond to major emergencies[‡] with the goal of being better able to respond to such emergencies.

Achieving safe, high-quality, care depends on the culture of a service. Leaders at all levels have an important role to play in strengthening and encouraging their service's culture. A service with a culture of quality and safety continually seeks to improve outcomes and experiences of people who use the service. It also aims to minimise harm by placing the safety of people who use the service at the centre of the service's agenda.

Leaders and organisational arrangements support all members of the workforce to exercise their personal and professional responsibility for the quality and safety of the services they are delivering. The service promotes a culture of openness and accountability and facilitates members of the workforce to raise issues of concern or make protected disclosures about the quality and safety of services in line with legislation.

A well-run service monitors its performance to ensure the consistency, reliability and quality of the care, treatment and support it provides, with minimal variation in provision across the system. Service providers systematically monitor the care and service they provide in order to identify and act on opportunities for improvement. Improvements should be planned, implemented, monitored and evaluated through an organised patient-safety improvement programme that is tailored to the size and scope of the service.

[‡] A major emergency is any event which usually, with little or no warning, causes or threatens death or injury, serious disruption of essential service or damage to property, the environment or infrastructure beyond the normal capabilities of the Health Service Executive (HSE) and other emergency services either locally, regionally or nationally. It usually requires the activation of specific additional procedures and the mobilisation of additional resources to ensure an effective, coordinated response.

The quality and safety of services that are sourced externally should be monitored through formalised agreements. Service providers also regularly review how contracted services meet their objectives and the developing needs of the service. Quality and safety is also assured by compliance with legislation and acting on standards, guidance and recommendations from relevant statutory bodies. In addition, service providers review, on an ongoing basis, any standards or alerts issued by regulatory bodies to ensure that the service complies with any relevant licensing, registration or regulatory requirements.

Dimension: Capacity and capability

Theme 5: Leadership, governance and management

Standard 5.1

Service providers have clear accountability arrangements to achieve the delivery of highquality, safe and reliable healthcare.

Scope of this standard

The scope of this national standard includes: an identified individual with overall accountability for the service; the role of that individual within the service's governance system; delegation of accountability and responsibility where services are located on more than one site.

See also national standards 5.2 and 5.5 to 5.11.

What compliance with this standard may look like

1. There is an identified individual whose role includes having overall executive accountability, responsibility and authority for the delivery of high-quality, safe and reliable services.
2. The role of this identified individual includes leading a governance system that clearly specifies, delegates and integrates corporate and clinical governance.
3. The role of this identified individual includes formally reporting on the quality and safety of the services through its relevant governance structures. This includes, but is not limited to, relevant oversight committees to oversee, monitor and review quality and safety.
4. This individual regularly reviews accountability arrangements to ensure that they are fit for their intended purpose and are effective.
5. When a service is located on more than one site, the person with overall executive accountability for the service delegates accountability and responsibility for the quality and safety of those services to another individual. This identified individual is involved in the management and delivery of the service and is at an appropriate level within the governance structure.

Examples of information that may be used to find out if a service is compliant with the standard:

Through observation:

- how the individual with overall accountability leads and is engaged with corporate and clinical leaders, management and staff; for example, observation of safety walk arounds
- who is present.

Through communication with members of staff and management by asking about:

- do staff know who is in charge during on-site inspections
- accountability and reporting arrangements between staff, clinical management, senior management and the person with overall accountability for the service and if these are effective to ensure high-quality, safe and reliable healthcare for people using the service
- if clear and appropriate accountability and responsibility arrangements are in place during and outside core working hours and are in place 24 hours a day, seven days a week
- if there is an identified individual in charge if the service is located on more than one site
- accountability and reporting arrangements between the individual with overall executive accountability, responsibility and authority and boards of management, hospital group and national HSE executives.

Through a review of documents, such as:

- organisational charts and or organograms
- documents that may define roles and reflect accountability and reporting structures
- terms of reference and minutes of meetings for relevant governance and oversight committee meetings
- annual reports on the quality and safety of the service.

Dimension: Capacity and capability

Theme 5: Leadership, governance and management

Standard 5.2

Service providers have formalised governance arrangements for assuring the delivery of high-quality, safe and reliable healthcare.

Scope of this standard

The scope of this national standard includes: integrated corporate and clinical governance arrangements for assuring the quality and safety of services; views and interests of people who use the service; skills and competencies of those governing the service; and public reporting on the quality and safety of the service.

See also national standards 1.1, 2.8, 3.1, 5.1, 5.8 and 8.1.

What compliance with this standard looks like

1. There are integrated corporate and clinical governance arrangements in place which are appropriate for the size, scope and complexity of the service provided.
2. These governance arrangements define roles, accountability and responsibilities for assuring the quality and safety of the service and are made publicly available.
3. Corporate and clinical governance arrangements in place provide assurance that the primary focus is on quality and safety outcomes for people using the service by:
    a) gathering information that is evidence based, focused on the quality and safety of outcomes for people who use the service and in line with any nationally agreed policies and guidance
    b) regularly reviewing information about the quality and safety of services.
4. There are arrangements in place to ensure the collective interests of people who use the service are taken into consideration when decisions are being made about the planning, design and delivery of services.
5. Governance arrangements provide assurance that the people involved in the governance of the service have the skills and competencies necessary to provide effective assurance of high-quality, safe and reliable healthcare.
6. Those governing the service publicly report on the quality and safety of their services.

Examples of information that may be used to find out if a service is compliant with the standard:

Through observation:

- if accountability and responsibility arrangements for the service are publicly available; for example, a hospital website, the display of organisational charts or staff and management photos on notice boards on display
- are the healthcare services provided high quality, safe and reliable
- are healthcare services responsive to information relating to quality and safety outcomes.

Through communication with people who use the service, members of staff and management by asking:

People who use the service

- are they experiencing high quality, safe and reliable healthcare.

Members of staff and management

- how corporate and clinical governance arrangements assure the quality and safety of care
- the structures and systems in place for the monitoring and evaluation of the service
- the effectiveness of oversight arrangements in place for monitoring the quality and safety of the service
- if governance arrangements provide assurance that the people involved in the governance of the service have the skills and competencies necessary
- if the collective interests of people who use the service are taken into consideration
- whether there is public reporting on the safety of services.

Through a review of documents, such as:

- organisational charts and or organograms
- terms of reference and minutes of meetings of relevant governance and oversight committees
- quality and safety performance assurance reports
- records of quality and safety walk arounds
- annual report(s)
- records demonstrating public reporting on the quality and safety of services where applicable
- records of engagement with representatives of people using services
- records of evaluations and formal reviews of relevant committees with responsibility for assuring quality and safety.

Dimension: Capacity and capability

Theme 5: Leadership, governance and management

Standard 5.3

Service providers maintain a publicly available statement of purpose that accurately describes the service provided, including how and where they are provided.

Scope of this standard

The scope of this national standard includes a publicly available detailed statement of purpose.

What compliance with this standard looks like

1. A statement of purpose is available that accurately describes the service provider itself, the type of service it provides and the people for whom the service is provided. The statement of purpose includes the following information:
    a) name and address of the service provider
    b) legal status of the service provider
    c) description of the governance arrangements for the service
    d) the name of the identified person with overall responsibility and accountability for the quality and safety of the service
    e) the types of services provided, such as medical services, surgical services, and the specific services and specialties under each of these
    f) location or locations of where services are delivered
    g) description of services provided
    h) description of the intended service-user population, their profile and specific needs in relation to healthcare delivery and planning
    i) models of service delivery and aligned resources necessary to deliver high-quality, safe and reliable healthcare.
2. The statement of purpose is publicly available and accessible through different media; for example, the service's website, information leaflets in different languages and other accessible formats.
3. The statement of purpose is communicated to all stakeholders and interested parties, including people who use the service.

4. Service providers periodically review the services they provide to ensure the statement of purpose reflects what can be delivered safely, sustainably and within available resources. Service providers take any necessary action to ensure they continue to deliver services according to their statements of purpose.
5. Service providers inform relevant interested parties, stakeholders and people who use the service about any proposed changes that may affect the function or purpose of the service. For example, if services decide to:

    a) offer any additional service or services
    b) discontinue an existing service
    c) change the location of a service
    d) change the model of service delivery
    e) transfer services to and from another provider.

6. Notification of proposed changes is provided in a timely manner so that it allows those interested parties and people who use the service appropriate time to respond to proposed changes.
7. If changes to the statement of purpose are proposed, the necessary approval is sought at the appropriate level of governance and expertise before changes are made.
8. Governance arrangements within the service incorporate a review and evaluation process to provide assurance that services are being delivered within the scope of the statement of purpose.

Examples of information that may be used to find out if a service is compliant with the standard:

Through observation:

- if a statement of purpose is publicly available, accurately reflects the services provided and is clearly demonstrated in practice
- how accessible the statement of purpose is for people who use the service.

Through communication with members of staff and management by asking:

- if they are aware of the statement of purpose, where to access it and how it is communicated
- how the statement of purpose is reviewed and evaluated
- the process for seeking changes, and approval of these changes, to the services provided as outlined in the statement of purpose
- how relevant stakeholders and interested parties and people who use the service are notified and consulted about proposed changes to services provided as outlined in the statement of purpose

- how proposed service changes are evaluated to ensure the statement of purpose reflects what can be delivered safely, sustainably and within available resources.

Through a review of documents, such as:

- statements of purpose
- admission policies
- minutes of relevant governance meetings outlining reviews or changes to service provision
- annual reports.

Dimension: Capacity and capability

Theme 5: Leadership, governance and Management

Standard 5.4

Service providers set clear objectives and develop a clear plan for delivering high-quality, safe and reliable healthcare services.

Scope of this standard

The scope of this national standard includes: service planning objectives in the short, medium and long term; and representation of the interests of people who use the service in planning, monitoring and reporting performance against service objectives.

See also national standards 1.1, 2.1, 3.1, 4.1, 5.8 and 7.2.

What compliance with this standard looks like

1. Service providers have a service-planning process in place.
2. Service plans sets a clear direction for delivering healthcare services in the short, medium and long term.
3. Service plans take into account:
    a) quality and safety of healthcare
    b) national strategies, policies and standards
    c) views of stakeholders and interested parties
    d) the needs of the population served
    e) best available evidence
    f) legislation
    g) resources available and
    h) information relevant to the provision of safe high-quality services.
4. The service-planning process includes details of the care and services to be provided, in consultation with clinical leaders, to determine the requirements of the patient population (such as diagnostic, therapeutic, rehabilitative and other requirements).
5. Service planning includes formal mechanisms to routinely involve and obtain feedback from stakeholders, such as people who use the service, local community groups, independent patient support groups, and primary and community care services.

6. People who use the service are kept informed about key decisions in the planning of services.
7. The performance of the service against service objectives is:
    a) monitored
    b) benchmarked where appropriate
    c) managed and reported through the relevant governance structures.

Examples of information that may be used to find out if a service is compliant with the standard:

Through observation:

- Posters or leaflets and or other information about service plans and performance against service objectives which are on display in public areas; for example, service changes and building plans.

Through communication with members of staff and management by asking:

Members of staff

- how the views and experiences of people who use the service are sought in relation to service planning
- if and how they are informed of changes to the services delivered or future plans for the service.

Management

- how the service planning process works
- how clinical leaders are involved in the planning process
- what short, medium and long-term plans are in place for the service
- how national policies, standards and the needs of the population who use the service have been considered when planning for the delivery of quality and safe healthcare
- how their views and the views of people who use the service and relevant stakeholders and other interested parties are used to inform service plans
- how people who use the service, staff and relevant stakeholders are kept informed of key decisions and progress against service plans
- how it measures performance locally against service objectives and reports on this through the governance structures
- how feedback is provided to staff in relation to performance against service objectives.

Through a review of documents, such as:

- service plans and objectives
- service planning meeting minutes
- individual department service plans
- records of stakeholder engagement and feedback
- publicly available documents outlining service and strategic plans
- evaluation and monitoring of performance against service plans.

Dimension: Capacity and capability

Theme 5: Leadership, governance and management

Standard 5.5

Service providers have effective management arrangements to support and promote the delivery of high-quality, safe and reliable healthcare services.

Scope of this standard

The scope of this national standard includes: effective management arrangements; involvement of management at all levels to achieve service objectives; arrangements in place to manage increases and decreases in service demands; major emergency planning; and service change and transition.

See also national standards 1.1, 1.4, 2.1, 2.2, 2.7, 2.8, 3.1, 3.7, 5.8, 6.1, 6.4, 7.1, 7.2 and 8.1.

What compliance with this standard looks like

1. There are effective management arrangements in place to achieve planned objectives that involve all levels of the service. These arrangements may include, but are not limited to:
    a) workforce management
    b) communication management
    c) information management
    d) risk management
    e) patient safety improvement
    f) service design, improvement and innovation
    g) environment and physical infrastructure management
    h) financial and resource management
    i) major emergency management.
2. Management arrangements, structures and mechanisms involve all levels of the service to achieve planned objectives for quality and safety.
3. There are arrangements to identify, manage, prepare and respond to increases or decreases in service demand, including short-term changes, predictable changes and sudden or unexpected changes in demand such as:
    a) major emergencies

b) escalations or surges in admissions and in the number of people attending emergency departments
c) predictable seasonal changes in demand, such as winter surges
d) workforce shortages and turnover
e) outbreak management
f) practice drills for selected major disaster or emergency scenarios.

4. There are arrangements in place to plan and manage service change and transition, including:
    a) identification of an accountable person responsible for leading and managing change
    b) setting clear objectives for the service change and transition
    c) prior assessment of service interdependencies at local, regional and national levels where relevant
    d) modelling of demand and capacity through estimating current and future requirements
    e) assessment of staffing implications and determination of staffing requirements
    f) consideration of impact and associated risk to stakeholders and interested parties
    g) implementation of communication and engagement strategies
    h) development and monitoring of performance indicators relevant to change and service transition.

    These arrangements ensure the quality and safety of healthcare delivered to people who use the service.

Examples of information that may be used to find out if a service is compliant with the standard:

Through observation:

- safety signage
- emergency communication systems in place
- information displayed regarding service transition and or change.
- Clinical environment and infrastructure

Through communication with members of staff and management by asking:

Members of staff

- if appropriate management arrangements are in place for:

  - workforce planning
  - quality, patient safety and risk management
  - communication management
  - information management
  - service design, improvement and innovation
  - environment and physical infrastructure management
  - financial and resource management
  - major emergency management.
- if management arrangements, structures and mechanisms involve all levels of the service to achieve planned objectives for quality and safety
- how gaps in these arrangements are escalated and managed
- what contingency arrangements are in place to manage increases in activity or acuity; for example, capacity increases, infection outbreaks or major emergencies
- what type of emergency plans and drills are in place.

Management

- how management are assured that current management arrangements in place are efficient and effective in supporting and promoting the delivery of high-quality, safe and reliable healthcare services
- about the arrangements in place to respond effectively to short and long-term increases and decreases in service demand
- about the arrangements in place to respond to unexpected increases in demand, such as a capacity surge, an infection outbreak or a major emergency
- about the arrangements in place to enable the hospital to assess its level of preparedness to respond effectively to a major emergency situation or disasters which will require a significant and immediate acute healthcare response
  - major emergencies
  - escalations or surges in admissions and in the number of people attending emergency departments
  - predictable seasonal changes in demand, such as winter surges
  - workforce shortages and turnover
  - outbreak management
  - practice drills for selected major disaster or emergency scenarios.
- if there are any planned service changes or transitioning of services currently taking place or due to take place
- how the service manages change to ensure effective transition takes place including:

- identification of an accountable person responsible for leading and managing change
- setting clear objectives for the service change and transition
- prior assessment of service interdependencies at local, regional and national levels where relevant
- modelling of demand and capacity through estimating current and future requirements
- assessment of staffing implications and determination of staffing requirements
- consideration of impact and associated risk to stakeholders and interested parties
- implementation of communication and engagement strategies
- development and monitoring of performance indicators relevant to change and service transition
- how these arrangements ensure the quality and safety of healthcare delivered to people who use the service.

Through a review of documents, such as:

- service plans, strategies and business objectives
- organograms detailing management arrangements
- contingency plans for increases or decreases in service demands
- winter planning documents and meeting records
- risk management policies, risk registers and risk assessments
- incident management reports
- workforce planning and contingency arrangements
- major emergency plans
- outbreak management policies and plans
- escalation protocols
- bypass protocols
- disaster preparedness assessments
- records or reports following emergency drills
- service transition strategies or plans.

Dimension: Capacity and capability

Theme 5: Leadership, governance and management

Standard 5.6

Leaders at all levels promote and strengthen a culture of quality and safety throughout the service.

Scope of this standard

The scope of this national standard includes: leadership in the promotion of a culture of quality and safety; facilitation of leaders' skills, knowledge and competencies in relation to a culture of quality and safety; and review and evaluation of the culture of quality and safety.

What compliance with this standard looks like

1. There is active promotion and strengthening of a culture of quality and safety in the service through the following:
    a) mission statement
    b) service design
    c) code of governance
    d) code of conduct
    e) management of conflict of interests
    f) allocation of resources to achieve the service's plans for quality and safety.
2. Leaders demonstrate a clear commitment to promoting a culture of quality and safety by:
    a) encouraging a shared appreciation of the importance of quality and safety throughout the service
    b) placing the safety of people who use the service at the centre of the service's agenda
    c) promotion of a just culture and an environment that encourages and supports reporting throughout the service, especially when things go wrong.
3. Leaders at all levels are facilitated in maintaining and improving the skills, knowledge and competencies to fulfil their roles and responsibilities in promoting and strengthening a culture of quality and safety by:

a) explicitly describing the competencies required for leadership roles in the service to facilitate a culture of quality and safety in the service
b) having educational and developmental programmes for leaders to facilitate a culture of quality and safety
c) having arrangements in place to monitor and regularly review individuals' performance in their leadership roles to ensure that they are meeting the requirements of their roles and to identify any training and development needs.

4. Leaders survey staff to assess and understand the culture of quality and safety.
5. There is review of any concerns about the quality and safety of the service which are brought to their attention by people who use the service or members of the workforce.
6. Review and evaluation of the culture of quality and safety includes feedback from people who use the service.

Examples of information that may be used to find out if a service is compliant with the standard:

Through observation:

- how a culture of quality and safety is promoted in clinical areas
- if people who use the service experience a culture of quality and safety
- if notice boards publicly display quality improvement and safety initiatives.

Through communication with people who use the service, members of staff and management by asking:

People who use the service

- how feedback is sought in relation to the culture of quality and safety
- how they experience the culture of quality and safety.

Members of staff and management

- how leaders and senior management demonstrate a commitment to and promote a culture of quality and safety
- how staff are encouraged to discuss or highlight any issues relating to the quality and safety of services
- how senior management and those with leadership roles are facilitated to develop and promote a culture of quality and safety in the service
- is there an education and development programme in place which enables leaders to maintain and further develop the competencies required to promote a culture of quality and safety

- what systems are in place to proactively evaluate the culture of quality and safety; what changes have been implemented in response; and how are results communicated back to staff
- how progress with improving culture is monitored to demonstrate improvement where required
- if and how the service benchmarks the culture of quality and safety
- how learning gained from patient safety incidents is shared with staff
- how feedback from people who use the service is incorporated into review of the culture of quality and safety.

Through a review of documents, such as:

- mission statements promoting a culture of quality and safety
- minutes of relevant quality and safety oversight committee meetings
- culture assessments and surveys (patient safety culture surveys)
- staff surveys
- documents outlining feedback from people who use the service
- action plans, quality improvement plans and recommendations from culture surveys
- records of education and training in relation to quality and safety.

Dimension: Capacity and capability

Theme 5: Leadership, governance and management

Standard 5.7

Members of the workforce at all levels are enabled to exercise their personal and professional responsibility for the quality and safety of services provided.

Scope of this standard

The scope of this national standard includes: enabling staff to exercise professional responsibility; encouraging innovation and initiative; promoting a culture of openness and accountability; and systems to facilitate the workforce to report concerns.

See also national standards 2.4, 5.5 and 6.4.

What compliance with this standard looks like

1. Members of the workforce are enabled to effectively exercise their personal, professional and collective responsibility for the provision of high-quality, safe and reliable healthcare.
2. Service providers ensure that healthcare professionals are supported and enabled to exercise their specific responsibility and accountability requirements related to their professional practice.
3. A culture of openness and accountability is promoted throughout the service, so that the workforce can exercise their personal, professional and collective responsibility to report in good faith any concerns that they have in relation to the safety and quality of the service.
4. The service provider produces and shares information on making protected disclosures and facilitates members of the workforce who wish to make protected disclosures about the quality and safety of the service in line with legislative requirements.

Examples of information that may be used to find out if a service is compliant with the standard:

Through observation

- availability and accessibility of information for staff on issues such as how to raise concerns, undertake open disclosure and making protected disclosures.

Through communication with members of staff and management by asking:

Members of staff

- how staff are enabled to exercise their personal, professional and collective responsibilities
- if staff feel supported and are facilitated to report any concerns they have about the quality and safety of the service
- what systems and processes are in place to raise any concerns or make protected disclosures about the quality and safety of services
- if staff have job descriptions which explicitly describe the personal, professional and individual responsibilities that each role or position in the service entails
- if staff have reported any concerns in relation to the quality and safety of the service and were they satisfied with how it was managed
- if they have received any training on protected disclosures
- if they have access to relevant information on how to make a protected disclosure.

Management

- how management are assured that there are appropriate systems and processes in place to enable the workforce to exercise their personal, professional and collective responsibility for the provision of safe, quality care
- how the service promotes a culture of openness and accountability to enable the workforce to report any concerns
- if staff have job descriptions which explicitly describe the personal, professional and individual responsibilities that each role or position in the service entails
- how the service facilitates staff to make protected disclosures in line with legislative requirements
- how they are assured that staff are informed of the systems in place for reporting concerns and making protected disclosures
- how they are assured that concerns and protected disclosures are managed in line with national guidelines and legislative requirements

- what measures are in place to ensure individuals reporting concerns are not negatively impacted
- how learning from concerns is shared in order to improve the quality and safety of the service.

Through a review of documents, such as:

- local risk management policies
- policies, information for staff and training contents outlining the personal, professional and collective responsibilities of staff (such as safeguarding policies and policies in relation to the protection of children and minors)
- a sample of job descriptions
- local complaints policy
- dignity at work and grievance policies
- the service's code of conduct
- local and available HSE procedures for protected disclosures
- training records for staff on making a protected disclosure
- information for staff on making a protected disclosure.

Dimension: Capacity and capability

Theme 5: Leadership, governance and management

Standard 5.8

Service providers have systematic monitoring arrangements for identifying and acting on opportunities to continually improve the quality, safety and reliability of healthcare services.

Scope of this standard

The scope of this national standard includes risk management, learning from patient safety incidents, performance management and quality and safety programmes.

What compliance with this standard looks like

1. There are risk management structures and processes in place to proactively identify, manage and minimise risk, including the following:
    a) clinical risk
    b) financial risk
    c) viability risks[§].
2. There is proactive identification, documentation, monitoring and analysis of patient safety incidents.
3. There are effective internal and external communication processes to learn from patient safety incidents to improve the quality, safety and reliability of the healthcare service.
4. There are systematic monitoring arrangements in place to monitor the service's performance.
5. Information from monitoring performance is used to improve the quality, safety and reliability of healthcare services.
6. Information from feedback, compliments and complaints from people who use the service is shared within and across services where relevant to promote learning.

[§] Viability risks in healthcare exclude financial viability risks and are those risks that may impact on the ability of a service provider to deliver services sustainably, achieve its objectives and fulfil its mission over the long term. An example of a viability risk could result from workforce deficiencies or critical volumes of people using a service that affect safe service provision.

7. Services have an overarching quality and safety programme, approved by the governing body, to actively assess, monitor, and improve the quality, safety and reliability of healthcare services. This programme:

    a) is based on identified needs and priorities
    b) is resourced appropriately
    c) is tailored to the size and scope of the service
    d) incorporates specific evidence-based interventions that are proportionate to the context, nature and scale of the service provided
    e) includes regular reporting to governance
    f) includes communication to staff
    g) is regularly evaluated to determine its effectiveness.

8. Service providers take part in and provide data to national quality and safety improvement programmes.
9. Services publicly report on their outcomes in order to share learning within and across services.
10. There is a proactive approach to learning from the findings and recommendations from national and international reviews and investigations
11. Services support and promote effective communication with people who use the service, relevant patient support groups, external agencies and other service providers.

Examples of information that may be used to find out if a service is compliant with the standard:

Through observation

- information leaflets on display in clinical areas and available to people who use the service on providing feedback, compliments and complaints
- quality improvements implemented in clinical areas.

Through communication with people who use the service, members of staff and management by asking:

People who use the service

- how they provide feedback or make a complaint.

Members of staff

- how risks are identified, escalated and managed (clinical, financial and viability risks)
- what type of patient safety incidents are reported and how they are reported

- how they learn from patient safety incidents within their work areas and from incidents in other areas
- what performance data is being monitored and how this is collected and used to improve the quality and safety of the service
- how feedback from people who use the service has been used to change practice or improve the service
- what type of local and national quality improvement programmes they are aware of and involved with
- details of proactive ways in which they learn about the findings and recommendations from incident reviews in other services and hospitals.

Management

- what assurance is in place that risk is effectively managed (clinical, financial and viability risks)
- how risks to the quality and safety of care provided to people using the service are identified, managed and minimised
- how risks to the quality and safety of care provided to people using the service are monitored and reviewed
- what measures are in place to ensure that learning from patient safety incident reviews occurs and that such learning is communicated internally and externally to improve service quality
- how information on performance relating to the quality and safety of the service is monitored and used to improve the service
- what local and national quality improvement programmes the service is implementing and whether these are effective (and what national programmes have not been implemented at the time of inspection)
- how feedback, complaints and compliments from people who use the service are collected and used to improve the quality, safety and reliability of the service
- how the service ensures that they learn from the findings and recommendations from patient safety incident reviews in other units and services, including local, hospital group, national and international reviews and investigations.

Through a review of documents, such as:

- records from the quality, risk and safety committees
- records from the service's executive meetings
- records from finance committees
- risk management policies, risk registers and risk assessments
- the quality and safety programme or strategy and associated action plans and reports for governance
- quality improvement plans

- records from departmental quality improvement meetings
- performance reports
- analysis of patient safety incidents
- analysis of complaints
- analysis of patient surveys or feedback
- audit schedule or plans
- annual reports
- investigation or review reports.

Dimension: Capacity and capability

Theme 5: Leadership, governance and management

Standard 5.9

The quality and safety of services provided on behalf of healthcare service providers are monitored through formalised agreements.

Scope of this standard

The scope of this national standard includes formalised agreements (contracts) and monitoring of formalised arrangements.

See also national standards 2.8, 5.1, 5.5, 5.8 and 6.2.

What compliance with this standard looks like

1. There are contracts of agreement in place covering the quality of services sourced externally. Contracts of agreement include:
   - the scope of service provided
   - resources required
   - monitoring and quality assurance of contracts
   - governance arrangements for the quality and safety of services delivered, including compliance with relevant standards
   - regular review of such contracts.
2. Staff with the relevant expertise are involved in procurement decisions for externally contracted services.
3. There is regular formal review and oversight of contracted services to ensure they meet objectives and the needs of the service.
4. There is ongoing monitoring and performance management of externally contracted services to ensure the quality and safety of these services, including assurances that any issues arising are addressed in a timely and effective manner.
5. There is regular monitoring of the formalised arrangements in place with external recruitment agencies. Such monitoring provides assurance that the contracted recruitment service meets best practice guidelines, relevant standards and complies with legislation. These arrangements include the agency's roles, responsibilities and accountability in the recruitment process.

Examples of information that may be used to find out if a service is compliant with the standard:

Through observation

- externally contracted services in clinical areas.

Through communication with people who use the service, members of staff and management by asking:

People using the service

- about their experience with services that are sourced externally, such as agency staff and or externally contracted meals.

Members of staff

- if there are any services provided in the clinical area by external providers; for example, contract cleaning staff or agency nursing staff
- how often agency staff are used in the clinical area
- how staff are assured that agency staff have the skills and competencies to provide safe and effective care
- how staff can highlight any issues relating to the quality and safety of externally provided services.

Management

- if the service has formal agreements in place for contracted services
- how management are assured of the provision of a safe and quality service for any services sourced externally
- about the processes in place to identify and escalate any concerns relating to externally provided services
- how the service monitors any formalised agreements in place with external recruitment agencies.

Through a review of documents, such as:

- service-level agreements
- contracts
- policies on externally sourced services and agreements
- monitoring and evaluation reports on externally provided services
- policy on the use of agency staff
- induction policy
- education and training records for contracted and agency staff.

Dimension: Capacity and capability

Theme 5: Leadership, governance and management

Standard 5.10

The conduct and provision of healthcare services are compliant with relevant Irish and European legislation.

Scope of this standard

The scope of this national standard includes identification by the service of — and compliance with — relevant Irish and European legislation and regulations.

See also standards 1.2, 1.3, 1.5, 1.6, 2.3, 2.6, 2.8, 3.3, 3.4, 5.4, 6.1, 6.2, 6.4, 7.1, 8.1 to 8.3.

What compliance with this standard looks like

1. The service provider has formally identified the legislation relevant to its service.
2. There is regular review of existing and new legislation (Irish and European) to ensure compliance with all relevant Irish and European legislation.
3. There is a clearly documented risk assessment in response to any gaps in its compliance with Irish and European legislation.
4. Compliance plans are developed to ensure that compliance with relevant legislation is achieved in a timely manner.

Examples of information that may be used to find out if a service is compliant with the standard:

Through communication with members of staff and management by asking:

Members of staff

- how they are informed about changes in legislation that affect their work
- how they are informed of changes or quality improvement plans in place to address compliance issues relevant to certain legislation, such as the management of blood, blood components or health and safety legislation.

Management

- how they identify relevant legislation

- how they access specialist legal advice
- if the service carries out regular reviews of Irish and European legislation to determine what is relevant for the service
- how gaps in compliance with relevant legislation are identified and addressed in a timely manner
- the monitoring arrangements in place to ensure the service is meeting all necessary legislative requirements
- how management communicates and consults with people who use the service about legislative changes that impact on service design, planning and provision.

Through a review of documents, such as:

- list of laws and regulations relevant to the service
- gap analysis in relation to compliance with legislation
- risk assessments, quality improvement plans and or compliance plans
- relevant policies that reflect the implementation of legislation.

Dimension: Capacity and capability

Theme 5: Leadership, governance and management

Standard 5.11

Service providers act on standards and alerts, and take into account recommendations and guidance, as formally issued by relevant regulatory bodies as they apply to their service.

Scope of this standard

The scope of this national standard includes identification and acting by the service of recommendations and guidance, as formally issued by relevant regulatory bodies where relevant.

See also standards 1.2, 1.3, 1.5, 1.6, 2.3, 2.6, 2.8, 3.3, 3.4, 5.4, 6.1, 6.2, 6.4, 7.1, 8.1 to 8.3.

What compliance with this standard looks like

1. Services regularly review standards, guidance, alerts and recommendations formally issued by regulatory bodies in order to determine what is relevant to the services provided, and take action to address any identified gaps.
2. Service providers have arrangements in place to identify and share relevant alerts promptly and to act in line with the alerts in order to ensure the quality and safety of the service.
3. There is appropriate and timely action on recommendations made by regulatory bodies relating to the quality and safety of services. This includes recommendations made following an investigation or review into the service.

Examples of information that may be used to find out if a service is compliant with the standard:

Through observation

- examples of relevant standards, alerts, recommendations and guidance displayed on notice boards or in folders
- practice changes that have occurred in response to standards and alerts.

Through communication with members of staff and management by asking:

Members of staff and management

- who is responsible for ensuring that standards, alerts, recommendations and guidance from regulatory bodies are acted on
- the process in place to share standards, alerts, recommendations and alerts issued by regulatory bodies
- the process in place to ensure alerts (such as patient safety alerts) are acted on in a timely and appropriate manner
- how standards, alerts, recommendations and guidance from regulatory bodies have resulted in changes in practice
- how people who use the service are notified of standards, alerts, recommendations and guidance from regulatory bodies that may affect them
- how information from regulatory bodies is incorporated into the service's planning processes
- how management is assured that appropriate and timely action is taken in response to standards and alerts and how it takes account of recommendations and guidance issued by relevant regulatory bodies.

Through a review of documents, such as:

- policies and procedures for identifying and responding to standards and alerts
- a list of recommendations formally issued by regulatory bodies
- a list of alerts relevant to the service
- compliance plans
- communication books and or folders in clinical areas.

Theme 6: Workforce

This section describes the standards associated with workforce. The workforce is the most important resource of a service and is key to providing high-quality, person-centred and safe care. The workforce includes everyone either working directly or indirectly with the health service provider to provide services required by the people who use the service. A health service needs an appropriate mix and quantity of skilled and qualified people to fulfil its mission.

The service provider plans and determines its workforce requirements based on regulations and standards set by regulatory bodies, evidence-based information and the assessed needs of the population. The service provider recruits and manages staff in compliance with legal requirements and standards set by the relevant regulatory bodies, government policies and evidence-based practice. This includes seeking national Garda Síochána (police) vetting, occupational health screening, character references and professional registration with regulatory bodies as appropriate.

The service provider configures its workforce according to recommended models of care, ensuring value for money. This level of planning, organisation and development is reflected in the delivery and effectiveness of agreed service objectives and in health outcomes for the population. The service has feasible plans in place to respond appropriately to surges in demand, unexpected and or uncommon events such as a major accidents, global pandemics or changes in available resources while also maintaining essential services.

The service provider has systems in place to ensure that staff are competent. All new staff are provided with a general induction programme which includes specific elements relevant to their roles in the service. There are systems and supports in place to regularly monitor and attend to competency needs. The service provider regularly reviews the training needs of the staff and provides a schedule of programmes to support and develop the competencies and skill set of each member of staff (whether directly employed or via external contract). This includes effective two-way feedback mechanisms, supervision and ongoing assessment and management of performance. The service provider enables compliance with professional codes of conduct.

People are the most valuable asset within healthcare. As such, the service provider ensures that the workforce are provided with a safe physical and psychological work environment, where they feel valued and where their opinions and feedback are regularly sought and used to make material improvements in the service.

The service provider also ensures that staff are protected from bullying and harassment and has policies and processes in place to deal with breaches in the

service's code of conduct or performance issues not resolved through support and training. The service provider ensures access to support services, such as occupational health, employment assistance programmes, and critical incident debriefing for staff.

The service provider regularly monitors and updates its processes related to the recruitment, management and development of staff. The service provider assures the public, people using services and staff that each person working in the service is contributing to the delivery of a high-quality, person-centred and safe service.

Dimension: Capacity and capability

Theme 6: Workforce

Standard 6.1

Service providers plan, organise and manage their workforce to achieve the service objectives for high-quality, safe and reliable healthcare.

Scope of this standard

The scope of this national standard includes: workforce planning, organisation and management of the workforce, response to changes in workload needs and succession planning.

See also standards 1.1, 1.5, 2.1 to 2.4, 2.6, 2.8, 4.1, 5.2, 5.3, 5.7 to 5.11, 7.1, 7.2 and 8.1.

What compliance with this standard looks like

1. There is planning, organisation and management of the workforce which takes account of:
   - the assessed needs of the population
   - national and international best available evidence regarding the model or type of service being provided
   - size, complexity and specialties of the service being provided
   - number of staff required to deliver the service
   - skill-mix and competencies required to deliver the service
   - resources available
   - changes in the workload
   - succession planning
   - relevant legislation and government policy.
2. The workforce is planned, managed and developed to ensure it consistently responds, in a timely manner, to changes in the workload or in available resources.
3. The organisation of the workforce is in line with best available evidence.
4. Where the model of care delivery includes multidisciplinary teams, the workforce is organised and managed to work in such teams.
5. There is regular review and evaluation of the management of the workforce, the service's response to changes in workload and resources available.

Examples of information that may be used to find out if a service is compliant with the standard:

Through observation

- staffing levels in clinical areas including during meal breaks, nurse-to-patient ratios and level of assistance provided
- skill-mix of staff
- quality initiatives in progress (for example, *Productive Ward Initiative: Releasing Time to Care*).

Through communication with people who use the service, members of staff and management by asking:

People who use the service

- their experience of the care they receive from staff
- if they are responded to in a timely way if they seek assistance
- their views on current staffing levels.

Members of staff

- their views on current staffing levels and skill mix
- their experience of, or involvement in, workforce planning, including succession planning for their unit or department
- on-site supervisory arrangements
- escalation procedures during out-of-hours
- how staff feedback is sought and used in the design and development of the service
- if they work within a multidisciplinary team, how their teams are organised and managed
- what is the process used by staff to raise concerns regarding staffing, and how are these managed
- what measures and supports are put in place when workload exceeds workforce resources, (major accident plan, surge in clinical activity, pandemic)
- access to training, development and career opportunities

Management

- how workforce requirements are planned, monitored and reviewed
- what measures are taken and supports put in place when:
    - workload exceeds workforce resources, (major accident plan, pandemic)
    - introducing service redesign or innovation (cessation, relocation, re-assignment of existing resources)
    - succession planning

  - acquiring additional resources, such as extra posts
- how multidisciplinary teams are organised and managed
- arrangements for those services for whom there are no out-of-hours cover
- if there are regular reviews and evaluation of the management of the workforce, the service's response to changes in workload and resources available
- responding to findings of internal and external reports regarding staffing reviews and audits.

Through a review of documents, such as:

- staff rotas and rosters
- local policies, procedures and guidelines related to workforce
- the hospital's strategy, workforce strategy and or workforce plans
- statements of purpose
- service plans
- annual clinical reports
- records from the hospital's board, executive management and human resource department regarding workforce planning meetings
- business cases regarding any requirements and or deficiencies in workforce
- contracts with agencies for staff, locum consultant services and other contracted services
- reports on leave and attendance management
- training needs analysis, in-service training schedule and attendance records
- patient safety incidents or review recommendations related to staffing
- trended incident reports related to staffing, for example unwitnessed falls
- risk registers relating to identification of workforce issues
- annual analysis of exit interview records
- quarterly and annual expenditure reports on agency and locum staff
- sample of staff files from across disciplines
  sample of job descriptions and person specifications for a range of staff members.

Dimension: Capacity and capability

Theme 6: Workforce

Standard 6.2

Service providers recruit people with the required competencies to provide high quality, safe and reliable healthcare.

Scope of this standard

The scope of this national standard includes selection and recruitment of the workforce.

See also standards 1.1, 1.3, 1.5 to 1.8, 2.1, 3.1, 3.4, 5.1, 5.6, 7.2 and 8.1.

What compliance with this standard looks like

1. The service provider is compliant with all legal requirements, evidence-based practice and ethical practices when recruiting staff.
2. The service provider recruits people** with the required qualifications, experience, registration (where relevant), credentials and competencies, in sufficient numbers and in line with accepted national or international standards (where these exist), to deliver on service objectives and provide high-quality, safe care.
3. The service provider monitors and evaluates the effectiveness of recruitment processes and addresses identified gaps.
4. The service provider has recruitment and selection arrangements that incorporate all reasonable measures to protect people who use the service from harm.

Examples of information that may be used to find out if a service is compliant with the standard:

Through communication with members of staff and management by asking:

Members of staff

** This includes staff on temporary and locum contracts.

- About their awareness of individual obligations in respect of recruitment processes, whether as part of recruitment, induction and or probation (where these apply), including:
  - if there is a planned induction programme for new staff
  - if training is available for staff who mentor new staff
  - how the performance of new staff is evaluated
  - if procedures are in place to verify identification and registration on site for staff being hired at short notice, or agency or locum staff being hired out of hours
  - if there is a probation period and how it is managed
  - if procedures are in place to orientate and induct staff being hired at short notice, or agency or locum staff hired out of hours
  - if there is timely filling of vacancies
  - if feedback is sought from new starters on the recruitment processes
- does the organisation conduct exit interviews and how is this feedback used
- what is the process for annual re-certification of all staff registered with a regulatory or professional body
- what measures are taken to vet new staff to protect people who use the service from harm.

Management

- how management assure themselves that recruitment of the workforce is in line with relevant Irish and European legislation and informed by evidence-based human resource practices
- what staff are in place to assist in recruitment
- what informs job descriptions and person specifications
- the mode of communication between executive management and the human resources department in respect of recruitment issues
- what is the process for review of human resources recruitment policies and procedures
- is there available training for staff on recruitment practices and standards
- is there availability of an induction programme for all grades and disciplines of staff and is this evaluated
- what oversight is in place for the application and management of probation period for new starters
- how is the executive management team assured that the recruitment processes are effective
- how is the executive management team assured that Garda vetting procedures are effective.

Through a review of documents, such as:

- recruitment policies, procedures and guidelines

- records from executive management and human resources workforce planning meetings
- contracts with agencies for staff, locum consultant services and other contracted services, including regular and infrequent support services
- a sample of staff files for inclusion of:
  - job description and person specifications
  - essential qualification(s)
  - current registration with the specific regulatory body
  - Garda (police) vetting
  - occupational health clearance
  - reference checks
  - management and sign-off of the probation period.

Dimension: Capacity and capability

Theme 6: Workforce

Standard 6.3

Service providers ensure their workforce have the competencies required to deliver high-quality, safe and reliable healthcare.

The scope of this standard includes: competency of workforce, induction of staff, continuing professional development, supervision, staff support and the service's code of conduct.

See also standards 1.1, 1.3 to 1.9, 2.1 to 2.8, 3.1 to 3.7, 4.1, 5.2, 5.4 to 5.11, 7.1, 7.2, and 8.1 to 8.3.

What compliance with this standard looks like

1. There are systems in place to ensure the workforce is provided with induction and ongoing mandatory training and support, supervision and monitoring, and that staff are enabled to deliver high-quality safe and reliable healthcare.
2. There is a formal mandatory induction programme for the workforce which includes a focus on communication skills and ensuring the safety of people who use the service.
3. There is facilitation of each member of the workforce to maintain and develop their competencies to fulfil their roles and responsibilities in delivering high-quality and safe care.
4. Members of the workforce are facilitated to maintain the necessary competencies to meet their relevant professional registration requirements.
5. There are regular reviews of the development needs of the workforce to deliver high-quality and safe care, and action is taken to address any identified gaps.
6. There is a training, educational and development programme which has a specific focus on patient safety, communication and person-centred care. This includes:
    a) a programme with clear objectives tailored to specific members of the workforce to develop their competencies.
7. The provision of care is supervised, monitored and reviewed to ensure all members of the workforce work within their competencies.
8. Members of the workforce are facilitated to seek support or advice, including advice from decision-makers and senior team members.

9. The workforce have the competencies to work effectively in teams to deliver safe and integrated care within and between services.
10. There are measures in place to ensure that each member of the workforce adheres to the code of conduct for the service. Members of the workforce are facilitated to adhere to their relevant regulatory professional codes.

Examples of information that may be used to find out if a service is compliant with the standard:

Through observation

- general interaction and communication (verbal and written) both between staff and between staff and people who use the service
- notices of study days, grand rounds, journal clubs, teaching sessions, reflective learning and upcoming in-service training
- evidence of supervision in practice
- evidence of working in multidisciplinary teams, such as ward rounds.

Through communication with members of staff and management by asking:

Members of staff

- if staff have completed an induction programme, mandatory training and other training relevant to the specialty
- if induction training and ongoing training included patient safety, communication and person-centred care
- how staff are facilitated to maintain and develop competencies relevant to their roles and responsibilities
- the availability of personal development training and support
- if staff are consulted and contribute to training needs analysis
- about the schedule of training and how it relates to staff needs and service objectives
- about the mechanisms for supervision and two-way feedback with staff
- about the performance management systems in use
- for examples of supports in place for multidisciplinary team meetings
- if staff are provided with multidisciplinary training where appropriate
- about availability and access for staff to the hospital's code of conduct.

Management

- about the availability and applicability of the induction programme
- how staff are facilitated in maintaining and developing competencies relevant to their roles and responsibilities
- if a training needs analysis is undertaken

- about the frequency and drivers for the training needs analysis and how staff are involved in this
- about the systems in place to record and monitor attendance at mandatory training
- how management are assured that training meets its objectives
- about assurance mechanisms in place to check annual professional registration is completed for relevant staff
- about the mechanisms in place to supervise and monitor performance
- how multidisciplinary team working is promoted and supported
- about the degree of multidisciplinary team meetings at the service and what additional supports were and are required to establish them
- how management assures itself, the staff and the public that each member of the workforce adheres to the service's code of conduct
- how the hospital deals with breaches in its code of conduct or those set down by relevant regulatory bodies.

Through a review of documents, such as:

- the service's code of conduct for all staff
- induction programmes
- records of attendance at induction
- information packs sent to all new staff
- sample of job descriptions
- contracts with agencies for staff, locum consultant services and other contracted services including information provided to agency staff regarding induction, orientation and code of conduct in respect of work carried out at the hospital or service
- probation policy and templates in use for providing feedback to staff
- training needs analysis and accompanying schedule of training
- mandatory training programme and schedule
- records of attendance at mandatory training
- records of attendance at training relevant to service delivery
- study leave policy
- sample of competency assessment tools, personal development planning and team-based performance management plans
- internal rotation policy
- mentoring and coaching policies
- annual schedule of events such as grand rounds, teaching sessions, case presentations, journal clubs, mentoring, coaching
- arrangements and rosters for supervision
- copy of performance monitoring plans for current year
- risk registers as they relate to workforce issues
- notices for, and records of, multidisciplinary or team meetings.

Dimension: Capacity and capability

Theme 6: Workforce

Standard 6.4

Service providers support their workforce in delivering high-quality, safe and reliable healthcare.

Scope of this standard

The scope of this national standard includes: culture, values, respect, policies and procedures regarding behaviours such as bullying and harassment; workforce performance management; job descriptions and role clarity; responsibilities; openness and accountability; and support to assist in goal achievement.

See also standards 1.1 to 1.8, 2.1 to 2.8, 3.1 to 3.7, 4.1, 5.1 to 5.11, 7.1, 7.2 and 8.1 to 8.3.

What compliance with this standard looks like

1. There is support and promotion of a culture that values, respects, actively listens to and responds to the views and feedback from all members of the workforce.
2. The workforce is provided with a clear description of their roles, responsibilities and lines of accountability.
3. The working environment is in line with relevant legislation and national policy, and supports and protects the workforce as they deliver high-quality, safe care.
4. There are measures in place to protect the workforce by minimising the risk of violence, bullying and harassment by other members of the workforce or people using the services.
5. The performance of the workforce is monitored, managed and developed, at individual and team level, including the evaluation of feedback from people who use the services. Action is taken to address identified areas for improvement.
6. There are effective systems in place to address underperformance.
7. There are procedures in place to inform the relevant professional body, where it is considered that the behaviour, conduct, practice, performance or health of a healthcare professional is not what would be expected of such a healthcare professional.
8. There are fair and transparent arrangements in place to support and manage a member of the workforce if a complaint or a concern has been expressed about them.
9. The service provider:

a) promotes a culture of openness and accountability throughout the service,
b) has arrangements in place, in line with legislation, to enable the workforce to report in good faith any concerns that they may have in relation to the safety and quality of the service
c) provides a safe physical and psychological working environment
d) promotes open and effective two-way communication between staff and management.

10. There is support for, and facilitation of, the workforce to identify and propose areas for improvement in the delivery of healthcare which reflect best available evidence.
11. There is regular evaluation and response to feedback about the workforce received from people using the service and members of the workforce.

Examples of information that may be used to find out if a service is compliant with the standard:

Through observation

- notices regarding
  - access (self-referral) to employment assistance programme for staff
  - who to contact in confidence should they have concerns
  - awareness and training about protected disclosure legislation
  - the service's policy on the use of abusive language and or behaviour
- suggestion boxes for staff
- staff forums
- displays of quality improvement plans, action plans initiated in response to feedback and culture-survey results

Through communication with people who use the service, members of staff and management by asking:

People who use the service

- about their experience with staff.

Members of staff

- how staff describe the culture of the workplace and whether they feel valued and respected
- how feedback from all members of the workforce is sought and used
- if staff have been provided with a job description outlining role, responsibilities and lines of accountability
- how staff describe the working environment

- what is it that makes them feel supported and protected and enabled to deliver safe, high-quality safe care
- what measures and supports are in place to minimise the risk of violence, bullying and harassment by other members of the workforce or by people using the services
- what arrangements are in place to monitor, manage and develop the performance of staff
- availability and access to services that support the workforce including occupational health services and employment assistance programmes
- examples of how feedback from people using services and staff has been used to bring about service improvements
- what processes are in place for staff who have concerns about the wellbeing or performance of a colleague
- what processes are in place to support and manage a member of the workforce if a complaint or a concern has been expressed about them
- what arrangements are in place for staff to report in good faith any concerns that they may have in relation to the safety and quality of the service
- what changes if any, have occurred in the workforce in response to feedback from staff or people who use the service.

Management

- how the management describes the current culture of the hospital
- how do they promote and support a culture that values, respects, actively listens to and responds to the views and feedback from all members of the workforce
- what mechanisms are in place for staff engagement
- what arrangements are in place to monitor, manage and develop the performance of the individual members of staff
- what arrangements are in place to identify and manage underperformance or breaches in code of conduct
- what arrangements are in place to promote a working environment that, in line with relevant legislation and national policy, supports and protects the workforce in delivering high-quality, safe care
- about the availability and access to services that support the workforce including occupational health services and employment assistance programmes
- what systems are in place to protect the workforce from violence, bullying and harassment by other members of the workforce or by people using the services.

Through a review of documents, such as:

- records of board, executive management and workforce planning meetings
- records about service improvements arising from workforce suggestions
- reports on culture surveys
- documented evidence of quality and safety walk-arounds
- examples of changes to the workplace to meet particular needs of staff
- sample of job descriptions and person specifications
- lone-working policies
- leave policies such as maternity, parental, parents, adoptive, carer's, force majeure and compassionate leave
- risk assessments as they relate to workforce issues
- protected disclosure policy
- procedures to access occupational health services, employee assistance programmes and incident debriefing services
- training records
- procedures to monitor and manage individual and team performance
- results of benchmarking at national and or international level of various services
- complaints register, volume, themes, effectiveness of the complaints procedures.

Theme 7: Use of resources

This section of the guidance describes the national standards associated with the use of resources to deliver high-quality, safe and reliable healthcare efficiently and sustainably.

How a service uses the resources available to it impacts on the quality and safety of the care and support it provides, including how care and support is planned, managed and delivered. These resources include human, physical, financial and natural resources.

These resources are finite. Therefore, effective and responsible stewardship of resources, including decisions on how they are allocated, is a fundamental factor in planning, delivering and managing healthcare services. A well-managed and governed service closely tracks how resources are used.

It also uses data to support resource allocation and proactively seeks opportunities to provide better care using the same amount of resources or less resources. Furthermore, emerging technologies and evidence are continually used to improve the efficient use of resources while delivering high-quality care.

Decisions on the use of resources must be informed and accountable. Services that are publicly funded ensure decision-making about the use of their resources is transparent and that the people using the service, staff and the public understand the decisions being made.

Dimension: Capacity and capability

Theme 7: Use of resources

Standard 7.1

Service providers plan and manage the use of resources to deliver high-quality, safe and reliable healthcare efficiently and sustainably.

Scope of this standard

The scope of this national standard includes: resource planning and decision-making; financial management and reporting; the management of physical assets; and management of waste and hazardous materials in relation to their impact on the safety of services.

See also national standards 2.7, 5.4, 5.5, 5.8, 5.9 and 6.1 to 6.4,

What compliance with this standard looks like

1. There is a clear planning process, with accompanying service and business plans, that takes account of the funding and resources required to deliver high-quality, safe and reliable healthcare. The planning process:
    a) details what resources are needed
    b) details the allocation of resources to safely and sustainably deliver services and achieve good outcomes for people who use the service
    c) considers the sustainability and viability of services delivered
    d) includes consultation with key stakeholders and interested parties (including people who use the service, policy-makers and the workforce) regarding the allocation of resources to achieve the best quality and safety outcomes for people using the services.
2. Resource decisions are informed by:
    a) consideration of the quality, safety and ethical implications of decisions
    b) risk assessments
    c) best available evidence
    d) views of clinical staff and people who use the service.
3. There are arrangements in place to manage financial performance and evaluate its impact on the quality and safety of services, including any deterioration in performance. In addition:

a) there is transparent reporting on financial performance in line with legislation and national policy
b) there is reporting on financial performance including the quality and safety outcomes achieved as a result of resource allocation and usage
c) there are transparent and effective decision-making arrangements for planning and managing the use of resources in those services receiving public funding.

4. The management of physical assets[††] including equipment is based on analysis of what is needed to ensure the quality and safety of services provided.
5. Natural resources, hazardous materials and waste are managed to minimise any potential negative impact or risk of harm to people using the service.

Examples of information that may be used to find out if a service is compliant with the standard:

Through observation

- if people using the service have the required equipment and resources they need
- if staff have the required resources to deliver high-quality and safe patient care
- how physical assets, such as medical equipment, facilities and clinical areas, are serviced and maintained
- systems in place for management of waste and hazardous materials.

Through communication with people who use the service, members of staff and management by asking:

People who use the service

- about their experience of availability of resources during their stay in hospital.

Members of staff

- if they have access to resources, supplies and physical equipment in clinical areas and at the point of care if required
- how they are involved in decision-making about resources and allocation of resources within their work area
- how the use of resources is monitored and evaluated to ensure the ongoing delivery of safe and effective services

[††] Physical assets include cash, equipment, vehicles, stock and buildings or properties owned by a service provider.

- how they report issues with physical assets and equipment
- how they manage waste, including hazardous materials.

Management

- how resources are planned, managed and best used, and how they involve staff in decision-making about resources
- how the use of resources is monitored and evaluated to ensure the services that are delivered are safe and reliable
- what measures are taken to identify and reduce waste, eliminate wasteful practices and those no longer supported by evidence
- what structures and systems are in place to ensure financial reporting is transparent and in line with legislation
- about the assurance and monitoring arrangements in place for the management of physical assets and waste management as they impact on patient safety.

Through a review of documents, such as:

- service plans
- annual business plans
- business proposals for required resources
- plans for capital investment
- annual reports and financial statements
- salary costs, including overtime and agency costs
- internal and external audit reports
- risk assessments
- local policies, procedures and guidelines related to resource management and waste management as they relate to patient safety.

Dimension: Capacity and capability

Theme 7: Use of resources

Standard 7.2

Service providers have arrangements in place to achieve best possible quality and safety outcomes for service users for the money and resources used.

Scope of this standard

The scope of this national standard includes: the arrangements for managing, maintaining and evaluating resources; promotion of awareness among staff regarding the use of resources; and ensuring value for money when purchasing goods and services.

See also national standards 5.3 to 5.5, 5.7, 5.8, 7.1 and 8.1.

What compliance with this standard looks like

1. There are management arrangements in place for the planning, design, development and use of resources.
2. There are systems in place for the maintenance of resources.
3. Management arrangements include regular evaluation of the efficiency and cost-effectiveness of services and or technologies. The evaluation process uses best available evidence to maximise quality and safety and to inform investment and disinvestment decisions.
4. There is promotion of awareness within the workforce of the resource consequences of service delivery and active promotion of individual and collective responsibility and accountability for resource management.
5. Procurement of external goods and services, purchased in line with legislation and national and local policy, achieves the best possible quality and safety outcomes for people who use the service for the money and resources used.

Examples of information that may be used to find out if a service is compliant with the standard:

Through observation

- how resources are maintained and used in the best way in patient care areas
- awareness campaigns on cost-effectiveness in clinical areas
- the use of products or services outsourced to third parties in patient care areas; for example, meal services provided by an external company.

Through communication with members of staff and management by asking:

Members of staff and management

- how resources and money are used to ensure people using the service receive high-quality care
- how resources are maintained
- how the use of resources is monitored and evaluated to ensure care is both safe and cost-effective
- what systems are in place for buying resources and how these processes ensure value for money
- how decisions are made when there are competing considerations between safety and cost-effectiveness.

Management

- about the assurance arrangements in place to ensure the purchasing of goods and services delivers high-quality care experiences and value for money.

Through a review of documents, such as:

- records from relevant committees
- monitoring and evaluation records and or reports
- finance and activity reports for the hospital's executive and its board of management
- resource impact reports
- internal financial audit reports
- local policies, procedures and guidelines related to use of resources and making the best use of resources
- testing, service, maintenance and calibration records for equipment and medical devices
- third-party contracts and service-level agreements.

Theme 8: Use of information

Good quality information is an important resource for healthcare service providers and is essential to the planning, delivery, management and improvement of these services. Systems and technologies, such as information and communications technology (ICT) — together with effective information governance — enable services to collect, use, report on and manage services using high-quality information.

An efficient and effective information governance framework enables healthcare services to handle all information, including personal health information, securely and in line with legislation, best available evidence and professional codes of conduct. It supports the delivery of person-centred, safe, high-quality healthcare and helps ensure that information is protected and managed in a sensitive and responsible manner when shared within the organisation and between other services.

In this guidance, healthcare records refer to information in all formats — paper and electronic — relating to the individual care of a person using the service. It includes (but is not limited to) demographics (such as name, address, date of birth), medical history, social history, findings from physical examination, images and specimens, the results of diagnostic tests, prescriptions, procedures and all communication relating to the care of the person.

Where possible, personal health information is obtained from the people using the service and not from a third party. Effective management of healthcare records ensures that all relevant parts of the healthcare record are held securely while being available in a timely and appropriate manner at the point of clinical decision-making. Best available evidence and national guidance promotes the use of an individual health identifier (IHI) for the safety of people who use the service and the provision and management of high-quality, safe care.

Dimension: Capacity and capability

Theme 8: Use of information

Standard 8.1

Service providers use information as a resource in planning, delivering, managing and improving the quality, safety and reliability of healthcare.

Scope of this standard

The scope of this national standard includes: use of information in planning, delivery, and improvement of healthcare; and information and communication technology (ICT) systems.

See also national standards 1.1, 1.2, 2.5, 2.8, 5.4, 7.1 and 8.2.

What compliance with this standard looks like

1. Services identify the information they need, relevant to the current and anticipated needs of the people using the service and the population it serves, and use this information when planning, designing, delivering and managing services.
2. Services have effective arrangements along with information and communication technology (ICT) systems in place to collect, manage and process data and information in a timely, efficient, accessible, accurate and confidential way.
3. High-quality data is used to support management decision-making, including decisions made on the use of resources. The management team has up-to-date information which it reviews regularly and which is used when making decisions on the planning, design, delivery and management of healthcare. This information includes:
    a) clinical activity and outcomes
    b) service demand
    c) views of service users
    d) workforce requirements
    e) finance and other resources.
4. There are arrangements, facilities and resources in place to ensure healthcare professionals have access to high-quality and up-to-date information to enable evidence-based practice.
5. Strategic plans for the service take into consideration the current and future needs of the service in relation to information systems and aligned with the short, medium and long-term objectives and plans for the service.

6. There are systems in place for business intelligence and to monitor performance using evidence-based key performance indicators and metrics. These are evidence based, in line with national guidance and proportionate to the size, scope and nature of the service provided.
7. The effectiveness of the arrangements for the collection and management of information is evaluated and the service takes steps to address any identified areas for improvement.
8. There is timely sharing of information within the organisation and with other services. Sharing of information is in line with legislation, evidence, national standards and guidance, and respects the privacy of people using the service.
9. Information systems are integrated and interface with other information systems to support the delivery of high-quality safe healthcare.
10. There are systems and processes in place to enable the receipt, handover, collection and management of information. The effectiveness of these systems and processes are regularly evaluated.

Examples of information that may be used to find out if a service is compliant with the standard:

Through observation

- the systems used to collect information
- the location and type of resources available to staff to access up-to-date information to enable evidence-based practice.

Through communication with people who use the service, members of staff and management by asking:

People using the service

- how their personal information and health information was or is collected
- whether their healthcare professionals have access to their information without undue delay, such as test results, and whether it is shared in a way that respects their privacy.

Members of staff

- what systems and processes are in place to manage information — both in electronic and paper format
- what policies, procedures, guidelines and protocols are available to guide the management and processing of information
- if information management systems, whether electronic or paper format, are compatible with and capable of being incorporated into other systems to support the delivery of high-quality, safe healthcare

- if the information management systems facilitate and support the sharing of information in a timely manner within the organisation and between other services
- whether staff have access to up-to-date information to inform clinical decision-making and enable the delivery of evidence-based practice
- what systems are available for business intelligence, management reports and to monitor performance using evidence-based key performance indicators and metrics
- whether staff receive training and regular training updates on the management of information and information management systems used in the organisation
- do staff participate in the evaluation of the information management systems used in the organisation.

Management

- how management is assured that the information management systems used in the organisation are effective and that information generated is of high quality
- how current and future information management system needs are aligned with the short, medium and long-term plans as set out in the service's strategic plan
- what type of information and data is used in management decision-making, including decisions made on the use of resources
- if there are gaps in how information management systems, whether electronic or paper-based, integrate and interface and if so what is the plan to address these gaps
- if there are systems in place to enable staff to access high-quality information, (including best available evidence) to enable evidence-based practice, and if these systems are available in clinical areas 24 hours a day, seven days a week
- how receipt and handover of information is evaluated
- how the effectiveness of information systems is monitored and evaluated.

Through a review of documents, such as:

- the service's strategic plan
- ICT strategies
- records from relevant governance committees that are responsible and accountable for oversight of the information management systems
- policies, procedures, guidelines and protocols relevant to information management
- templates and forms used to collect information
- training records relevant to information management

- monitoring, evaluation, audits and compliance reports relevant to information management
- quality improvement plans relating to information management
- annual reports on information management.

Dimension: Capacity and capability

Theme 8: Use of information

Standard 8.2

Service providers have effective arrangements in place for information governance.

Scope of this standard

The scope of this national standard includes measures to support good information governance in the service.

What compliance with this standard looks like

1. Service providers have information governance arrangements in place to ensure the service uses information ethically and complies with legislation, national guidance and standards.
2. These arrangements take account of the need for compatibility, interoperability and sharing of information between departments inside the organisation and with services outside the organisation.
3. Services have an overarching information governance framework or policy — including a 'statement of information practices and privacy notice‡‡' — that ensures all requirements and responsibilities regarding information governance are met.
4. Services have a designated lead with assigned responsibility for information governance within the organisation.
5. All databases and or information management systems used in the service are registered with the Data Protection Commission in Ireland.
6. Services have structured arrangements in place to ensure information is:
    a) obtained fairly and efficiently
    b) recorded accurately and reliably
    c) held securely and confidentially
    d) used effectively and ethically

‡‡ Statement of information practices and privacy notice: a statement which is made available to the public that clearly outlines how an organisation handles personal information. It provides details on the type of personal information held by the organisation and the way in which this information is processed.

e) shared appropriately and lawfully
f) validated and evaluated for compliance and quality.

7. Services ensure that a privacy impact assessment (PIA) is conducted, at the planning stage, for all new projects and initiatives that involve the processing of personal health information. PIAs are also conducted for any proposals to amend existing information systems, sources or processes.
8. Services have appropriate arrangements and safeguards in place that ensure all formats of healthcare information (paper and electronic) and portable electronic devices are secure from unauthorised access.
9. Services have contingency plans in place to deal with expected and unexpected interruptions in access to information management.
10. All members of the workforce receive training and ongoing refresher training on information governance, appropriate to their role and responsibilities.
11. Services have arrangements in place, in line with relevant legislation, to facilitate people using the service to access a copy of their personal health information.
12. Services have a structure and process in place to manage information governance breaches and or near misses and a mechanism to enable the sharing of learning from such breaches and or near misses across the organisation.
13. Services regularly evaluate the effectiveness of their information governance systems and practices. Areas for improvement are identified and acted on.

Examples of information that may be used to find out if a service is compliant with the standard:

Through observation

- work practices in relation to how staff collect and record information
- arrangements in place to safeguard personal health information; for example, whiteboards, staff having to enter password details in order to log in and access electronic records or information systems.

Through communication with people who use the service, members of staff and management by asking:

People who use the service

- their views and experiences of:
  - their right to access information held about them
  - how their information may be used
  - the safeguards in place to protect their information
  - if they were informed about how their information would be stored, managed and disposed of when no longer needed.

Members of staff

- if staff are aware of their obligations in relation to information governance
- if staff receive training (induction and refresher training) in:
  - collecting, managing and processing information
  - information governance
- whether there is a data retention and destruction policy, procedure, guideline or protocol
- if all databases and portable electronic devices where health information is stored and displayed are password protected and encrypted
- what arrangements are in place to maintain the security of information
- if staff have an individual login and password to access electronic records.

Management

- how management assures itself that the service complies with relevant legislation, guidance, evidence-based practice and professional codes of conduct on the management of information
- how management assures itself that information governance arrangements, systems and processes used across the organisation are effective.

The relevant senior manager with responsibility for information governance

- if the service is fully compliant with its legal requirements, best available practice and professional codes of practice on information governance
- if the service has developed a 'statement of information practices and privacy notice' and if this is publicly available
- whether all the information management systems used in the organisation are registered with the Data Protection Commission
- if all members of the workforce are provided with training and refresher training on information governance appropriate to their role and responsibilities
- how often the policies, procedures, guidelines and protocols related to information governance are reviewed and updated
- what procedures are in place for the reporting of information governance breaches and or near misses
- how learning from information governance breaches and or near misses is shared across the organisation.

Through a review of documents, such as:

- information governance framework or policy
- statement of information practices
- privacy notices
- privacy impact assessments, where available

- self-assessments and associated action plans against relevant national standards for information governance
- relevant policies, procedures, guidance and protocols relating to information governance
- training records
- monitoring and evaluation records
- reports and associated quality improvement plans in relation to information governance and information governance breaches and or near misses.

Dimension: Capacity and capability

Theme 8: Use of information

Standard 8.3

Service providers have effective arrangements for the management of healthcare records.

Scope of this standard

The scope of this national standard includes arrangements for managing healthcare records.

What compliance with this standard looks like

1. There are arrangements in place to ensure that people using the service, and their records, are identified uniquely to avoid duplication and misidentification.
2. The management of healthcare records is in line with legislation, best available evidence, national standards and nationally agreed definitions. This includes accountability arrangements, management of individual records and records as a collective.
3. The service regularly evaluates the effectiveness of its healthcare records management systems and practices.
4. There are arrangements in place for the creation, use, storage and disposal of personal health information. These arrangements are in line with legislation, best available evidence and national guidance.
5. There is compliance with health information technical standards, where they exist, to facilitate the interoperability of systems and sharing of information.

Examples of information that may be used to find out if a service is compliant with the standard:

Through observation

- the location, storage and security of personal health information, in both paper and electronic formats
- how the service protects patients personal health information
- all databases and portable electronic devices that are capable of handling or displaying personal health information are password protected and encrypted

- access to stored healthcare records is only available to staff who have a professional need to access these records
- **reception areas** — to observe if people using the service are afforded sufficient space and privacy to provide personal information without the risk of being overheard by passers-by and bystanders
- **treatment areas —** to observe if services have implemented a range of measures to protect the privacy and confidentiality of people using services
- all filing cabinets used to store healthcare records or other personal data of people who use the service are locked securely to prohibit unauthorised access.

Through communication with people who use the service, members of staff and management by asking:

People using the service

- if they were advised about how their information would be managed
- if they were advised on how to access their healthcare records.

Members of staff

- what arrangements are in place to protect and safeguard the privacy and confidentiality of healthcare records and to protect them from loss and or accidental damage
- if all databases and portable electronic devices where health information is stored and displayed is password protected and encrypted
- if staff have an individual login and password to access electronic records
- how healthcare records are protected when being manually moved from one area in the organisation to another area
- if healthcare records are organised using a standard format
- if information in healthcare records is easily accessed when required in a timely and appropriate manner at the point of clinical decision-making at all times
- how healthcare records are retrieved when needed, including out of hours
- what the process is for identifying and reconciling duplicate healthcare records
- if there is an electronic tracking system in place to help identify the location of healthcare records
- what systems are in place to ensure that access to personal health information is limited to those who need access to it.

Management

- what procedures are in place to ensure that the use, storage and disposal of all records are in line with relevant legislation, guidance and standards

- what systems are in place to ensure buildings and areas where records are physically stored are secure and are only accessible by authorised persons
- if there is a data retention and destruction policy, procedure, destruction schedule or record, guideline or protocol
- how access to personal health information by authorised personnel is monitored and audited
- what measures are in place in relation to the security of healthcare records and protection against loss from flood or fire or other significant events
- what processes are in place to ensure that referrals are managed in line with national standards and guidelines
- what systems are in place to monitor and evaluate the management of healthcare records, including access to personal health information, to ensure compliance with legislation, guidance and standards.

Through a review of documents, such as:

- policies, procedures, guidelines or protocols related to healthcare records management
- data retention and destruction policy
- data or record retention schedule
- monitoring and evaluation records and or reports related to healthcare records management
- a sample of healthcare records.

4.2 Guidance on the assessment-judgment framework for the *National Standards for Safer Better Healthcare* related to quality and safety

This section discusses the themes and standards relevant to the dimension of quality and safety. It outlines standards related to care and support provided to people who use the service related to safe care, effective care and person-centred care. It also includes how healthcare services support people to improve their health and wellbeing.

Theme 1: Person-centred care and support

This section of the guidance describes the national standards relevant to person-centred care and support. Respecting and promoting the dignity, privacy and autonomy of people using services are core aspects of this theme. Person-centred care and support also prioritises the protection of the rights of people accessing and receiving healthcare and ensures that a culture of kindness, consideration and respect is promoted and valued.

Healthcare service providers consider the needs and preferences of people using the service in the planning, design and delivery of services. By doing so, they can achieve a better service experience for patients and people using services. Healthcare services engage with local communities and people living in the service's catchment area whenever they are making key decisions about services.

Assessing the collective healthcare needs and priorities of both these communities and those populations — and using best available evidence of what works best in terms of service structure, design and delivery — supports providers to better plan and design services.

Person-centred care supports equitable access to healthcare so that access to healthcare services is based on a person's assessed needs. Service providers should also ensure that the access needs of people using the service are identified and met in line with their needs and relevant legislation.

Good communication with people using services is also a central focus of this theme. People using the service need clear and relevant information, which is communicated to them in an appropriate manner, in order to enable them to make decisions about their care and treatment. Information is provided in different formats and languages and is widely available and easily accessible.

People are facilitated to make informed decisions about their care and treatment. Service providers ensure that people using the service have as much information as they need and want about their condition, and the risks, benefits or alternatives of any proposed treatments. Healthcare teams ensure that people using the service are

given regular opportunities and adequate time to discuss their condition. People using the service are also encouraged to ask questions and to indicate how well they have understood the information they have been given.

Obtaining informed consent for treatment is a two-way process of communication between the person using the service and an appropriate healthcare professional. Consent may be in writing, spoken or implied (in exceptional circumstances, such as in an emergency situation). Service providers follow evidence-based practice for obtaining consent and ensure it is obtained in line with legislation and up-to-date guidance.

Good communication is also central to successful complaints-handling and will assist in minimising the likelihood of complaints occurring in the first place. Having an effective complaints process in place provides people using the service with the opportunity to express their views when they feel their experience and the care they have received have been poor. A good complaints process allows service providers to identify areas for service improvement.

Publicly-funded healthcare services have clear and transparent decision-making processes in place to ensure that people using the service can access the care they need based solely on their assessed clinical needs, in order to achieve the best possible outcomes. Decision-making processes in person-centred services take account of the availability of resources and the responsibility to act in the collective best interests of all people using the service.

Health services and staff recognise the diversity of Ireland's population. People using the service have differing social, cultural and other needs, and service providers need to facilitate those receiving healthcare services to exercise their civil and religious rights as enshrined in law. In addition, access to and receipt of healthcare should be equitable and comply with legislation irrespective of age, gender, sexual orientation, disability, marital status, family status, race, religion or membership of the Traveller community.

How a service promotes and respects the dignity, privacy and autonomy of people using the service is fundamental to person-centred care. It can also contribute to better healthcare outcomes. Respecting a person's autonomy involves meaningful communication. People who use services must be listened to, and what is important to them must be viewed as important to the service. Dignity means treating people with compassion and in a way that values them as human beings and supports their self-respect, even if their wishes are not known at the time.

Dimension: Quality and safety

Theme 1: Person-centred care and support

Standard 1.1

The planning, design and delivery of services are informed by service users' identified needs and preferences.

Scope of this standard

The scope of this national standard includes: identifying the needs and preferences of people using the service; involving people using the service in the planning, design and delivery of services; using feedback to improve services; and evaluating how services meet the needs and preferences of people who use the service.

See also national standards 2.2, 2.6 to 2.8, 3.1, 3.2, 3.5, 3.7, 4.1, 5.2, 5.4, 5.8, 6.1, 6.4, 7.1 and 8.1.

What compliance with this standard looks like

1. The collective needs and preferences of people using the services are proactively and systematically identified through a population healthcare needs assessment. This involves identifying the collective healthcare needs of the local population (which may differ depending on demographic profile, common health conditions and social needs of the population) so that services can be planned and delivered to meet those needs.
2. People using the service are involved in key stages of planning, design and delivery of healthcare services and are kept informed regarding key decisions and how their collective needs and preferences have been considered.
3. Services are delivered at a time and place which takes into account the preferences of people who use the service, where this can be provided safely, effectively and efficiently.
4. Services are flexible and respond to the changing needs and preferences of people using the service by changing services where this can be done safely, effectively and efficiently.

5. There is coordination of care within and between services that takes account of the needs and preferences of people using the services.
6. Feedback from people using the service is sought and is used to continually improve the experience of all people using the service.
7. Services are regularly evaluated to assess how well the identified needs and preferences of people using the service are being met.

Examples of information that may be used to find out if a service is compliant with the standard:

Through observation

- information on display about how people using the service can provide feedback on the service
- availability of feedback forms
- implementation of changes to services as a result of feedback received from people using the service.

Through communication with people who use the service, members of staff and management by asking:

People who use the service

- how their individual and collective needs, preferences and choices are identified
- if and how they were involved and kept informed about the design and planning of services
- if services are flexible to their needs and delivered at a time and place that takes into account their needs and preferences, where this can be delivered safely, effectively and efficiently
- if and how their feedback is sought regarding how care or services could be improved.

Members of staff and management

- how the collective healthcare needs and preferences of people using the service are proactively identified and how this is communicated
- how feedback from people using the service, including their collective needs and preferences, is sought and used in planning, design and delivery of services
- how the service can be flexible and respond to the changing needs of people who use the service
- how services are coordinated within and between services
- how people using the service and staff are kept informed of key decisions during the process
- if services are evaluated to assess how well they are meeting the identified needs and preferences of people using the service
- what improvements have been implemented following evaluation of the collective needs and preferences of people using the services.

Through a review of documents, such as:

- population healthcare needs assessments
- National Care Experience Programme reports and resulting quality improvement plans (QIPs)
- feedback from people using the service
- patient experience survey reports
- complaints analysis reports
- service improvement plans developed in response to feedback from people using the service
- records of feedback from stakeholders and interested parties
- records of meetings held with advocacy groups and representatives of people using the service in relation to planning, design and delivery of services
- assessment documentation, including recording of needs and preferences
- a sample of healthcare records.

Dimension: Quality and safety

Theme 1: Person-centred care and support

Standard 1.2

Service users have equitable access to healthcare services based on their assessed needs.

Scope of this standard

The scope of this national standard includes: equitable access to healthcare services; decision-making processes supporting access to care; provision of clear information about accessing services; and access for people with additional physical, sensory and language-access needs.

See also national standards 2.2, 2.7, 4.1, 5.5 and 7.1.

What compliance with this standard looks like

1. Services are designed to promote equitable access for people using the service irrespective of factors such as gender, age or geographical location. Access to services is based on:

    a) needs assessment
    b) best available evidence
    c) relevant eligibility criteria
    d) the fair deployment of resources
    e) collective best interests of all people using the service.

2. There are clear and transparent decision-making processes to facilitate people's access to healthcare services, including:

    a) referral pathways
    b) systems for screening referrals
    c) systems for managing patient flow
    d) systems, policies and criteria for admission, transfer and discharge
    e) regular evaluation of the effectiveness of these processes.

3. There is clear and relevant information about the services available and how these can be accessed, in different formats, to facilitate the diverse needs of people using the service.

4. The access needs of the population served are identified, including their physical, sensory and language needs, and there are arrangements in place to meet these needs in line with relevant legislation.

Examples of information that may be used to find out if a service is compliant with the standard:

Through observation

- information displayed on how to access services
- signage and way finding[§§]
- how facilities and services are designed and delivered for people with additional physical, sensory and language-access needs.

Through communication with people who use the service, members of staff and management by asking:

People who use the service

- how they accessed the service
- the time frame when accessing services
- how facilities and services met their additional physical, sensory and language-access needs.

Members of staff and management

- how services are designed to promote equitable access and ensure available resources are deployed fairly
- how people who use the service access services based on their assessed needs, best available evidence and eligibility criteria
- what decision-making processes are in place, including referral pathways, to facilitate access to healthcare services
- what systems are in place to manage patient flow to ensure people can access services
- what types of delays or challenges exist in relation to patient flow and access to services
- what information is available about accessing services and whether it is available in a usable format for people using the service
- how services meet the physical, sensory and language needs of the population served, in line with relevant legislation.

[§§] Way finding refers to information systems that guide people through a physical environment and enhance their understanding and experience of the space.

Through a review of documents, such as:

- admission, transfer, discharge policies and criteria
- needs assessment
- referral criteria or pathways
- monitoring and evaluation of referral pathways, access to care, patient flow, accessibility, way finding
- signage and way finding plans
- patient information leaflets
- a sample of healthcare records.

Dimension: Quality and safety

Theme 1: Person-centred care and support

Standard 1.3

Service users experience healthcare which respects their diversity and protects their rights.

Scope of this standard

The scope of this national standard includes diversity and the rights of people using the service, and training for the workforce on diversity awareness.

See also national standards 1.2, 2.2 and 4.1.

What compliance with this standard looks like

1. People who use the service are facilitated to exercise their civil and religious rights as enshrined in Irish law, as far as reasonably practicable, when they are receiving healthcare.
2. The service ensures that people's initial and ongoing access to healthcare complies with relevant equality and anti-discrimination legislation in Ireland.
3. Service providers have arrangements in place that ensures all people using the service — regardless of age, gender, sexual orientation, disability, marital status, family status, race, religious belief or membership of the Traveller community — experience the same level of access to healthcare services.
4. Services promote autonomy and respect the diversity of those who use the services.
5. There is engagement with support agencies in the community and specific initiatives to target the needs of diverse groups in the service's catchment area.
6. The service provides diversity awareness training (including intercultural awareness and disability awareness training) for all staff.

Examples of information that may be used to find out if a service is compliant with the standard:

Through observation

- staff interactions with people using the service
- information displayed about access to interpreting services
- arrangements in place to address the diverse needs of people using the service.

Through communication with people who use the service, members of staff and management by asking:

People who use the service

- how their cultural, religious, language and literacy needs are met
- if their specific dietary requirements are catered for
- for their views about how their care was provided in a way that respected their rights, diverse values, beliefs and needs.

Members of staff

- how they provide care that respect rights, diverse values, beliefs and needs of people using the service
- how the service makes appropriate provision, where possible, for cultural practices, such as specific dietary requirements
- how the service provides information in accessible, culturally responsive ways
- if there is a process or list of contacts for accessing religious group representatives when needed
- if interpreter services are available for people using the service and if staff have 24/7 access to the service
- what advocacy services are available for people who use the service
- if they have had diversity awareness training (including intercultural awareness and disability awareness training).

Management

- how people who use the service are facilitated to exercise their civil and religious rights as enshrined in Irish law and in human rights based legislation, as far as reasonably practicable, when they are receiving healthcare
- how the service is assured that the service complies with relevant equality and anti-discrimination legislation
- what arrangements are in place that ensures all people using the services (regardless of age, gender, sexual orientation, disability, marital status, family

status, race, religious belief or membership of the Traveller Community) experience the same level of access to and delivery of services
- how the service actively engages with people from minority ethnic groups, advocacy groups and support agencies in the community
- how the service uses feedback from these groups and agencies in the design, planning, delivery and evaluation of services, while ensuring the needs of diverse groups are met
- how facilities are designed to support access for people with disabilities who are using the service
- whether policies, procedures and guidelines are developed to include and outline how care is to be provided that is respectful of rights, diverse values, beliefs and behaviours
- if staff receive diversity awareness training (including intercultural awareness and disability awareness training).

Through a review of documents, such as:

- policies, procedures, protocols and guidelines in relation to delivering care which respects the diversity and protects the rights of people using the service
- patient information leaflets about advocacy or interpreting services
- those outlining the monitoring and evaluation of information and complaints in relation to respecting diversity
- patient experience survey reports
- sample menus that meet specific dietary requirements
- a sample of healthcare records
- records of meetings with community advocacy groups and support agencies
- staff training records.

Dimension: Quality and safety

Theme 1: Person-centred care and support

Standard 1.4

Service users are enabled to participate in making informed decisions about their care.

Scope of this standard

The scope of this national standard includes: access to clear, timely and relevant information and support services for people using the service; and enabling individuals to exercise choice and make informed decisions about care.

See also national standard 2.2.

What compliance with this standard looks like

1. Service providers ensure that access to clear, timely and relevant information is available for people using the service about their condition, treatment options and health services available to them.
2. People using the service are actively facilitated to exercise choice, as much as possible, in the ongoing planning and delivery of their care and treatment. This includes giving people regular opportunities and adequate time to discuss their condition, ask questions and to indicate how well they have understood the information they have been given.
3. Service providers facilitate people using the service in accessing patient support services and advocacy groups where appropriate.
4. People using the service are informed in advance of any direct financial costs to them for services they may receive.

Examples of information that may be used to find out if a service is compliant with the standard:

Through observation

- how staff interact with people who use the service to see how they are enabled to make decisions about their care.

Through communication with people who use the service, members of staff and management by asking:

People using the service

- if they are given the opportunity to be involved in decisions about their care and treatment
- if they are informed about patient support services including, where appropriate, independent support groups
- if they are informed about direct financial costs where relevant.

Members of staff and management

- how people using the service are provided with information about their condition, treatment options and services available to them
- how people using the service are actively facilitated, in so far as possible, to exercise their choice in the ongoing planning and delivery of their care and treatment
- about the availability of professional interpretation services when required
- how people using the service are facilitated to access patient support services and advocacy groups if they wish to do so
- how people using the service are informed about any direct financial costs to them prior to receiving treatments.

Through a review of documents, such as:

- patient information leaflets
- feedback from people using the service
- records held by the service provider of engagement with stakeholders and interested parties
- a sample of healthcare records.

Dimension: Quality and safety

Theme 1: Person-centred care and support

Standard 1.5

Service users' informed consent to care and treatment is obtained in accordance with legislation and best available evidence.

Scope of this standard

The scope of this national standard includes: informed consent to care and treatment; consent process and policy; and consent for children and those who lack capacity.

See also national standard 5.10.

What compliance with this standard looks like

1. There are arrangements in place to obtain informed consent from people who use the service in line with legislation and best available evidence.
2. There are effective arrangements in place that protect the best interests of children and people using the service who lack the capacity to give informed consent.
3. Education, development and training is provided to ensure all members of the workforce understand the consent process, including the exceptional circumstances under which obtaining consent may not be possible; for example, in an emergency situation.
4. There are arrangements in place to monitor and evaluate the effectiveness of obtaining informed consent. Steps are taken to address any identified areas for improvement.

Examples of information that may be used to find out if a service is compliant with the standard:

Through communication with people who use the service, members of staff and management by asking:

People using the service

- How they were supported to make informed decisions about their care and whether they had access to advocacy services

- how informed consent was obtained in relation to their care and treatment and if the benefits and disadvantages or potential risks of treatment or care were explained to them
- if they were given appropriate opportunities to ask questions
- if information was provided in a clear and easy-to-understand way.

Members of staff and management

- about the process for obtaining informed consent from people using the service for their treatment and care
- if there is access to interpreters 24/7 if needed to obtain consent
- if staff are provided with education and training on how to obtain consent and on the consent policy and form
- about the procedures in place for obtaining informed consent
- if there are specific requirements in place for obtaining consent for or on behalf of children or those who lack capacity to give consent
- if consent is always sought by the appropriate person with the required knowledge and expertise
- how they are assured that consent is always obtained in line with relevant legislation and best available evidence
- if the hospital has an up-to-date guidance on 'do not attempt cardiopulmonary resuscitation (DNACPR).

Through a review of documents, such as:

- local consent policies
- local consent forms
- education and training records
- guidance on cardiopulmonary resuscitation (CPR) and do not attempt resuscitation (DNAR) and associated forms
- monitoring and evaluation records and or reports of obtaining consent
- a sample of healthcare records.

Dimension: Quality and safety

Theme 1: Person-centred care and support

Standard 1.6

Service users' dignity, privacy and autonomy are respected and promoted.

Scope of this standard

The scope of this national standard includes: dignity, privacy and autonomy in relation to the physical environment; communication; provision of individual care; and protection of personal information.

See also national standards 1.1, 1.3, 1.4, 1.7, 2.2, 2.3, 5.2, 5.5, 8.1 and 8.2.

What compliance with this standard looks like

1. Care, including end-of-life care, is designed and delivered in a manner that promotes the dignity, privacy and autonomy of people using the service.
2. The service provider designs, manages and ensures the physical environment promotes and protects the dignity, privacy and autonomy of people using the service.
3. The service provider has systems and structures in place so that a person using the service:
    a) is communicated with in a manner that respects their dignity and privacy
    b) is cared for in an environment that ensures their dignity and privacy when they are receiving personal care
    c) is made familiar with their immediate surroundings and advised about how to get assistance
    d) is supported with their specific individual needs to ensure their dignity and privacy is respected and maintained
    e) has their autonomy promoted and supported while receiving care and treatment.

4. The service has systems in place to ensure that the personal information of people using the service is protected at all times in line with legislation and best available evidence.

Examples of information that may be used to find out if a service is compliant with the standard:

Through observation

- clinical areas to ensure the privacy and dignity of people using the service is maintained
- the physical environment to establish if it meets the needs of people using the service with regard to promoting their dignity, privacy and autonomy
- how staff communicate with people who use the service
- how people using the service are supported with their individual needs in a way that ensures their dignity and privacy is respected and promoted
- how their autonomy is promoted and supported while receiving care and treatment
- how personal information of people using the service is protected.

Through communication with people who use the service, members of staff and management by asking:

People using the service

- about their experiences of how their dignity, privacy and autonomy are promoted and protected
- if the physical environment promotes and protects their dignity and privacy
- whether they were advised about how to get assistance if needed.

Members of staff

- how the dignity, privacy and autonomy of people who use the service are promoted and protected when care, including end-of-life care, is being provided
- how the physical environment is managed to promote and protect the dignity, privacy and autonomy of people who use the service
- how the personal information of people using the service is protected at all times in line with legislation and best available evidence.

Management

- how management are assured that staff communicate in a manner that respects the dignity and privacy of people using the service
- how management are assured that staff at all times respect people's dignity and privacy when they are receiving personal care or attending to their own personal care
- about the systems and processes in place to ensure end-of-life care is provided in a manner which promotes the dignity, privacy and autonomy of people using the service.

Through a review of documents, such as:

- relevant policies, procedures and guidelines
- education and training records
- patient experience survey reports
- feedback from people using the service
- quality improvement plans
- codes of conduct
- a sample of healthcare records.

Dimension: Quality and safety

Theme 1: Person-centred care and support

Standard 1.7

Service providers promote a culture of kindness, consideration and respect.

Scope of this standard

The scope of this national standard includes: promotion of a culture of kindness, active listening and communication with people who use the service; proactive identification of individuals that may be more vulnerable than others; and taking into account people's views, values and preferences.

See also national standards 1.1, 1.4, 1.6, 2.2, 2.4, 3.4 to 3.6, 4.1, 4.2 and 5.6.

What compliance with this standard looks like

1. The service actively promotes a culture of kindness, consideration and respect through its:
    a) mission statement
    b) service design
    c) code of conduct
    d) training and development of staff
    e) evaluation processes.
2. People using the service are:
    a) communicated with in an open and sensitive manner
    b) actively listened to in line with their expressed preferences and needs
    c) offered opportunities to raise any issues relevant to their care and are supported to explore and discuss these issues.
3. The service provider proactively identifies and recognises stages of care (for example, approaching end of life) and treatment where a person using the service may be more vulnerable. The service provider then provides mechanisms to support such people using the service.
4. People's views, values and preferences are actively sought and taken into account in the provision of their care.

Examples of information that may be used to find out if a service is compliant with the standard:

Through observation

- how staff communicate and interact with people who use the service
- mission statements on display in public and clinical areas.

Through communication with people who use the service, members of staff and management by asking:

People who use the service

- if they experience kindness, consideration and respect when care is being provided
- if staff actively listen and communicate in a manner that is open and sensitive
- if their views, values and preferences are actively sought and taken into account
- if their expressed needs and preferences are sought.

Members of staff and management

- how the service promotes a culture of kindness, consideration and respect for people using the service and how this is evaluated
- how feedback is actively sought from people using the service with regard to their views, values and preferences and how these are taken into account in the provision of their care
- what mechanisms are in place to support stages of care and treatment where a person using the service may be more vulnerable, such as end of life or transitioning from paediatric to adult services
- if staff are aware of the service's mission statement
- if the hospital provides effective communication skills training.

Through a review of documents, such as:

- mission statements
- feedback from people using the service
- patient experience survey reports
- complaints analysis reports
- education and training records
- a sample of healthcare records.

Dimension: Quality and safety

Theme 1: Person-centred care and support

Standard 1.8

Service users' complaints and concerns are responded to promptly, openly and effectively with clear communication and support provided throughout this process.

Scope of this standard

The scope of this national standard includes: management of complaints and concerns; timely response to complaints and concerns; communication; and access to support services for people making complaints or raising concerns.

See also national standards 1.4, 3.1, 3.5, 5.7, 5.8 and 6.4.

What compliance with this standard looks like

1. The service provider has a complaints procedure in place that takes account of legislation, relevant regulations, national guidelines and best available evidence. The complaints procedure is clear, transparent, open and accessible to people using the service.
2. The service provider has a complaints officer in place.
3. There is oversight and monitoring of the timeliness of response and management of complaints, taking into account the requirements to fully address the issues raised by the complainant.
4. The complaints procedure identifies the expectations of people using the service who make complaints and ensures their expectations are taken into account, explored and addressed.
5. There is a coordinated response to people who make a complaint. This response includes information from healthcare professionals when their care is shared or transferred from one service provider to another. The sharing of people's information is carried out in line with data protection legislation and best practice.
6. There is support for a culture in which a person's care is not negatively affected as a result of them having made a complaint or having expressed a concern.

7. The service provider ensures that there is a supportive environment for people using the service that encourages them to provide feedback, raise concerns or make complaints verbally or in writing in a culture of openness and partnership.

8. The service provider has arrangements in place to provide and or facilitate support services such as independent advocacy services.

Examples of information that may be used to find out if a service is compliant with the standard:

Through observation

- information on display for people using the service about how to make a complaint provide feedback or raise a concern
- information available about advocacy services.

Through communication with people who use the service, members of staff and management by asking:

People who use the service

- if and how they would go about providing feedback, raising concerns or making a complaint.

Members of staff

- how a complaint, concern or feedback from a person using the service is processed and managed
- if staff receive education and training in the management of complaints and concerns to fulfil their roles and responsibilities
- how staff provide people using the service with information on how to make a complaint, provide feedback or raise a concern
- how a person who uses the service is facilitated to access support services, such as independent advocacy services
- about ways in which all individuals are supported to provide feedback, raise a concern or make a complaint.

Management

- how they are assured that the service complies with legislative requirements for the management of complaints
- if there is an identified staff member responsible for the management of complaints and concerns

- how the service proactively monitors, analyses and responds to complaints, concerns and compliments to ensure response timelines are met, taking into account the requirements to fully address the issues raised
- if there is a review of the effectiveness of the complaints management process that includes feedback from people using the service of their experience of the process
- if a resolution is not possible, does the complaints mechanism ensure that the complaint is addressed at the appropriate level within the governance structure
- if there is an annual report that details:
  - the total number of complaints received
  - the nature of the complaints
  - the number of complaints resolved by informal means
  - the number of any investigations not yet completed
- what arrangements are in place to ensure a person using the service who makes a complaint is not negatively affected as a result
- what arrangements are in place to ensure that a person using the service who makes a complaint is facilitated to access support services, such as independent advocacy services.

Through a review of documents, such as:

- complaints policy
- monitoring and evaluation records of complaints, concerns and or compliments
- complaints analysis reports
- patient experience survey reports
- feedback from people using the service
- records of meetings regarding the management of complaints, concerns and or compliments
- annual reports
- a sample of complaints
- a sample of healthcare records.

Dimension: Quality and safety

Theme 1: Person-centred care and support

Standard 1.9

Service users are supported in maintaining and improving their own health and wellbeing.

Scope of this standard

The scope of this national standard includes: promoting and supporting better health for people using the service; and supporting individuals to identify key health priorities and opportunities to maintain and improve their health and wellbeing.

See also national standards 2.2, 2.7, 3.6, 4.1 and 5.6.

What compliance with this standard looks like

1. The service provider has initiatives and programmes to actively develop and support a culture that promotes better health for people using the service.
2. There is a structured approach to support people using the service to identify their key health priorities and identify opportunities on how to maintain and improve their health and wellbeing.
3. The service provider has initiatives and programmes in place to facilitate people who use the service to have greater responsibility for maintaining and improving their own health and wellbeing.

Examples of information that may be used to find out if a service is compliant with the standard:

Through observation

- health promotion posters displayed in clinical areas
- patient information leaflets which are available.

Through communication with people who use the service, members of staff and management by asking:

People who use the service

- about their views on initiatives, programmes and ways they were assisted to identify their key health priorities and ways of how to maintain and improve their health and wellbeing

- whether they were offered information in accessible formats in relation to activities and practices that maintain and improve their own health and wellbeing.

Members of staff

- what systems or structures are in place to support a person using the service to identify key health priorities and opportunities on how to maintain and take responsibility for their own health and wellbeing
- if the hospital is proactive in developing support systems for people using the service to identify their key health priorities and to identify opportunities about how to maintain and improve their health and wellbeing
- how prevention, early detection and models of self-care for people living with chronic conditions have been incorporated into clinical strategies or programmes
- what initiatives or programmes are in place to facilitate people who use the service to have greater responsibility for maintaining and improving their own health and wellbeing.

Management

- how the service supports a culture that promotes better health for all people using the service
- if health and wellbeing goals are incorporated into the organisation's service plan or strategy
- what specific mechanisms or structures has the service in place to engage with people using the service in order to discuss ways of maintaining and improving their current and future health
- what type of events are organised to promote beneficial lifestyle habits or changes to lifestyle.

Through a review of documents, such as:

- health promotion material
- a sample of healthcare records.

Theme 2: Effective care and support

This section of the guidance describes the standards associated with the delivery of effective care and support. As set out in the standards, the fundamental principle of effective care and support is that it consistently delivers the best achievable outcomes for people using a service within the context of that service, and the resources available to it.

The delivery of healthcare is complex and to be effective, it needs to be planned, organised and managed based on best available evidence that will maximise the benefits for people using the service. Service providers should develop and implement evidence-based policies, procedures, protocols and guidelines that incorporates national and international clinical guidelines and care pathways.

Access to high-quality information that is accurate and up to date should be at the centre of healthcare decision-making at all times. This enables staff to make timely clinical decisions based on evidence, and it is critical to improving outcomes for people who use the service and for supporting delivery of effective care.

Care should be planned in consultation with the person using the service, in order to meet their initial and ongoing assessed needs. Each person should have an individual plan of care developed and delivered in a timely manner by healthcare staff who have the appropriate competencies and which is based on best information available.

Each person using a service should have a clearly identified and documented healthcare professional who has overall responsibility and accountability for their care. Each person should know who the responsible healthcare professional is, and be able to discuss their care with them.

Services should have formal systems in place for the effective coordination of care within and between services where there are multiple healthcare professionals involved. When a person's healthcare needs cannot be met within the scope of the service, their care should be transferred to the appropriate service. Referral and transfer pathways should be supported by evidence-based guidance which supports the safe and effective management of integrated care.

Where a person transfers to another service, the individual is consulted with and there should be a formal, documented handover of information and accountability for the overall care of the person.

Care is provided through a model of service designed to deliver high-quality, safe and reliable healthcare. Services should be continually reviewed to ensure the model of care meets the needs of the population, is in line with up-to-date evidence and is achieving expected outcomes.

The environment in which healthcare is delivered supports the effectiveness of care. A well-planned physical environment promotes the dignity and respect of the people who use the service. It also considers their clinical, physical and sensory needs, protects them from harm and adverse events and supports healthcare staff to provide good quality and safe care. Premises and facilities need to comply with legislation and guidance, be well planned, continually assessed and maintained to meet the needs of people who use the service and promote delivery of high-quality, safe and reliable care.

An effective service continually looks for opportunities to improve how it cares for and supports people who use the service. Continual monitoring and evaluation is key to the provision of safe and effective care. Monitoring and evaluation of the quality of the service, including feedback from people using the service and the workforce, provides assurance about the effectiveness of the service and allows the service provider to address any areas for improvement.

Dimension: Quality and safety

Theme 2: Effective care and support

Standard 2.1

Healthcare reflects national and international evidence of what is known to achieve best outcomes for service users.

Scope of this standard

The scope of this national standard includes: delivery of healthcare according to best available national and international evidence through policies, procedures, protocols, guidelines, care pathways and care bundles; and supporting staff in evidence-based decision-making and practice.

See also national standards 2.6, 3.1, 3.3, 3.4, 5.4. and 6.3.

What compliance with this standard looks like

1. Healthcare is delivered in line with policies, procedures and guidelines based on best available evidence.[***]
2. National clinical guidelines and nationally agreed policies, procedures and guidelines are used.
3. National clinical guidelines are regularly reviewed to see what is relevant to the care and treatment provided. Where gaps are identified (between guidelines and current practice) steps are taken to address identified gaps to ensure guidelines are implemented.
4. If national clinical guidelines cannot be fully implemented, a risk assessment is undertaken and clearly documented and appropriate action is taken to ensure the quality and safety of services.
5. National clinical guidelines are adopted and adapted for local use, and considered when assessing and planning the care of each individual using the service.

[***] Policies, procedures and guidelines also include national clinical guidelines, protocols, care pathways and care bundles.

6. There is an evidenced-based process for the development of policies, procedures, and guidelines.

7. The workforce are supported and facilitated in making decisions based on best available evidence.

8. Staff are supported in making evidence-based clinical decisions which will maximise benefits to people using the service and minimise unnecessary treatment and care.

Examples of information that may be used to find out if a service is compliant with the standard:

Through observation

- if the care provided to the people who use the service is in line with the hospital's policies, procedures, and guidelines and relevant national clinical guidelines.

Through communication with people who use the service, members of staff and management by asking:

People who use the service

- if the care, education and information they receive is in line with hospital policies, procedures, and guidelines and relevant national clinical guidelines.

Members of staff:

- how staff are aware of and use the relevant hospital's policies, procedures, and guidelines and relevant national clinical guidelines
- how staff are supported and facilitated in making evidence-based clinical decisions.

Management

- the approval and development process for the hospital's policies, procedures, and guidelines and relevant national clinical guidelines
- how the hospital's policies, procedures and guidelines are reviewed and updated
- how management are assured that healthcare is delivered based on the hospital's policies, procedures, and guidelines and relevant national clinical guidelines
- how they ensure national clinical guidelines are consistently implemented
- what action is taken where national clinical guidelines cannot be fully implemented to ensure the quality and safety of services, such as carrying out risk assessments.

Through a review of documents, such as:

- the hospital's policy for developing, approving, monitoring and implementing of the hospital's policies, procedures, and guidelines
- local policies, procedures, and guidelines
- monitoring and evaluation of policies, procedures, and guidelines
- risk assessments where national guidance cannot be fully implemented
- action plans
- records from the governing committees that review and approve policies, procedures, and guidelines
- audits undertaken by the service to assess compliance with policies, procedures and guidelines.
- a sample of healthcare records

Dimension: Quality and safety

Theme 2: Effective care and support

Standard 2.2

Care is planned and delivered to meet the individual service user's initial and ongoing assessed healthcare needs, while taking account of the needs of other service users.

Scope of this standard

The scope of this national standard includes assessment of individual's healthcare needs by the appropriate healthcare professional; providing timely appropriate care and treatment; identifying, discussing and reviewing outcome goals; and transfer of care.

See also standards 1.1, 1.4, 6.2 and 6.3.

What compliance with this standard looks like

1. Care is planned and delivered based on an individual's initial and ongoing assessed healthcare needs.
2. The planning and delivery of care considers the collective priorities and the healthcare needs of people using the service as a whole.
3. Assessment of the individual's healthcare needs is undertaken by healthcare professionals with the necessary expertise and competencies to assess, plan and deliver their care.
4. Each individual is assessed and treated in line with their prioritised needs in a timely and appropriate way. Assessment includes the individual's initial and ongoing physical, psychosocial, spiritual, cultural, social and emotional needs. It also considers their health history and any relevant socioeconomic factors.
5. Assessment and treatment is responsive to an individual's changing needs.

6. Individual outcome goals are clearly defined and are:

    a) based on the individual's assessed needs
    b) planned and agreed between the individual and their healthcare professional
    c) regularly reviewed and revised to ensure effectiveness
    d) regularly reviewed with the individual to make sure they are still in line with their changing needs and preferences.

7. When a person's care and treatment cannot be provided by the service, the necessary arrangements are made, in consultation with the person, to transfer their care to the appropriate service.

Examples of information that may be used to find out if a service is compliant with the standard:

Through observation

- how care of people who use the service is assessed, planned, delivered and evaluated
- if people who use the service are involved in the assessment, planning, delivery and evaluation of their care
- visual displays and or directional signs to guide staff and visitors of people's care needs
- staff practices.

Through communication with people who use the service, members of staff and management by asking:

People who use the service

- for their views about the care they are receiving
- if staff consult with them about their care
- if they know what care is planned for them.

Members of staff and management

- what systems are in place to ensure care is planned and delivered to meet the initial and ongoing needs of the people who use the service
- how the collective priorities and needs of others using the service are considered in the planning and delivery of care
- if people who use the service are assessed by a healthcare professional with the necessary competencies and information to plan and deliver their care
- if people who use the service are assessed and treated in a timely and appropriate manner

- how the systems in place ensure each individual is assessed and treated in line with their prioritised needs in a timely and appropriate way
- whether assessments include the individual's initial and ongoing physical, psychosocial, spiritual, cultural, social and emotional needs, health history and any relevant socioeconomic factors
- what arrangements are in place to ensure early detection and emergency response for a patient whose condition is deteriorating
- what systems are in place to ensure effective assessment and care planning for people at end of life
- if people who use the service have their care prioritised according to their needs
- if outcome goals are clearly defined, based on the needs and preferences of the person who uses the service and regularly reviewed and changed if needed
- the arrangements in place for when an individual's care or treatment cannot be provided by the service
- how the service consults with people using the service about arrangements in place if their care or treatment cannot be provided.

Through a review of documents, such as:

- policies, procedures and guidelines for assessment, planning and delivery of care
- patient assessment tools
- transfer and referral pathways and policies (internal and external)
- records of monitoring and evaluation of assessment, planning and delivery of care
- a sample of healthcare records
- risk assessments
- audits of compliance with policies, procedures and guidelines
- staff training records.

Dimension: Quality and safety

Theme 2: Effective care and support

Standard 2.3

Service users receive integrated care which is coordinated effectively within and between services.

Scope of this standard

The scope of this national standard includes: coordination of care, including transfers of care, integrated care, sharing of information between healthcare professionals and services, and clinical handovers.

See also national standards 2.4 to 2.6, 3.1 and 8.1.

What compliance with this standard looks like

1. Services have formal systems in place to coordinate safe and effective care for individuals whose care is provided by more than one healthcare professional, team or service. This is done in partnership with people using the service while respecting their confidentiality.
2. Services which are sharing or transferring an individual's care work together to ensure best possible patient outcomes.
3. Information is shared between relevant healthcare professionals, teams or services, in a timely and appropriate manner, in line with relevant policies, national guidelines, professional codes and data protection legislation.
4. Appropriate arrangements are in place to facilitate effective communication and multidisciplinary team working to deliver integrated care.
5. Information is provided to people using services and other service providers about the process for transfer of care, to ensure clarity for both parties.

Examples of information that may be used to find out if a service is compliant with the standard:

Through observation

- clinical handover
- multidisciplinary team meetings
- safety pauses
- surgical safety checklist practices.

Through communication with people who use the service, members of staff and management by asking:

People who use the service

- if they are satisfied with the coordination of their care between healthcare professionals or services
- if they are satisfied with the manner in which their information is shared between healthcare professionals or services
- how they are kept informed about any sharing or transfer of their care.

Members of staff and management

- how an individual's care is coordinated when care is provided by, or transferred between, more than one healthcare professional, team or service
- how effective is the multidisciplinary team working and communication when delivering integrated care
- if there is timely sharing of accurate information to facilitate care, in a manner which respects the individual's confidentiality and in line with relevant legislation
- how safety is maintained when people who use the service move between departments, units or services (transitions in care)
- how the service ensures the individual using the service is involved and informed
- how information is handed over at the end of each shift cycle, or when transferring patients between units, services or other departments (transitions in care).

Through a review of documents, such as:

- admission, referral, discharge and transfer policies and transfer forms
- records from multidisciplinary meetings and case conferences
- local protocols for surgical safety checklists preventing wrong-site, wrong-procedure and wrong-person surgery 'time-outs'
- local guidance on safety pauses
- monitoring and evaluation of referrals and transfers
- monitoring and evaluation of transitions in care between units, departments and or services
- monitoring and evaluation of surgical safety checklists
- a sample of healthcare records.

Dimension: Quality and safety

Theme 2: Effective care and support

Standard 2.4

An identified healthcare professional has overall responsibility and accountability for a service user's care during an episode of care.

Scope of this standard

The scope of this national standard includes: an identified healthcare professional being in place with overall responsibility and accountability for the care of each person who uses the service; formal handover of care; identification of the healthcare professional with primary accountability where there are multiple specialties involved during an episode of care.

What compliance with this standard looks like

1. People who use the service know which healthcare professional is responsible for their care and are able to discuss their care with them.
2. The healthcare professional with overall responsibility and accountability for the person using the service is clearly identified and documented at all times (even when a number of specialties are involved in their care).
3. When a person's care is transferred within or between a service or services, and the responsible healthcare professional changes, there is a timely, formal handover of information and accountability for the overall care of that person. This change is clearly documented, and the person using the service is informed.

Examples of information that may be used to find out if a service is compliant with the standard:

Through observation

- named healthcare professionals on patient flow and communication whiteboards.

Through communication with people who use the service, members of staff and management by asking:

People who use the service

- if they know which healthcare professional is responsible for their care
- if they have been able to discuss their care with that healthcare professional
- which healthcare professional has overall responsibility for their care in situations where there is more than one team or healthcare professional involved.

Members of staff and management

- if each person using the service has an identified, documented healthcare professional who has overall responsibility for their care at all times (even when a number of specialties are involved)
- how people who use the service are kept informed about who is the healthcare professional with overall responsibility for their care at all times, particularly when this changes
- how people using the services are facilitated to discuss their care with the responsible healthcare professional
- about the systems in place to ensure formal handover of information and accountability when a person's care is transferred within or between services and when the person's responsible healthcare professional changes.

Through a review of documents, such as:

- admission, referral, discharge and transfer policies
- admission, referral, discharge and transfer forms
- records from multidisciplinary meetings and case conferences
- patient surveys
- clinical handover records
- a sample of healthcare records.

Dimension: Quality and safety

Theme 2: Effective care and support

Standard 2.5

All information necessary to support the provision of effective care, including information provided by the service user, is available at the point of clinical decision making.

Scope of this standard

The scope of this national standard includes the availability of easily accessible, accurate, up-to-date and high-quality information to support effective care and the timely sharing of relevant information whenever care is shared or transferred.

See also standards 2.3 and 8.1 to 8.3.

What compliance with this standard looks like

1. Relevant information is shared in a timely and appropriate manner to facilitate the transfer or sharing of care within and between multidisciplinary healthcare teams and services from referral through to transfer or discharge.
2. Necessary information to support the provision of care is shared in a manner that respects the privacy and confidentiality of people using the service.
3. Accurate, up-to-date, high-quality information — including information from people using the service — is readily available to, and easily retrievable by, healthcare providers involved in each individual's care.

Examples of information that may be used to find out if a service is compliant with the standard:

Through observation

- if staff can access the necessary information required to support safe and effective care at the point of clinical decision-making
- the sharing of information between clinical staff, and between clinical staff and patients
- staff access to information and healthcare records at the point of care.

Through communication with people who use the service, members of staff and management by asking:

People who use the service

- for their views on whether staff have all the information necessary to provide care to them
- for their views on whether staff share their information in a manner that maintains their privacy and confidentially.

Members of staff and management

- what systems are in place to provide staff with accessible information at the point of clinical decision-making to support the provision of effective care
- how they ensure that the information necessary for the provision of effective care is accurate, up to date and high quality
- what systems are in place to ensure critical results of diagnostic tests are documented and communicated to healthcare professionals
- what systems are in place to provide evidence-based information to inform clinical decision-making
- does the information available include information from people using the service
- how information is shared within and between multidisciplinary healthcare teams and services from referral to admission, transfer or discharge
- how they are assured that relevant information is shared in a timely and appropriate manner to facilitate the transfer or sharing of care
- if information is shared appropriately and in a manner that respect patient's privacy and confidentiality.

Through a review of documents, such as:

- policies, procedures, protocols and guidelines related to:
  - providing information at the point of clinical decision-making
  - sharing of information (healthcare records management)
- admission, referral, discharge and transfer policies and forms
- electronic patient information systems
- monitoring and evaluation which has been undertaken to ensure the availability of necessary information for clinical decision-making
- a sample of healthcare records.

Dimension: Quality and safety

Theme 2: Effective care and support

Standard 2.6

Care is provided through a model of service designed to deliver high-quality, safe and reliable healthcare.

Scope of this standard

The scope of this national standard includes: models of service delivered to meet healthcare needs; clinical services; transfer arrangements; review and ongoing assessment of models of services; and scope of healthcare delivery.

See also standards 1.1, 2.1 to 2.3, 2.5, 3.1, 5.3, 5.5, 5.10, 6.1, 6.3, 7.1 and 7.2.

What compliance with this standard looks like

1. There is a clear description of how the service will be delivered and communication of the scope, objectives and intended quality outcomes of the service through a publicly available statement of purpose.
2. Care is delivered using high-quality, safe and reliable models of service delivery with the required clinical services. The model of care meets legislative requirements and takes into account best available evidence and guidance, local population health needs and available resources.
3. When an individual's healthcare needs cannot be met within the model of care, the necessary arrangements are in place for the transfer of care to the appropriate service, keeping the individual involved and informed.
4. Models of service delivery are regularly reviewed to provide assurance that the model of service can be safely delivered. This review includes the:
    a) assessed needs of the population being served
    b) size, complexity and specialties of the service being provided
    c) interdependencies of internal and external clinical and non-clinical services and support arrangements
    d) national and international evidence regarding the model of service or type of service being provided
    e) relevant legislation and Government policy

f) findings from consultation with key stakeholders and interested parties
g) number of staff required to deliver the service
h) skill-mix and competencies required to deliver the service
i) resources and facilities available
j) changes in the workload.

5. There is ongoing assessment of the volumes and cohorts of people using the model of service. This is carried out to provide assurance that:

   a) sufficient numbers of people are being treated to maintain the skills and competencies of clinical teams based on best available evidence or advice from the relevant professional and expert bodies
   b) clinical teams receive adequate experience of the management of complex and rare conditions and complications
   c) resources, including the workforce, are managed to deliver the defined model of service safely and sustainably at all times and meet legislative and regulatory or professional requirements.

6. Services are planned, managed and delivered to maintain the quality and safety of care when demand, service requirements, resources or capabilities change.

7. Healthcare is delivered within the stated scope of what can be delivered safely and effectively.

Examples of information that may be used to find out if a service is compliant with the standard:

Through observation

- Publicly displayed information on models of care.

Through communication with members of staff and management by asking:

Members of staff and management

- about the model and type of services provided
- if staff have the necessary resources and competencies to deliver the defined model of service safely and sustainably at all times. These include:

  — access to evidence-based guidance incorporating national clinical programmes, protocols and guidelines
  — adequate resources and staff for the delivery of safe services 24/7
  — adequate exposure to clinical conditions in order to maintain the necessary competencies relevant to the services provided

  - formal arrangements, with supporting guidance, to transfer patients to other services if the care or treatment is outside the scope of the model of service provided
  - contingency plans for surges in demand or changes in capabilities
  - monitoring and evaluation arrangements to ensure delivered services are within the stated model of service

- how management are assured that the model of service delivers high-quality, safe and reliable healthcare.

Through a review of documents, such as:

- statement of purpose
- policies, procedures, protocols, guidelines, care pathways and care bundles
- records of monitoring and evaluation of models of care and services provided
- population needs assessments
- activity data reports for services provided
- contingency plans for surges in demand; for example, major emergency or pandemic
- staff rosters
- bypass protocols, where relevant, and monitoring and evaluation of compliance against these protocols.

Dimension: Quality and safety

Theme 2: Effective care and support

Standard 2.7

Healthcare is provided in a physical environment which supports the delivery of high-quality, safe, reliable care and protects the health and welfare of service users.

Scope of this standard

The scope of this national standard includes the physical environment, premises and facilities, accessibility of premises and facilities, management of waste and hazardous material, security and proactive identification of risks associated with the physical environment and minimisation of the risk of acquiring a healthcare-associated infection

See also national standards 1.2, 3.1, 5.5 and 7.1.

What compliance with this standard looks like

1. The physical environment, premises and facilities are:
    a) compliant with relevant legislative requirements
    b) planned, designed, developed and maintained to address the needs of the people who use the service, including people's rights to privacy and dignity and to achieve the best possible outcomes for the resources used
    c) developed and managed to promote better health and wellbeing for people who use the service and healthcare staff
    d) accessible and responsive to the physical and sensory needs of people using the service
    e) developed and managed to minimise risks (to people who use the service and to healthcare staff) of acquiring a healthcare-associated infection
    f) planned and managed, including ongoing assessment of risk, to maintain the quality and safety of care when the demand, services delivered or resources change
    g) safe and secure for people who use the service and for healthcare staff.
2. There is appropriate management of hazardous materials and waste, including safe handling, storage, use and disposal, as it impacts on patient safety.

3. There are appropriate measures in place to ensure the security of the premises.

4. There is proactive identification of risks associated with changes to the environment where care is delivered, and service providers take the necessary action to eliminate or minimise such risks.

Examples of information that may be used to find out if a service is compliant with the standard:

Through observation

- the physical environment (layout, facilities, equipment)
- the overall condition, maintenance and cleanliness of facilities
- how the physical environment meets the clinical, physical or sensory needs of individuals who use the service
- how the physical environment ensures the delivery of high-quality, safe and reliable healthcare and protects people using the service (such as arrangements to ensure comfort, privacy, safety and reduction of risk)
- how the physical environment supports and protects the health and wellbeing of the people who use the service and healthcare workers
- bed spacing, single room and isolation room capacity
- availability of safety signage
- availability of hand hygiene facilities
- availability of personal protective equipment
- areas for preparation of medications
- facilities for safe storage of medications
- if there is appropriate storage of supplies and patient equipment
- availability and storage of cleaning equipment and supplies
- arrangements for waste management and management of hazardous materials
- arrangements for linen, reusable cleaning textiles and laundry management
- security arrangements.

Through communication with people who use the service, members of staff and management by asking:

People who use the service

- about their experience of whether the accommodation is accessible and responsive to their physical and sensory needs
- about their experience of the suitability of the accommodation provided and whether the facilities are suitably clean, private, warm and quiet
- if they feel safe in the accommodation provided
- if they have adequate storage for their belongings
- if they have access to hand hygiene facilities

- if they have access to suitable and clean bathroom and toilet facilities
- for their views on the standard of hygiene during their episode of care.

Members of staff and management

- if the physical environment (layout, facilities, equipment) enables staff to provide high-quality, safe and reliable care for the people who use the service
- how the needs of individuals who use the service (clinical, physical or sensory) are accommodated
- if there is appropriate placement of people who require transmission-based precautions
- about the processes and systems in place to reduce the risk of healthcare-associated infections
- about the processes and systems in place to ensure environmental and patient equipment hygiene
- about the systems in place for the handling, storage, use and disposal of hazardous materials and waste as it impacts on patient safety
- about the arrangements and specifications in place for linen and laundry management
- about the arrangements and specifications in place for the management of reusable cleaning textiles
- about the arrangements in place for security of the physical environment
- if staff are involved in, or aware of, the monitoring of the physical environment and whether they get feedback if they have reported incidents related to it
- how the environment is continually monitored and evaluated to ensure quality and safe care are maintained
- how they ensure that the physical environment is planned, developed and maintained to support the delivery of safe, high-quality care in line with legislative requirements and best available guidance
- what actions have been taken when issues are identified and how such issues are escalated through the appropriate management structures
- how the physical environment supports the health and wellbeing of staff.

Through a review of documents, such as:

- documents related to planning, designing, developing and maintaining the physical environment
- contingency/emergency plans
- documents relating to the monitoring and evaluation of the physical environment
- cleaning and disinfection specifications and schedules for the physical environment
- cleaning and disinfection specifications and schedules for patient equipment

- specifications for reusable cleaning textiles
- specifications for linen and laundry management
- maintenance schedules, plans and records
- service-level agreements with external contractors used for maintenance, building, cleaning and security
- records from the governing committee with responsibility for oversight of the physical environment, security and waste management
- strategic plan for physical and capital development and investment
- risk assessments related to the physical environment
- risk assessments undertaken relevant to building works or renovations
- infection prevention and control permits (method statements)
- risk register related to the physical environment
- patient experience surveys
- feedback from people who use the service
- patient safety incidents reports related to the environment.

Dimension: Quality and safety

Theme 2: Effective care and support

Standard 2.8

The effectiveness of healthcare is systematically monitored, evaluated and continuously improved.

Scope of this standard

The scope of this national standard includes: monitoring and evaluation arrangements; systems for quality and performance monitoring and improvement; shared learning and public reporting; and reporting to relevant agencies.

See also standards 1.7, 3.2, 3.7, 5.2, 5.8 and 8.1

What compliance with this standard looks like

1. The quality and safety of the care and its outcomes are measured using existing national performance indicators and benchmarks.
2. Where national performance indicators and benchmarks do not exist, performance indicators and benchmarks are developed, adopted and or adapted in line with best available evidence.
3. A variety of outcome measures are used to evaluate the effectiveness of healthcare including:
    a) clinical outcomes
    b) outcomes from the perspective of people using the service
    c) experience of care from the perspective of people using the service
    d) feedback from healthcare professionals.
4. Information from monitoring and evaluation is used to improve care and share learning.
5. Performance is monitored and evaluated, using clinical and non-clinical audits, with improvements implemented based on the findings.
6. There is an agreed annual audit plan that incorporates participation in national audit programmes and local targeted audits based on service requirements and priorities.

7. Evidence-based methodologies, in line with national guidelines, are used when conducting audits.

8. There are clinical governance arrangements in place that ensure findings from clinical audits are reported and monitored effectively.

9. Services share and publicly report information about the quality and safety of care delivered and quality improvement programmes.

10. Requested information is provided to relevant agencies, including national statutory bodies, in line with relevant legislation and good practice.

Examples of information that may be used to find out if a service is compliant with the standard:

Through observation

- quality improvements or changes in practice undertaken following internal or external monitoring and evaluation activities
- displays of key performance indicators and outcomes in clinical areas.

Through communication with people who use the service, members of staff and management by asking:

People who use the service

- how they are given the opportunity to take part in surveys or provide feedback on the care they received.

Members of staff and management

- how the services that are delivered are monitored and evaluated
- how members of staff and management are assured of the quality and safety of the care provided
- what clinical governance arrangements are in place that ensure findings from monitoring and evaluation, including non-clinical and clinical audits, are reported, and that:
  - recommendations are made and implemented
  - actions arising are monitored effectively
  - staff are provided with feedback as appropriate
- whether an annual audit plan is determined and agreed
- how staff are involved in the monitoring of services delivered
- about the changes made as a result of findings from such monitoring activity
- whether information about the quality and safety of care delivered, along with quality improvement programmes, is shared and publicly reported
- whether requested information made by relevant agencies and national statutory bodies is provided in line with relevant legislation and good practice.

Through a review of documents, such as:

- audit plans and schedules
- audit registers (for the central coordination of audits)
- monitoring and evaluation records and reports
- action plans
- quality improvement plans and programmes
- records of the sharing of learning from audit findings
- records of the sharing and public reporting of information about the quality and safety of care delivered
- records of relevant governance and oversight committee meetings
- annual reports
- directorate-level reports at hospital-group level.

Theme 3: Safe care and support

This section of the guidance describes the standards associated with the theme of safe care and support in a healthcare service. Safe care and support recognises that maintaining the highest levels of safety is a fundamental priority for people who use the service and healthcare service providers.

Healthcare is a high-risk area and, despite the best efforts of people working in it, risk cannot be eliminated entirely. However, healthcare service providers must protect people who use the service, as far as is reasonably practicable, from the risk of avoidable harm. People who use the service and their families expect to be kept safe. Maintaining the highest levels of safety is a fundamental priority for people who use the service and healthcare services. A service focused on safe care and support is continually looking for ways to be more reliable and to improve quality and safety.

Information relevant to providing safe services comes from, and should be gathered from, a variety of sources. These sources include findings from risk assessment, investigations or reviews of patient safety incidents, complaints or concerns raised by people using the service, audits and reviews of outcomes for people using the service. Service providers must analyse and learn from these information sources and use such information to continually improve the safety of services. Furthermore, this information should be shared throughout the service and wherever possible with other healthcare services.

Healthcare services have formal arrangements in place to respond to and learn from adverse incidents where people using the service are harmed. They fully and openly inform them about such incidents, and support them and their families. Healthcare services strive to ensure that patient safety incidents are not repeated. Reporting of patient safety incidents can:

- improve care and safety (especially when it is based on a cycle of quality improvement)
- change the way healthcare staff and service providers think about risk
- raise awareness of good practice.

Service providers take all reasonable measures to try to protect people who use the service, particularly vulnerable people such as children and older people, from all forms of abuse. All services must have the capacity and capability to implement the necessary policies, procedures and guidelines in line with national legislation, where they exist, to ensure all reasonable measures are taken to protect people who use the service from abuse.

Key to the successful safeguarding of people using the service is an open culture with a person-centred approach to care and support, underpinned by a zero-tolerance policy towards abuse and neglect perpetrated by staff or other people using services. Service providers recognise the potential impact of abuse on people who use the service, put in place measures to prevent abuse from occurring and facilitate access to support services.

In a safe service, a focus on quality and safety improvement becomes part of a service-wide culture. Such a culture is embedded in the service's daily practices and processes rather than being viewed or undertaken as a separate activity.

A patient safety improvement programme is one of the arrangements that service providers have in place to optimise patient safety, minimise harm and to improve the overall outcomes for people using the service. It is a structured and coordinated programme that is in line with the service's overall quality and safety objectives. It is underpinned by a shared understanding of the inherent risks of providing healthcare and how these risks may be minimised.

Dimension: Quality and safety

Theme 3: Safe care and support

Standard 3.1

Service providers protect service users from the risk of harm associated with the design and delivery of healthcare services.

Scope of this standard

The scope of this national standard includes: proactive monitoring, analysis and response to information relevant to safe services; proactive identification, assessment and management of risk associated with changes to the design and delivery of healthcare; protection of people using the service from harm associated with delivery of healthcare; safe and effective medication management; and management of medical devices and equipment.

See also national standards 5.2, 5.5 to 5.8, 5.11, 6.4 and 8.1.

What compliance with this standard looks like

1. Service providers have arrangements in place to ensure there is proactive monitoring, analysis and response to information significant to the delivery of safe services. This information includes:
    a) patient-safety incidents and other incidents involving both people using the services and the staff
    b) complaints, concerns and compliments
    c) findings from risk assessments
    d) legal claims and or learning from legal cases both within the service and in other services
    e) audits
    f) satisfaction surveys, including the National Care Experience Programme
    g) findings and recommendations from national and international reviews and investigations
    h) clinical coding, activity and performance data
    i) learning from coroners' cases or juries in coroner cases.

2. The healthcare service has systems in place to proactively identify, evaluate and manage immediate and potential risks to people using the service. These systems include ensuring that the necessary actions are taken to eliminate or minimise these risks. Evaluation of such actions is reported through governance structures.

3. Where changes to design and delivery of healthcare services are planned or implemented, there is proactive identification and management of risks associated with these changes.
4. Services systematically identify aspects of care delivery which are associated with possible increased risk of harm to people who use the service. Healthcare services have structured arrangements in place to minimise these risks. These include, but are not limited to, the following:
   a) Risks relating to preventing and controlling healthcare-associated infections are identified, monitored, managed and reviewed. There is a well-organised, planned and managed infection prevention and control programme which is coordinated and integrated with an antimicrobial stewardship programme
   b) Risk of harm and potential for errors arising from medications are also identified, monitored, managed and reviewed. These risks are used to inform and implement a medication safety programme, with strategies implemented to reduce the risk of medicine-related error. These strategies include identifying high-risk medications and having associated systems in place to reduce the risk associated with them. The medication safety programme is in line with legal requirements, national policy and guidelines and best available national and international evidence
   c) Arrangements in place to reduce the risk associated with blood and blood-component transfusion which ensure the clinical use of blood and blood components is safe, appropriate and in line with legislative requirements and international evidence
   d) Systems in place to reduce the risk of harm associated with transfer in and between healthcare services (transitions in care) and to ensure the safe and timely referral of people who use the service. Central to these arrangements are effective and accurate communication when information is being shared between different healthcare professionals and services
   e) Systems in place to reduce the risk of harm associated with pressure injuries (ulcers). There are systems in place to ensure people who use the service and who are at risk of pressure ulcers are screened and assessed in line with national and international guidelines
   f) Systems in place to reduce the risk of malnutrition for people using the service. The risk of malnutrition is identified, assessed and managed across the healthcare service. There are policies, procedures and guidelines in place, based on best available evidence, for malnutrition screening and managing nutrition and food needs for people using the service
   g) Systems in place to identify, assess and manage risks associated with the management and use of medical devices and equipment
   h) Aspects of care that present a risk of harm from falls for people using the service. Evidence-based strategies are implemented and evaluated to minimise these risks

i) Arrangements in place to reduce the risk of harm associated with surgical and invasive procedures. These measures are based on best available national and international evidence
j) Systems in place to identify and reduce the risk of harm associated with a delay in recognising and responding to people using the service whose condition acutely deteriorates. Policies, procedures and guidelines are developed and implemented for early detection and emergency response for patients whose condition is deteriorating
k) Systems in place for the reduction, recognition and management of venothromboembolism
l) Risks related to healthcare records are identified and managed
m) Systems in place to ensure the risk of harm associated with incorrect patient identification are minimised and or eliminated. These systems ensure that people using the service are correctly identified so that they receive the treatment and care solely intended for them
n) Risks associated with diagnostic errors
o) Risks related to high-risk cohorts[†††] of people using the service[‡‡‡]
p) There are arrangements in place to protect people using the service who are involved in research and clinical trials.

5. In line with legal requirements, national policy and guidelines, and best available national and international evidence, there is:

    a) safe and effective management of medication, from procurement to disposal
    b) safe and effective management of medical devices and other equipment.

6. There is a risk management policy outlining risk identification, assessment and management processes appropriate to the complexity and size of the service. This policy clearly outlines the governance arrangements for the timely evaluation and review of risk assessments and risk registers.[§§§]

[†††] Any group of individuals affected by common diseases, environmental, temporal influences, treatments, or other traits.

[‡‡‡] Each provider should identify these cohorts specific to their service. High risk cohorts could include but are not limited to older adults in hospital (in particular those that have a risk of frailty and delirium), children in hospital, patients who are immunocompromised, women with high risk pregnancies, patients with infectious or communicable disease, patients receiving chemotherapy or radiotherapy, patients receiving critical care, patients receiving renal dialysis.

[§§§] A risk register is a risk management tool. It lists all risks identified by an organisation and for each risk, there is an assessment of its probability and impact and describes controls to manage the risks. It also includes the person or department responsible for managing each risk.

7. Healthcare staff and management are trained to identify risks or potential risks to the safety and efficacy of care, and which are relevant to their roles and remit.

Examples of information that may be used to find out if a service is compliant with the standard:

Through observation

- the care environment is safe, clean, clutter free and well maintained
- infection prevention and control measures are in place and in line with national standards
- the storage and use of high-risk medications are in line with policy and best practice
- space is adequate to meet the needs of people who use the service and to provide care in an emergency
- there are communication systems in place and equipment available to respond to people whose condition is deteriorating
- visual alerts for safe practices are in place, such as signage
- checking procedures in place for patient safety, for example checking patients identity, double checking relevant medications and blood products
- processes for positively identifying patients are in place, such as identification bracelets
- handovers are safe and effective
- equipment to minimise harm from pressure ulcers are in place
- equipment for measuring height and weight are in place
- medical devices and equipment are used safely
- the care environment has measures in place to reduce the risk of slips, trips and falls
- safe surgery checklists adhere to local and national policy and guidelines
- administration of blood and blood components is safe
- healthcare records are managed in line with local and national policy and guidelines
- medication management practices are safe
- medical devices are managed safely.

Through communication with people who use the service, members of staff and management by asking:

People who use the service

- if their views are sought in relation to their safety and how staff ensure they are kept safe
- if they were involved in risk assessments associated with their care.

Members of staff and management

- how staff and management learn from information, and use it to inform and change practice, such as:
  - patient safety incident reviews
  - other incidents involving people using the services and or staff
  - findings from risk assessments
  - feedback from people who use the service
- how staff and management monitor and manage risks to patient safety associated with:
  - healthcare-associated infections and infection prevention and control
  - use of antimicrobials
  - medication use, in particular known high-risk medications
  - blood and blood-component transfusion
  - transfer in and between healthcare services (transitions in care)[****]
  - pressure injuries (ulcers)
  - malnutrition
  - use of medical devices and equipment
  - risk of harm from falls for people using the service
  - surgical and invasive procedures
  - a delay in recognising and responding to people using the service whose condition acutely deteriorates
  - venothromboembolism
  - management of healthcare records
  - incorrect patient identification
  - diagnostic errors
  - high-risk cohorts[††††] of people using the service.
- if staff have the appropriate knowledge and skill to identify and manage risks relevant to their role
- if staff have been provided with training in relation to risk management and their role.

Through a review of documents, such as:

- risk registers and risk assessments
- records from quality and safety governance meetings
- risk management policies
- patient experience survey reports

[****] Transitions of care refers to the various points where a patient moves to, or returns from, a particular physical location or makes contact with a healthcare professional for the purpose of receiving healthcare. This includes transitions between home, hospital, residential care settings and consultations with different healthcare providers in outpatient facilities.

[††††] Any group of individuals affected by common diseases, environmental, temporal influences, treatments, or other traits.

- annual quality and safety and or risk management reports
- patient-outcome reports
- monitoring and evaluation records and or reports of safety and quality
- performance data
- compliance reports
- records detailing review of clinical incidents and analysis by a governing body, managers and or relevant clinical governance committees
- complaints investigation reports
- patient safety incident reviews
- preliminary assessment reports for the senior incident management team (SIMT)[‡‡‡‡]
- education and training records for risk management
- infection prevention and control plan and reports
- antimicrobial stewardship plan and reports
- medication safety programme and associated strategies and action plans
- high-risk medication lists
- policies, procedures and guidelines for
    - infection prevention and control
    - outbreak management
    - use of antimicrobials
    - high-risk medication
    - management of blood and blood components
    - safe transitions of care
    - assessment of skin integrity and management of pressure ulcers
    - nutrition and food
    - falls and fracture prevention
    - safe surgery
    - early detection and response to a patient whose condition is deteriorating
    - reduction, recognition and management of venothromboembolism
    - management of healthcare records management
    - positive patient identification
    - management and use of equipment and medical devices
    - conducting research and clinical trials
- policies, procedures and guidelines for safe and effective management of medication.

[‡‡‡‡] A serious incident management team (SIMT) is an established standing group and includes senior staff who are responsible for overseeing the management of patient safety incidents and reporting into the relevant senior accountable officer at regular intervals to update on the progress of reviews.

Dimension: Quality and safety
Theme 3: Safe care and support
Standard 3.2 Service providers monitor and learn from information relevant to the provision of safe services and actively promote learning both internally and externally.
Scope of this standard The scope of this national standard includes information relevant to the provision of safe services, continual improvements in safe care and sharing of learning from information. See also national standards 3.1, 5.4 to 5.6 and 5.8.

What compliance with this standard looks like

1. There are arrangements in place to gather, analyse and learn from information relevant to the provision of safe services.
2. Information relevant to the provision of safe services is used to inform the continual improvement in the safety of the service.
3. Learning from information relevant to the provision of safe services is shared throughout the service and where relevant, with external services.

Examples of information that may be used to find out if a service is compliant with the standard:

Through observation

- if safety and quality improvement initiatives are publicly displayed.

Through communication with people who use the service, members of staff and management by asking:

People who use the service

- if their views are sought to improve safety
- whether they were informed of patient safety initiatives
- if they were advised how to raise concerns.

Members of staff and management

- whether learning from analysis of complaints and or patient-safety-incident reviews is shared across the service
- if information is used to promote improvement of the safety and quality of care
- if effective arrangements are in place to learn from information relevant to providing safe services.

Through a review of documents, such as:

- risk registers
- patient experience survey reports
- a sample of patient safety-incident-review reports and associated implementation plans, based on the recommendations
- complaints analysis reports
- annual quality and safety reports
- gap analysis against guidelines, standards and best practice for patient safety
- monitoring and evaluation records and or reports of patient outcomes
- audit frameworks or schedules
- monitoring and evaluation records and or reports of safety and quality performance data, compliance reports and reports of clinical incidents
- records detailing reviews of clinical incidents and analysis by a governing body, managers and or relevant clinical governance committees
- workforce safety-and-quality-climate surveys
- records of sharing information to improve the safety of services.

Dimension: Quality and safety

Theme 3: Safe care and support

Standard 3.3

Service providers effectively identify, manage, respond to and report on patient-safety incidents.

Scope of this standard

The scope of this national standard includes: patient safety incident identification, classification, reporting and management; effective timely review of patient safety incidents; and evaluation of incident reporting processes.

See also national standards 3.1, 3.2, 5.4 and 5.8.

What compliance with this standard looks like

1. There is a patient safety incident management system to identify, manage, respond to and report patient safety incidents which includes a classification of patient-safety incidents using an agreed taxonomy, in line with national legislation, standards, policy and guidelines.
2. This system is supported by a clear policy framework that includes the following elements:
    a) defines the
        — roles and responsibilities of individuals and committees
        — type of incidents to be reported
        — process for reporting, investigating and monitoring patient safety incidents
    b) outlines the responsibility of healthcare staff to report incidents
    c) ensures that information arising from patient safety incidents is used to inform the governing body, the workforce and people using the service in order to promote improvements in safety and quality
    d) informs staff and people who use the service of these arrangements.
3. When patient safety incidents occur, they are reported in a timely manner through national reporting systems which are in line with national legislation, policy and guidelines.

4. There are arrangements in place to facilitate thorough, fair and effective reviews in order to identify the causes of patient-safety incidents and to identify necessary actions. People impacted by the patient safety incident are kept informed and supported during the review process.
5. There are arrangements in place to implement recommendations from investigations of patient safety incidents and to monitor the effectiveness of any action taken.
6. The service regularly reviews and acts to improve the effectiveness of management and review systems for patient safety incidents.
7. Staff working in the service are trained and knowledgeable in how to identify, manage, respond to and report on patient-safety incidents.

Examples of information that may be used to find out if a service is compliant with the standard:

Through communication with people who use the service, members of staff and management by asking:

People who use the service

- are they aware of, have they seen or been given any information about patient safety in the service.

Members of staff

- about staff members' responsibilities and the process in place for managing and reporting patient safety incidents
- about their understanding of how patient safety incidents are managed and responded to
- how information and learning from patient safety incident reviews is shared to improve practice.

Management

- how they ensure patient safety reviews are fair and effective and conducted in a timely manner
- how they ensure people impacted by a patient safety incident are kept informed and supported during the review process
- whether quality improvement initiatives have resulted from patient safety incident reviews
- about the arrangements in place to implement recommendations from patient safety incident reviews
- whether the patient safety incident-management system is reviewed and where necessary improved.

Through a review of documents, such as:

- policies, procedures and guidelines for patient safety incident management and review
- patient safety incident reporting forms
- risk registers and risk assessments to determine if patient safety incidents relevant to the clinical area are risk assessed, escalated, mitigated and monitored
- reports or data analysis undertaken on patient safety incidents
- audits or reviews of patient safety incident management and review systems
- information leaflets for people involved in patient safety incident reviews
- education and training records on how to identify, manage, respond to and report on patient safety incidents
- a sample of preliminary assessment forms and reviews into patient safety incidents
- a sample of healthcare records from patients who have experienced a patient safety incident.

Dimension: Quality and safety

Theme 3: Safe care and support

Standard 3.4

Service providers ensure all reasonable measures are taken to protect service users from abuse.

Scope of this standard

The scope of this national standard includes: arrangements to minimise the risk of abuse; workforce training on identifying and responding to abuse; responding to suspected abuse in line with legislation and national guidelines; arrangements to protect children and vulnerable adults from abuse; access to appropriate services for those who have experienced abuse or who are suspected of being victims of abuse; cooperation with relevant agencies to protect individuals from abuse.

See also national standards 3.1, 4.1 and 6.2.

What compliance with this standard looks like

1. There are arrangements in place to minimise the risk to people who use the service from all types of abuse from members of the workforce and other people who use the service while receiving care, including:
    a) physical abuse
    b) psychological abuse (ill-treatment, for example, bullying and harassment)
    c) financial or material abuse (theft)
    d) misuse or misappropriation of money or property
    e) sexual abuse
    f) discriminatory abuse
    g) neglect and acts of omission which cause harm or place people using the service at risk of harm
    h) institutional abuse.[§§§§]
2. These arrangements are in line with national legislation, policy, guidelines and guidance where they exist and include:

[§§§§] Institutional abuse can occur within residential care and acute settings, including nursing homes, acute hospitals and any other inpatient settings, and may involve poor standards of care, rigid routines and inadequate responses to complex needs.

a) appropriate recruitment and An Garda Síochána (police) vetting processes for the workforce
b) policies and procedures to ensure all reasonable measures are in place to protect people using the service from abuse.

3. The service has appropriate induction and ongoing training programmes for the workforce on the prevention, identification, response to and management of all types of abuse that people who use the service may experience. This includes clarity of staff roles and responsibilities.
4. There are arrangements in place to ensure that appropriate action is taken in line with legislation and national guidelines where suspected abuse is identified while healthcare is being provided.
5. There are arrangements in place to protect children and vulnerable adults from all forms of abuse while healthcare is being provided. These include:

    a) ensuring that the service's child protection and welfare policies and procedures are in line with *Children First: National Guidance for the Protection and Welfare of Children* (Children First) for services providing care to children
    b) staff members being aware of their responsibilities and receiving training appropriate to their role in relation to child protection and welfare and the reporting of any child protection concerns as outlined in Children First.

6. Arrangements are in place to ensure that people who use the service and who have experienced abuse, or who are suspected of being victims of abuse, are facilitated to access appropriate services, including support services.
7. The service provider has ensured cooperation, in line with legislation, with all relevant services and agencies both internally and externally, to protect people who use the service from abuse.

Examples of information that may be used to find out if a service is compliant with the standard:

Through observation

- verbal and non-verbal interaction of staff with people who use the service
- if people are enabled to make choices about their care
- if interactions are meaningful or task led
- if staff speak in a respectful and caring way about people
- if there is a culture of openness
- if practices are institutional in nature.

Through communication with people who use the service, members of staff and management by asking:

People who use the service

- for their views and experiences about how they are treated by staff
- whether they feel they are enabled to raise issues or concerns.

Members of staff

- about their knowledge and understanding of safeguarding and responsibilities regarding reporting
- how they protect people from abuse, discrimination and avoidable harm, including breaches of their dignity and respect
- about the safeguarding measures in place to protect vulnerable persons and children.

Members of staff and management

- about their awareness of the various types of abuse
- about the systems in place to protect people who use the service from the various types of abuse
- about the frequency, uptake and oversight of training on prevention, identification, response to and management of all types of abuse of people who use the service, and if their training is up to date
- how they are assured that systems and policies in place for reporting and responding to abuse are in line with national legislation, policy, guidelines and guidance where they exist
- about the arrangements in place to ensure that people who use the service and who have experienced abuse, or who are suspected of being victims of abuse, are facilitated to access appropriate services, including support services
- how the service has ensured cooperation, in line with legislation, with all relevant services and agencies both internally and externally, to protect people who use the service from abuse.

Through a review of documents, such as:

- safeguarding policies, procedures and guidelines
- care plans with risk assessments, including restrictive practice risk assessments
- records related to behavioural support
- medication records
- patient safety incident reports
- reports and reviews of incidents and allegations
- annual reports
- education and training records in relation to prevention, identification, response and management to all types of abuse

- records from relevant governance committees.

Dimension: Quality and safety

Theme 3: Safe care and support

Standard 3.5

Service providers fully and openly inform and support service users as soon as possible after an adverse event affecting them has occurred, or becomes known, and continue to provide information and support as needed.

Scope of this standard

The scope of this national standard includes: having a culture of quality and safety; open disclosure following an adverse incident; supports in place following an adverse incident, including advocacy services; opportunities for people affected by adverse incidents to be involved in a review process; arrangements to support and manage staff involved in an adverse incident.

See also national standards 5.6, 5.8 and 6.4

What compliance with this standard looks like

1. A culture of quality and safety is promoted.
2. There is open disclosure with people using services and where appropriate their families and carers following an adverse incident in line with national guidelines and legislation.
3. People who use the service are provided with information on how to access support services and independent patient support following an adverse incident.
4. There are systems in place to involve people impacted by an adverse incident in the review process and to keep them informed of the progress of the review.
5. The service actively seeks and takes into account the needs and preferences of people using the service who are affected by an adverse incident.
6. There are fair and transparent arrangements in place to support and manage staff who have been involved in an adverse incident, including return to work decisions.

Examples of information that may be used to find out if a service is compliant with the standard:

Through communication with people who use the service, members of staff and management by asking:

People who use the service

- for their views on how they were supported following an adverse incident
- how they can access independent patient supports and advocacy.

Members of staff

- about their knowledge of the service's policy and process of open disclosure
- if and how open disclosure is promoted across the service
- about the supports available to people impacted by an adverse incident
- how they can access independent patient supports
- if they have had training on open disclosure
- how they are supported following an adverse incident
- if they have access to occupational health services.

Management

- how the service promotes a culture of quality and safety
- if the service has a designated lead person responsible for open disclosure
- about the arrangements in place for ensuring open disclosure with people affected by an adverse incident
- about the arrangements in place to manage and support staff who have been involved in an adverse incident.

Through a review of documents, such as:

- policy, procedures and guidelines for open disclosure
- patient safety incident reporting forms
- records of open disclosure and minutes of meetings
- monitoring and evaluation records and or reports to monitor compliance with open disclosure policy
- information leaflets on independent support services and agencies for people impacted by an adverse incident
- feedback from people using the service who are affected by an adverse incident
- staff surveys of their experience of open disclosure
- education and training records for open disclosure training
- a sample of healthcare records.

Dimension: Quality and safety

Theme 3: Safe care and support

Standard 3.6

Service providers actively support and promote the safety of service users as part of a wider culture of quality and safety.

Scope of this standard

The scope of this national standard includes: commitment to quality and safety; promotion of a patient-safety culture; contribution of workforce to improving quality and safety; protected disclosures; and facilitation of members of the workforce and people who use the service to report concerns about the quality and safety of the service.

See also national standard 5.6.

What compliance with this standard looks like

1. There is a commitment to quality and safety articulated and demonstrated by those governing and leading the service.
2. The service clearly articulates the elements of a patient safety culture. There are specific arrangements that actively promote a patient safety culture through a mission statement, service design, code of conduct, allocation of resources, training and development, and evaluation processes.
3. There are clear accountability arrangements that ensure that all members of the workforce are aware of their responsibilities and contribute to improving the quality and safety of healthcare for people using the service.
4. Members of the workforce and people who use the service are facilitated to report concerns about the quality and safety of services and are not negatively affected as a result of reporting concerns.

Examples of information that may be used to find out if a service is compliant with the standard:

Through observation

- mission statements
- safety signage and alerts
- information displayed encouraging people using the service to raise concerns
- information displayed encouraging staff to raise concerns

- the staff handover to see if staff concerns are voiced
- if quality improvement initiatives are displayed in the clinical areas.

Through communication with people who use the service, members of staff and management by asking:

People who use the service

- whether they feel they are enabled and encouraged to raise issues or concerns
- if and how their views about the service are sought.

Members of staff

- about their experience of raising concerns
- about the systems in place to communicate with the management team
- if quality and safety walk arounds occur
- if there are systems in place to improve patient safety
- if staff feedback and views are sought on how to improve the quality and safety of care
- how resources are allocated to promote the safety of people who use the service
- if they have received specific training in relation to a patient safety culture.

Management

- how leaders and senior management demonstrate a commitment to and promote a culture of quality and safety
- about the arrangements in place to encourage staff to discuss or highlight any concerns relating to the quality and safety of services
- about the systems in place to proactively evaluate the culture of quality and safety
- what changes have been implemented in response to patient safety incidents
- how learning gained from patient safety incidents is communicated back to staff and used to improve the service
- how feedback is sought from people using the service and from staff
- how feedback from people using the service and from staff is used to improve the culture of quality and safety.

Through a review of documents, such as:

- mission statements
- codes of conduct
- patient experience survey reports
- records of relevant quality and safety oversight committee meetings
- staff surveys
- patient safety culture surveys
- documents outlining feedback from people who use the service

- action plans, quality improvement plans and recommendations from culture surveys
- records of education and training in relation to a quality and safety culture.

Dimension: Quality and safety

Theme 3: Safe care and support

Standard 3.7

Service providers implement, evaluate and publicly report on a structured patient-safety improvement programme.[*****]

Scope of this standard

The scope of this national standard includes public reporting of the patient safety programme.

What compliance with this standard looks like

1. There is a patient-safety improvement programme in place as part of the arrangements to improve the overall quality and safety of services delivered.
2. The patient safety improvement programme is based on identified needs and priorities, learning from patient safety incident reviews and national and international initiatives.
3. The patient safety improvement programme integrates specific evidence-based interventions that are proportionate to the context, nature and scale of the service provided.
4. The patient safety improvement programme is regularly evaluated through performance indicators and benchmarks to identify both positive outcomes and areas for improvement. Where possible, people who use the service are involved in this evaluation. Any necessary actions are taken to improve the quality and safety of the service and to share learning both inside and outside the service.
5. Service providers publicly report on the objectives, scope, progress and outcomes of the patient safety improvement programme.

Examples of information that may be used to find out if a service is compliant with the standard:

Through observation

[*****] A patient safety improvement programme aims to improve the safety and reliability of healthcare and reduce harm to people using the service and is often associated with the design and delivery of healthcare.

- if patient safety improvement programme initiatives are reflected in the clinical environment.

Through communication with people who use the service, members of staff and management by asking:

People who use the service

- if and how their views are sought to inform the patient-safety improvement programme.

Members of staff and management

- about their knowledge and understanding of the service's patient-safety improvement programme
- if staff have received training on patient safety and human factors, such as situational awareness, decision-making and team work
- how management use information relevant to the provision of safe services to develop the patient safety improvement programme
- how management have engaged with people who use the service and engaged with staff in order to improve patient safety
- how the patient safety improvement programme is monitored and evaluated
- how actions arising from patient safety improvement programmes are effectively implemented.

Through a review of documents, such as:

- the patient safety improvement programme and associated strategies and plans
- key performance indicator reports
- patient safety indicator reports
- annual reports
- monitoring and evaluation records and or reports of evaluations undertaken of the patient safety improvement programme.

Theme 4: Better health and wellbeing

This section of the guidance describes the national standard associated with better health and wellbeing. Healthcare services are uniquely placed to promote and protect the health and wellbeing of the people who use their service at both an individual level and population level.

A high-quality, safe and reliable service constantly works with people who use their service for ways and opportunities to improve the health and wellbeing of the population served. This enables the development of a culture that promotes better health and wellbeing, enhances the care and support environment and improves the experience of people who use the service.

Dimension: Capacity and capability
Theme 4: Better Health and Wellbeing
Standard 4.1 The health and wellbeing of service users are promoted, protected and improved.
Scope of this standard The scope of this national standard includes promotion, protection and improvement of health and wellbeing of people using the service and also that of staff. See also standards 1.9 and 6.4

What compliance with this standard looks like

1. Services identify and use opportunities to promote better health and wellbeing at an individual and population level.
2. Service providers can demonstrate a commitment to developing an environment and culture that promotes and continually seeks to improve better health and wellbeing for people using the services and all staff.
3. Services proactively collaborate with people who use the service and relevant stakeholders to identify:
    a) the issues that are a health priority
    b) ways of maintaining and improving current and future health.
4. Services have a coordinated and structured approach to improving the health and wellbeing of the population they serve. They:

a) endorse and implement international and national principles, health promotion standards, strategies and policies
b) have a written policy on health promotion
c) have an action plan that supports the promotion of health and wellbeing in the hospital, which is regularly evaluated
d) have a designated person with assigned responsibility for the coordination of health promotion in the hospital
e) benchmark health promotion initiatives and interventions against national and international performance measurement data.

5. Services use health promotion programmes, initiatives and interventions developed in collaboration with people who use the service and relevant agencies to support people using services to make informed decisions about their health.
6. Health promotion programmes or initiatives are developed and or delivered to protect health and promote better health and wellbeing. These programmes:
    a) have clearly set out goals, objectives, interventions and evaluation plans
    b) are in line with the service's objectives
    c) are proportionate to the context, nature and scale of services provided
    d) take account of national policies and the views of stakeholders and interested parties
    e) are based on best available evidence and national priority programmes†††††
    f) reflect the needs of the population served and resources available.
7. Services have arrangements in place to proactively identify health priorities and health inequalities and develop initiatives to minimise identified inequalities in health outcomes.
8. Services ensure that available resources are targeted to areas and or populations where they will have the greatest impact in improving health outcomes for people who use their service.
9. The health and wellbeing of people using the service is promoted through collaboration and working in partnership with other service providers, national and voluntary agencies and non-healthcare organisations (where appropriate).

††††† National policy priority programmes include: Healthy Ireland, Healthy Eating, Active Living, Positive Ageing, Alcohol, Tobacco Free Ireland, Sexual Health and Crisis Pregnancy, Healthy Childhood, Staff Health and Wellbeing, Nurture Programme - Infant Health and Wellbeing, National Healthy Childhood Programme, and Child Safety Programme.

Examples of information that may be used to find out if a service is compliant with the standard:

Through observation

- the resources available to promote and improve the health and wellbeing of people who use the service
- the initiatives and interventions in place and on display to promote and support the promotion of health and wellbeing.

Through communication with people who use the service, members of staff and management by asking:

People who use the service

- for their views on how their health is promoted, protected and improved
- if they have been given opportunities or information about partaking in health programmes or initiatives; for example, healthy eating and active living, smoking cessation or positive ageing.

Members of staff and management

- how the health needs and priorities of the population served are identified
- how the culture and environment in the service promotes and continually seeks to improve better health and wellbeing of people using the service
- how the health, wellbeing needs and preferences of people who use the services are assessed
- how accessible are services, including for groups that have poorer health outcomes (ethnic and minority groups)
- what health promotion programmes, initiatives and interventions are used to support people who use the service to make informed decisions about their health and wellbeing (such as cancer screening programmes, immunisation programmes, newborn screening and tobacco-free campus initiatives)
- about the process of referral for specialist services and advice, inside and outside the service, such as a dietitian, and the health information given to people who use the services when they are discharged from the service
- how feedback on the appropriateness and effectiveness of health promotion programmes, initiatives and interventions is obtained from people who use the service
- about accessibility and availability of occupational health for staff
- about the health promotion programmes, initiatives and interventions in place to achieve a healthier workplace for all staff
- how feedback from staff and people who use the service is collected and used in planning, developing, implementing and evaluating the appropriateness and effectiveness of health promotion programmes

- how they are assured that programmes, initiatives and interventions used to protect and promote health and wellbeing are in line with the service's objectives and reflect best available evidence, the needs of the population served and resources available
- about the health priorities and health inequalities in the health outcomes of people using the service and about initiatives developed to minimise identified inequalities.

Through a review of documents, such as:

- records detailing the adoption of international and national health promotion goals and frameworks
- a service's strategic plan
- records from committees that are responsible and accountable for the health and wellbeing of people using the service and staff members
- records from stakeholder and interested-party collaboration and engagement
- policies, procedures, protocols, guidelines related to better health and wellbeing
- records of health promotion programmes, initiatives and interventions developed to promote and improve the health and wellbeing of people who use the services and staff
- educational material and information provided to people who use the service to improve health and wellbeing
- reports from monitoring and evaluation of practice initiatives that promote and improve the health and wellbeing of people who use service and any associated quality improvement plans
- reports from evaluations and feedback received both from people who use the service and from staff related to health programmes, initiatives and interventions
- records of relevant vaccination scheme uptake by staff
- a sample of healthcare records.

5. Appendices

Appendix 1: HIQA's Regulation Risk Rating Matrix

Regulatory risk is the identification and assessment of risk caused by non-compliance with legislation (including regulations and standards) by the service provider and the impact of this risk on people using the service. In monitoring acute hospitals and healthcare facilities, the level of risk will be compared against the national standards to determine an acceptable level of risk.

In a risk based approach to regulation risk is assessed as the product of both the likelihood and impact of risk within a service that HIQA monitors. HIQA inspectors will assess risk by estimating the likelihood (scores 1-5) and impact of the risk (scores 1-5) and calculate an aggregate score using the matrix below.

Risk Rating	**1**	**2**	**3**	**4**	**5**
Likelihood x impact	**Rare**	**Unlikely**	**Possible**	**Likely**	**Almost certain**
5 Catastrophic					
4 Major					
3 Moderate					
2 Minor					
1 Negligible					

The calculated score indicates if risk is low, moderate or significant

Low risk - Risk levels 1-6

Risk levels 1-6 are deemed low risk and this falls within the 'trusted' and 'right-touch' regulation. This means that this is a level of risk that HIQA is willing to tolerate and does not require a regulatory response.

Moderate risk - Risk levels 8-12

This level of risk is not acceptable and requires a regulatory response and a compliance plan by providers to bring the service into compliance.

Significant risk - Risk level 15-25

This level of risk is unacceptable and requires an immediate regulatory response. This level of risk will result in an immediate review by HIQA with a recommendation on escalation action as part of the regulatory plan for the service.

6. Glossary of terms

This glossary details key terms and a description of their meaning within the context of this guidance document.

Abuse: A single or repeated act, or lack of appropriate action, occurring within any relationship where there is an expectation of trust, which causes harm or distress to a person or violates their human or civil rights.

Accountability: Being answerable to another person or organisation for decisions, behaviour and any consequences.

Adverse event: An incident that results in harm to a patient.

Advocacy: The practice of an individual acting independently of the service provider, on behalf of, and in the interests of a person using services, who may feel unable to represent themselves.

Assisted decision-making: a person whose capacity to make a decision is in question can appoint a person to assist with decision-making or have somebody appointed to represent them for the purpose of making a decision

Autonomy: Freedom to determine one's own actions and behaviour.

Best available evidence: The consistent and systematic identification, analysis and selection of data and information to evaluate options and make decisions in relation to a specific question.

Business intelligence: A technology-driven process for analysing data and delivering actionable information that helps make informed business decisions.

Bypass protocol: A rule that ensures that for certain conditions, such as stroke, people who use the emergency ambulance service may be taken to a more distant acute healthcare setting where they receive timely intervention from specialists using best-practice techniques that may not be routinely available in a more local acute healthcare setting. Such an approach is aimed at ensuring better health outcomes.

Casemix: The types of patients and complexity of their condition treated within a healthcare service, including diagnosis, treatments given and resources required for care.

Clinical coding: A process whereby information from hospital case notes for individuals who use the service is expressed as codes for the purpose of providing data and information.

Clinical governance: A system through which service providers are accountable for continually 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. This includes mechanisms for monitoring clinical quality and safety through structured programmes; for example, clinical audit.

Clinical guidelines: Systematically developed statements to assist healthcare professionals' and service users' decisions about appropriate healthcare for specific circumstances.

Clinical handover: The transfer of professional responsibility and accountability for some or all aspects of care to another person or professional group on a temporary or permanent basis.

Clinical outcome: Measureable changes in health, function or quality of life that results from the provision of care.

Code of conduct: A description of the values, principles and expected behaviours of individuals and teams working within a service.

Code of governance: A description of the roles and responsibilities of those governing the service including an oversight role with clear lines of accountability in respect of safety and quality of health services provided.

Cohort: Any group of individuals affected by common diseases, environmental, temporal influences, treatments, or other traits.

Competence: The knowledge, skills, abilities, behaviours and expertise sufficient to be able to perform a particular task and activity.

Complaint: An expression of dissatisfaction with any aspect of service provision.

Concern: A safety or quality issue regarding any aspect of service provision, raised by a service user, service provider, member of the workforce or general public.

Confidentiality: The right of individuals to keep information about themselves from being disclosed.

Contract of agreement: A document which explicitly describes the nature of the service being provided to the service provider by an external agency.

Core working hours: This refers to the hours when a department or area is fully functional and historically was classified as the working hours of 9am to 5pm, Monday to Friday.

Corporate governance: The system by which services direct and control their functions in order to achieve organisational objectives, manage their business

processes, meet required standards of accountability, integrity and propriety and relate to external stakeholders.

Cost-effectiveness: The point at which the minimum amount of input (such as financial or human resources) is used to achieve a defined health outcome.

Credentials: Evidence or proof of an individual's qualification, competence or authority.

Critical care services: Services for the provision of medical care for a critically ill or critically injured patient.

Culture: The shared attitudes, beliefs and values that define a group or groups of people and shape and influence perceptions and behaviours.

Dignity: The right to be treated with respect, courtesy and consideration.

Education and training records: This includes documentation such as training programmes (multidisciplinary, scenario-based simulation training), records of attendance at training (formal and informal), training uptake numbers, identified mandatory and ongoing training requirements, induction programmes, competency frameworks, training needs analysis and content of training days.

Effective: A measure of the extent to which a specific intervention, procedure, treatment, or service, when delivered, does what it is intended to do for a specified population.

Efficient: Use of resources to achieve optimal results with minimal waste.

Emergency care: The branch of medicine that deals with evaluation and initial treatment of medical conditions caused by trauma or sudden illness.

End-of-life care: Care in relation to all aspects of a person's end of life, the dying process, a person's death, and bereavement suffered by family and friends left behind, regardless of the person's age or diagnosis or whether death is anticipated or unexpected. It includes care for those with advanced, progressive and incurable illness. Aspects of end-of-life care may include management of pain and other symptoms and provision of psychological, social, and other supports.

Episode of care: A period of care for a specific medical problem or condition. It may be continuous or it may consist of a series of intervals marked by one or more brief separations. An episode of care is started with an initial assessment and acceptance of the patient by the organisation and is usually completed with discharge or appropriate referral.

Evaluation: See **Monitoring and evaluation**.

Evidence: Data and information used to make decisions. Evidence can be derived from research, experiential learning, indicator data and evaluations.

Evidence-based healthcare: The practice of consistently using current best available evidence in making decisions about the care of individual service users or the delivery of health services.

Evidence-based practice: The practice of using current best available clinical evidence and individual clinical expertise or judgment to make decisions about the care of individual service users.

Fieldwork: The term used by HIQA to describe all the activities associated with pre-inspection, on-site inspection and post-inspection activities. HIQA describes inspection-related activities which inspectors carry out as 'fieldwork events'.

Financial viability: Refers to the ability to generate sufficient income to meet operating demands, debt commitments and, where applicable, to allow growth while maintaining service levels.

General practitioner (GP): A doctor who has completed a recognised training programme in general practice and provides personal and continuing care to individuals and to families in the community.

Governance: In healthcare, an integration of corporate and clinical governance; the systems, processes and behaviours by which services lead, direct and control their functions in order to achieve their objectives, including the quality and safety of services for people using services. See also **Clinical governance** and **Corporate governance** above.

Grand rounds: A formal meeting involving a presentation of a clinical issue by a healthcare expert sometimes in the presence of patients

Harm: Impairment of structure or function of the body and or any detrimental effect arising from this, including disease, injury, suffering, disability and death and which may be physical, social or psychological.

Health: The state of complete physical, mental and social wellbeing and not merely the absence of disease or infirmity.

Health information technical standards: Standards that support interoperability between systems and meaningful sharing of data.

Healthcare-associated infections: Infections that are acquired as a result of healthcare interventions.

Healthcare: Services received by individuals or communities to promote, maintain, monitor or restore health.

Healthcare record: All information in both paper and electronic formats relating to the care of a person using a healthcare service.

Healthcare professional: A person who exercises skill or judgment in diagnosing, treating or caring for people using services, or preserving or improving the health of people using services.

Incident review: Incident review involves a structured analysis and is conducted using best practice methods, to determine what happened, how it happened, why it happened, and whether there are learning points for the service, wider organisation, or nationally.

Information and communication technology (ICT): The tools and resources used to communicate, create, share, store, and manage information electronically.

Information governance: The arrangements that service providers have in place to manage information to support their immediate and future regulatory, legal, risk, environmental and operational requirements.

Informed consent: Voluntary authorisation by a person using services with full comprehension of the risks and benefits involved for any medical treatment or intervention, provision of personal care, participation in research projects and provision of the person's personalised information to a third party.

Institutional abuse: This form of abuse can occur within residential care and acute settings, including nursing homes, acute hospitals and any other inpatient settings, and may involve poor standards of care, rigid routines and inadequate responses to complex needs.

Integrated care: Healthcare services working together, both internally and externally, to ensure service users receive continuous and coordinated care.

Ionising radiation: Radiation having sufficient energy to remove electrons from the orbit of an atom, making the atom charged or 'ionised'. Ionising radiation is used in, for example, X-rays and radiotherapy to treat cancer.

Just culture: A just culture is an environment which seeks to balance the need to learn from mistakes and the need to take disciplinary action.

Key performance indicators: See **Monitoring and evaluation.**

Licensing: The mandatory process by which a governmental authority grants permission to a healthcare organisation to operate.

Locum: A healthcare professional, with the required competencies, who is employed to temporarily cover the duties of another healthcare professional who is on leave.

Major emergency: A major emergency is any event which, usually with little or no warning, causes or threatens death or injury, serious disruption of essential services or damage to property, the environment or infrastructure beyond the normal capabilities of the Health Service Executive (HSE) and the other emergency services. A major emergency may happen either locally, regionally or nationally, and requires the activation of specific additional procedures and the mobilisation of additional resources to ensure an effective, coordinated response.

Medical device: Any product, except medicines, used in healthcare for the diagnosis, prevention, monitoring or treatment of illness or disability.

Medication management: The clinical, cost-effective and safe use of medicines to ensure that service users get the maximum benefit from the medicines they need, while at the same time minimising potential harm.

Model of service: The way a health service is delivered and which can be applied to a single service unit, to an organisation or a national service.

Monitoring and evaluation: This refers to the systematic process of gathering information and tracking change over time. Monitoring provides a verification of progress towards achieving objectives and goals. The evaluation process is used to determine the extent to which the planned or desired outcomes of an intervention are achieved. Records or activities can include:

- **Audit:** The assessment of performance against any standards and criteria (clinical and non-clinical) in a health or social care service.
- **Clinical audit:** A quality improvement process that seeks to improve patient care and outcomes through systematic review of care against explicit criteria and the implementation of change. Clinical audit is a cyclical process that aims to improve patient care and outcomes by a systematic, structured review and evaluation of clinical care against explicit clinical standards.
- **Benchmarking:** A continual process of measuring and comparing care and services with similar service providers.

- **Root cause analysis:** A tool to help healthcare organisations retrospectively study events where patient harm or undesired outcomes occurred in order to identify and address the root causes. By understanding the root cause of an event, patient safety can be improved by preventing future harm.
- **Key performance indicators:** Performance indicators are specific and measurable elements of practice that can be used to assess quality of care. Indicators are quantitative measures of structures, processes or outcomes that may be correlated with the quality of care delivered by the healthcare system
- **Domains of quality:** Are those definable, preferably measurable and actionable, attributes of the system that are related to its functioning to maintain, restore or improve health
- **Quality improvement toolkits:** A systematic and formal approach to analysing practice performance in order to improve the performance of projects, business operations and other organisational objectives
- **Metrics:** Measures of quantitative assessment commonly used for comparing, and tracking performance or production
- **Proactive assessments:** An approach that attempts to understand a system even before it fails in an attempt to identify how it could fail in the future; measures can then be put in place to prevent the failure or failures that have been anticipated.

Multidisciplinary: An approach to the planning of treatment and the delivery of care for a service user by a team of healthcare professionals who work together to provide integrated care.

Multidisciplinary meetings/Case conferences: Members of the multidisciplinary healthcare team come together to discuss the care of the person using the service, review how treatment is progressing and plan future therapies.

National Clinical Guidelines: Guidelines that meet specific quality assurance criteria and have been mandated by the designated national body in Ireland — the National Clinical Effectiveness Committee.

Needs assessment: Process of identifying and analysing the priority health problem and the nature of the target group for the purpose of planning any health promotion action.

Nominated advocate: A person nominated and trusted by an individual to speak or act on their behalf. An advocate:

- respects the individual they speak or act on behalf of and their wishes at all times
- acts in the best interests of that individual

- acts independently on behalf of that individual and
- protects their privacy.

Open disclosure: A comprehensive and clear discussion of an incident that resulted or may have resulted in harm to a patient while receiving healthcare. Open disclosure is an ongoing communication process with patients and their families or carers following an adverse event.

On-call: The provision or availability of clinical advice in addition to or outside of core working hours (out of hours).

Out of hours: Outside the historical core working hours of 9am to 5pm, Monday to Friday.

Organogram/organisational chart: A graphical representation of an organisation's structure. It is used to show hierarchical relationships between managers and the people who report to them, as well as departments.

Patient safety incident: An event or circumstance which could have resulted, or did result, in unnecessary harm to a patient. Patient safety incidents include an incident which reached the patient and caused harm (adverse event); an incident which did not reach the patient (near miss) and an incident which reached the patient, but resulted in no discernible harm to the patient (no harm event).

Patient safety improvement programme: A patient safety improvement programme aims, through the design and delivery of the service, to improve the safety and reliability of healthcare and reduce harm to people using the service.

People using services: The term 'people using services' includes: people who use healthcare services (this does not include service providers or other healthcare professionals who use or commission other services on behalf of their patients — such as GPs commissioning hospital laboratory services). It includes patients, spouses, partners, parents, other family members, guardians, carers, nominated advocates and all other potential users of healthcare services. The term is synonymous with 'service user'. Occasionally, the term 'patient' is used in this guidance where it is more appropriate.

Policies, procedures, protocols and guidelines (PPPGs): a set of statements or commitments to pursue courses of action aimed at achieving defined goals. This can include the following types:

- **Policy:** A written operational statement of intent which helps staff to make appropriate decisions and to take actions that are consistent with the aims of the service provider and in the best interests of people who use the service.
- **Procedure:** A written set of instructions that describe the approved and recommended steps of a particular act or sequence of events.

- **Protocol:** A written plan that specifies procedures to be followed in defined situations; a protocol represents a standard of care that describes an intervention or set of interventions. Protocols are more explicit and specific in their detail than guidelines; they specify who does 'what', 'when' and 'how'. Protocols are mostly and typically used when developing instructions for drug prescription, dispensing and administration, that is to say, medication protocols.
- **Guideline:** A principle or criterion that guides or directs action. Guideline development emphasises using clear evidence from the existing literature, rather than expert opinion alone.
- **Flowchart:** A graphic representation of a series of activities that define a process.
- **Checklist:** A tool that condenses a large volume of information and allows for systematic verification of steps or practices.
- **Integrated care pathway (clinical care pathway):** A multidisciplinary care plan that outlines the main clinical interventions that are carried out by different healthcare practitioners for people using services with a specific condition or set of symptoms. They are usually locally agreed, evidence-based plans that can incorporate local and national guidelines into everyday practice.
- **Care bundle:** A number of related evidence-based interventions which — when followed consistently for every patient each time care is delivered — result in improved patient outcomes.
- **Algorithm:** An evidence-based step-by-step visual interpretation of the decision-making and or associated actions relating to a particular guidance area.
- **Form:** A form is a paper with questions on it and spaces marked to write down the answers.
- **Template:** A template is a file that serves as a starting point for a new document

Population healthcare needs assessment: The purpose of a population needs assessment in healthcare is to gather the information required to bring about change which is beneficial to the health of that population.

Protected disclosure: A disclosure of relevant information which, in the reasonable belief of the worker, tends to show one or more relevant wrongdoings; and came to the attention of the worker in connection with the worker's employment; and is disclosed in the manner set out in the Act.

Primary care: An approach to care that includes a range of services designed to keep people well. These services range from promotion of health to screening for

disease, to assessment, diagnosis, treatment and rehabilitation, as well as personal social services.

Privacy impact assessments: Privacy impact assessments (PIAs) form a fundamental part of information governance in assuring that individuals' rights to privacy and confidentiality are appropriately protected. This applies not only to new projects but also to proposals to amend existing information systems, sources or processes.

Quality information: Data that has been processed or analysed to produce something useful and is accurate, valid, reliable, timely, relevant, legible and complete.

Quality improvement programme: A structured programme which includes a range of quality improvement initiatives that is based on identified needs and priorities, learning from patient safety incident reports and reviews, and national and international initiatives. The programme incorporates specific evidence-based interventions that are proportionate to the context, nature and scale of the service provided.

Records from relevant committees: This includes documentation such as terms of reference (TOR), membership, minutes of meetings, action plans, strategies and annual reports.

Regulation: A governmental order having the force of law.

Regulatory risk: In the context of this guidance, regulatory risk is about identifying and evaluating risk caused by non-compliance with legislation, regulations and national standards by a service provider, and the impact that this regulatory risk has on people using services.

Reliable healthcare: A reliable health service consistently performs its intended function in the required time under normal circumstances.

Risk: The likelihood of an adverse event or outcome.

Risk management: The systematic identification, evaluation and management of risk. It is a continual process with the aim of reducing risk to an organisation and individuals.

Risk register: A risk register is a risk management tool. It acts as a central repository for all risks identified by an organisation and, for each risk, includes information such as risk probability, impact, controls and risk owner.

Safeguarding: Measures that are put in place to reduce the risk of harm, promote and protect people’s human rights and their health and wellbeing, and empowering

people to protect themselves. Safeguarding is fundamental to high-quality health and social care.

Safety huddles or pauses: These are brief (usually 15–20 minutes) and routine meetings for sharing information about potential or existing safety and operational problems.

Safety walk arounds: Walk arounds allow executive/senior management team members to have a structured conversation around safety with front-line staff and people who use the service. They are intended to be helpful opportunities to share ideas and provide immediate feedback without taking responsibility away from line managers and front-line teams. They provide opportunities to identify and celebrate good practices and initiatives across the service.

Schwartz rounds: Schwartz Rounds are conversations with staff about the emotional impact of their work and provide an opportunity for staff from all disciplines across a healthcare organisation to reflect on the emotional aspects of their work.

Service: Anywhere health or social care is provided. Examples include — but are not limited to — acute hospitals, community hospitals, district hospitals, health centres, dental clinics, general practice surgeries, home care and so on.

Service-level agreement: A framework for the provision of services, including details of quality and governance requirements.

Service provider: Any person, organisation, or part of an organisation delivering healthcare services, as described in the Health Act 2007 (as amended) — section 8(1)(b)(i)–(ii).

Service user: See entry on **People using services.**

Serious incident management team (SIMT): A SIMT is an established standing group and includes senior staff who are responsible for overseeing the management of patient safety incidents and reporting into the relevant senior accountable officer at regular intervals to update on the progress of reviews.

Skill-mix: The combination of competencies including the skills needed in the workforce to accomplish the specific tasks or perform the given functions required for safe, high-quality care.

Serious reportable events: Serious reportable events are a defined subset of incidents which are either serious or that should not happen if the available preventative measures have been effectively implemented by healthcare providers. The Health Service Executive (HSE) developed a list of serious reportable events in

2015 which are mandatorily reportable by services to the senior accountable officer of the service.

Stakeholders and interested parties: A person, group or organisation that provides or funds healthcare services, or who are or can be directly or indirectly affected by the actions of healthcare services, or who has an interest in the actions, decisions and services of healthcare services.

Surgical safety checklist: This is a communication tool promoted by the World Health Organization that is used by operating theatre nurses, surgeons, anaesthetists and others to jointly discuss important details about a surgical case so that everyone is familiar with the case and that important steps are not forgotten.

Systems analysis investigations: This is a methodical investigation of an incident which involves:

- collection of data from the literature
- records (general records in the case of non-clinical incidents and healthcare records in the case of clinical incidents)
- individual interviews with those involved where the incident occurred.

The process involves analysis of this data to establish the chronology of events that led up to the incident, identifying the key causal factors that the investigator(s) considered had an effect on the eventual adverse outcome, the contributory factors, and recommended control actions to address the contributory factors to prevent future harm arising as far as is reasonably practicable

Standard: In the context of this document, a standard is a statement which describes the high-level outcome required to contribute to quality and safety.

Statement of information practices and privacy notice: A statement which is made available to the public that clearly outlines how an organisation handles personal information. It provides details on the type of personal information held by the organisation and the way in which this information is processed.

Statement of purpose: A description of the aims and objectives of the service, including how resources are aligned to deliver these objectives. It also describes in detail the range, availability and scope of services provided by the overall service.

Taxonomy: A system for describing and organising terms into groups that share similar characteristics.

Tertiary care: Refers to specialised consultative healthcare, usually for inpatients and on referral from a primary or secondary health professional, in a facility that has personnel and facilities for advanced medical investigation and treatment, such as a tertiary-level hospital.

Tissue viability management: The prevention and management of all aspects of the skin and soft tissue wounds.

Transitions in care: This refers to the various points where a person using the service moves to, or returns from, a particular physical location or makes contact with a healthcare professional for the purposes of receiving healthcare. This includes transitions between home, hospital, residential care settings and consultations with different healthcare providers in outpatient facilities.

Way finding: refers to information systems that guide people through a physical environment and enhance their understanding and experience of the space.

Workforce: The people who work in, for or with the service provider. This includes individuals that are employed, self-employed, temporary, volunteers, contracted or anyone who is responsible or accountable to the organisation when providing a service to people using the service.

Whole-time equivalent (WTE): one whole-time equivalent employee is an employee who works the total number of hours possible for their grade. WTEs are not the same as staff numbers, as many staff members work reduced hours; for example, two midwives each working 19.5 hours per week would be one WTE because full-time hours for midwifery staff are 39 hours per week.

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- Irish Human Rights and Equality Commission Act 2014
- Health Act 2004 (Complaints) Regulations 2006 SI No. 652 of 2006
- Health Act 2007, as amended
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- Irish Medicines Board Act 1995 and 2006
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- Mental Health Act 2001
- Non-Fatal Offences against the Person Act 1997
- Nurses and Midwives Act 2011
- Dentists Act 1985
- Pharmacy Act 2007
- Protections for Persons Reporting Child Abuse Act 1998
- Public Health (Tobacco) Acts 2002 to 2015
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[#] All online resources were accessed at the time of preparing this guidance. Please note that web addresses may change over time and that HIQA is not responsible for external website content. Any possible omissions of external sources are inadvertent and will be corrected in future editions.

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Published by the Health Information and Quality Authority (HIQA).

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