Healthcare Improvement Scotland

Clinical governance

Standards

February 2026

NHS SCOTLAND

We are committed to advancing equality, promoting diversity and championing human rights. These standards are intended to enhance improvements in health and social care for everyone, regardless of their age, disability, gender identity, marriage and civil partnership, pregnancy and maternity, race, religion or belief, sex, sexual orientation, socioeconomic status or any other status. Suggested aspects to consider and recommended practice throughout these standards should be interpreted as being inclusive of everyone living in Scotland.

We carried out an equality impact assessment (EQIA) to help us consider if everyone accessing health and social care services will experience the intended benefits of these standards in a fair and equitable way. A copy of the EQIA is available on request.

Healthcare Improvement Scotland is committed to ensuring that our standards are up-to-date, fit for purpose and informed by high-quality evidence and best practice. We consistently assess the validity of our standards, working with partners across health and social care, the third sector and those with lived and living experience. We encourage you to contact the standards and indicators team at his.standardsandindicators@nhs.scot.

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Introduction

Background

Governance is the framework of systems and processes that organisations use to assess and improve clinical care.[1] An effective governance infrastructure is essential to the delivery of high-quality healthcare and continuous improvement across health and social care. The primary functions of governance are to set direction and identify priorities, hold leaders to account, manage risks, engage with key stakeholders and influence the overall culture of the organisation.

Clinical governance is an integral and essential part of the delivery of high-quality, effective and safe clinical services.

Clinical governance is defined as 'a system through which NHS organisations are accountable for continuously improving the quality of their services and safeguarding high standards of care by creating an environment in which excellence in clinical care will flourish.'[2] Clinical governance should also be applied where people receive clinical services in a non-clinical environment, such as care homes or other care settings.

The governance requirements for NHS boards in Scotland are provided in the Blueprint for Good Governance (2022). Clinical and care governance of local integrated health and social care arrangements are described in the Clinical and Care Governance Framework: guidance (2015).

These standards describe the elements that make up robust and effective clinical governance. Implementing the standards will provide organisations with demonstrable assurance that they are consistently delivering high-quality and safe healthcare in line with best practice, national policy and legislation.

Quality management in healthcare

Whole-system quality management frameworks recognise the complex and person-specific nature of healthcare.[3-5] They allow continuous learning and adaptation to new technologies, global challenges and increasingly integrated systems. Involving staff, communities and people with lived experience in decisions about the design of services is an essential part of this approach to quality management.[6] In Scotland, the Scottish Patient Safety Programme recognises the benefits of a staff-led approach to continuous improvement and learning.

Standards are an essential part of a whole-system quality management system bringing strategic and operational benefits. Standards support:

- consistency in care delivery
- improved patient safety
- enhanced staff accountability and support
- data-driven improvements
- regulatory compliance and assurance
- person-centred and inclusive care
- continuous learning and innovation.

Standards are used in clinical governance to benchmark performance. As part of a wider quality management system, self-assessment against standards helps organisations understand their whole system. Healthcare organisations can use standards to plan and prioritise improvement and ensure that their aims are in line with current best practice and national strategies.

Scope of the standards

The standards apply to all settings where people of all ages receive clinical services within the health and social care system in Scotland.

Clinical is defined as any individual or population healthcare intervention or service requiring assessment, planning, provision, evaluation or oversight by a registered healthcare professional.

Who are the standards for

Providers responsible for meeting the standards include:

- providers of clinical services planned, delivered or commissioned by NHS Scotland
- providers of clinical services planned, delivered or commissioned by Health and Social Care Partnerships
- primary care providers
- national NHS boards
- independent healthcare providers, including third sector providers
- independent social care providers who deliver or provide clinical services.

The standards cover all staff involved in the planning, delivery or commissioning of clinical services. This includes locum staff, volunteers, contracted staff, those covered by reciprocal work arrangements and students on placement.

It is expected that the standards will be adhered to across all health settings, including NHSScotland settings and independent healthcare.

A clinical service could be an organisation, a Health and Social Care Partnership (HSCP) or a single service, ward or department within either. Examples of a single service, ward or department include dermatology services, cardiology wards or outpatient departments.

Where a principle or criterion applies to a specific setting, this has been highlighted throughout the document. The standards should be reviewed pragmatically by service providers. Individual criteria will be applied by service providers in different ways in recognition of the breadth of healthcare and support delivered across health and social care in Scotland.

Terminology

Wherever possible, we have used generic terminology that can be applied across all health and social care settings. All terminology is described in the glossary.

Standards summary

Standard 1: Leadership and staffing

Clinical services have effective leadership and oversight including staffing levels.

Standard 2: Quality management and continuous improvement

Clinical services implement a whole-system approach to plan, improve, maintain and assure safety and quality.

Standard 3: Clinical effectiveness

People receive timely, effective, personalised and evidence-based clinical care.

Standard 4: Clinical safety and risk management

Clinical services effectively manage healthcare-related risks, safety concerns, adverse events and near misses.

Standard 5: Education and training

Staff delivering clinical services have the skills, competencies, training and support to provide safe, effective and person-centred care.

Standard 6: Service user and patient involvement

People and communities are meaningfully engaged in the design, delivery and governance of clinical services, in line with statutory duties and national guidance.

Standard 7: Data and information

Clinical services store and share personal data appropriately and use safe, secure systems and tools.

Standard 1: Leadership and staffing

Standard statement

Clinical services have effective leadership and oversight including staffing levels.

Rationale

Leadership at all levels ensures that the organisation's strategic vision and values are developed with, and communicated to, staff.[7, 8] This supports effective planning and delivery of services.[8, 9] Leadership and effective strategic planning have a significant effect on all quality practices in healthcare.[10, 11] Leadership has been found to be the main driver of quality and has a significant impact on other quality domains.[12-14] Leadership should be values-based, person-centred and trauma-informed.

Where clinical services are planned or delivered through formal or informal partnerships, clear lines of accountability ensure that staff are aware of governance and reporting mechanisms. Where appropriate, partnership-wide self-assessment, governance frameworks and improvement plans can support effective integration.

Organisations should ensure that there is robust oversight and leadership for safe staffing levels and workforce planning. The Health and Care (Staffing) (Scotland) Act 2019 provides a statutory basis for the provision of appropriate staffing in healthcare services. The statutory guidance supports organisations in meeting governance and accountability requirements.

Staff should uphold the professional standards expected of them by their professional regulator or NHS Scotland.[15-22] For further criteria on staff education and training, see Standard 5.

Criteria

1.1. Organisations have objectives and priorities that:

- reflect their overall vision, values, strategy and aims
- are driven by what is relevant and important to people who use the services they provide
- are effectively communicated and well understood across the organisation and the community it serves
- are reflected in the objectives of services, teams and staff job roles.

1.2 Organisations ensure effective leadership and staffing governance through:

- a clear and well-publicised management structure
- defined roles and responsibilities for escalation and management of clinical risk (see Standard 4)
- documented processes for direct reporting to the multi-disciplinary clinical leadership team
- regular reporting in line with The Health and Care (Staffing) (Scotland) Act 2019 where appropriate.

1.3 Each service has a staffing method agreed in partnership with the workforce, which:

- emphasises values-based practice, including compassion and understanding[7]
- involves staff in decision making, where appropriate
- promotes inclusivity, dignity and respect for all staff
- enables continuous safe care and support to be provided
- ensures workforce plans for future levels of staffing are safe and sustainable.

1.4 Organisations implement the appropriate skills mix and numbers of suitably qualified and competent staff to ensure the:

- health, wellbeing and safety of patients, staff and visitors
- provision of safe and high-quality care.

1.5 Organisations have an escalation process to identify and mitigate risks relating to:

- staffing numbers and skills mix
- succession planning
- availability of senior clinical decision makers.

1.6 Staff experience leadership at all levels that is values-based, person-centred and trauma-informed.

1.7 Organisations ensure systems and processes are in place to address fairly any workplace issues in a timely manner.

1.8 Staff work within defined clinical and professional competencies and:

- understand their responsibilities and respect the professional competencies and contributions of all members of the care team
- seek specialist advice, second opinion or further clarification where needed.

1.9 Organisations check and validate the professional qualifications and registration (where applicable) of staff:

- prior to their starting employment
- throughout the duration of their employment.

1.10 Staff are supported to meet the revalidation requirements set by their respective professional regulator, including collecting and submitting evidence.

1.11 Organisations demonstrate implementation of Disclosure (Scotland) Act (2020) and have robust processes in place to identify and mitigate the risk of employing staff who have criminal convictions for, or previous upheld or current ongoing investigations into, abuse, harm or unsafe practice.

1.12 Organisations have robust process in place for the recruitment (including background and safeguarding checks), deployment and supervision of volunteers as well as staff. This includes access to compassionate and inclusive leadership, appropriate training and support and role descriptions.

What does the standard mean for people?
• You can be confident that the organisation is well led and managed. • Staff will have time and support from their teams to care for you. • You will be supported by staff who are confident in their organisation and leadership. • You can be confident that staff are appropriately and safely recruited.
What does the standard mean for staff?
Staff, in line with roles, responsibilities and workplace setting: • experience values-based, person-centred and trauma-informed leadership • understand and act in line with core values • understand their role within a multi-disciplinary team • are supported and feel valued and enabled • work in appropriately staffed teams and services.

What does the standard mean for the organisation?

Organisations, in line with their respective governance and delivery structures:

- provide clear leadership and oversight of healthcare services
- ensure appropriate and sustainable levels of staffing and skills mix to ensure continuity of care and support in line with The Health and Care (Staffing) (Scotland) Act 2019 (see also Standard 5)
- have workforce resilience plans and implementation monitoring
- support staff through effective, values-based, person-centred and trauma-informed leadership
- have a clearly communicated vision that is in line with national priorities.

Benchmarking and measuring performance: Examples of what meeting this standard might look like [linked criteria]

Examples may vary according to the size and scale of the service, NHS board, organisation.

- Documented organisational priorities and objectives, for example strategy documents or annual reports. [1.1]
- Board reports on adherence to provisions of The Health and Care (Staffing) (Scotland) Act 2019. [1.2]
- Workforce resilience plans, such as mutual staffing cover arrangements between small organisations or practices. [1.3 – 1.5]
- Use of staffing tools and workload models to plan required capacity. [1.3 – 1.5]
- Audit of staff vacancies, succession planning, staff retention and safe staffing levels and action plans. [1.3 – 1.5]
- Processes for escalating and mitigating staffing risk with contracting NHS boards. [1.5]
- Evidence of leadership training and development pathways and frameworks.[10, 14] [1.6]
- Evidence of staff feedback and experience of leadership, such as iMatter. [1.6]
- Clear organisational charts describing lines of accountability and defined roles and responsibilities, accountability and funding structure for multiagency teams and services. [1.2 – 1.8]
- Audit of response to workplace issues. [1.7]
- Enhanced background checks for staff and compliance with professional regulators. [1.9 – 1.11]
- Policies for volunteer recruitment, training and management. [1.12]

Standard 2: Quality management and continuous improvement

Standard statement

Clinical services implement a whole-system approach to plan, improve, maintain and assure safety and quality.

Rationale

Implementing a whole-system approach to quality means the organisation learns how to continually, reliably and sustainably meet the changing needs of staff, service users and communities.[3, 4, 23] A coordinated and consistent way of managing quality ensures an interconnected approach to planning, improving, maintaining and assuring high-quality care. Whole-system quality management requires commitment and capacity to drive continuous improvement.[24] Proactive management of quality requires organisations to identify and plan improvement before issues arise.

An effective quality management infrastructure is essential for the delivery of high-quality care. Organisations benefit from, and share expertise through, continuous learning and planned improvement. This enables learning, sharing of data and identification of 'bright spots.' A learning system, with data and intelligence from different sources, allows services and systems to understand and plan more effectively, be responsive to the needs of their local populations and share good practice.[25] See also Standard 7 on data and information.

Criteria

2.1 Organisations demonstrate a robust governance and oversight process for monitoring the quality and safety outcomes of clinical services.

2.2 Organisations implement a systematic and evidence-based whole-system quality management approach that covers all clinical services.

2.3 Clinical services demonstrate participation in the collection and monitoring of relevant data to inform planning and improvement.

2.4 Organisations have processes to monitor service and system data to identify and respond to:

- signals of safety or quality issues
- areas of learning and good practice.

2.5 Organisations have systems and processes in place to improve the quality and safety of clinical services across the whole system by:

- participating in local improvement work, national datasets and research
- sharing intelligence and learning
- embedding and sustaining good practice.

2.6 Organisations collect anonymised demographic data in their population and use this data to reduce health inequalities in:

- clinical and health outcomes
- quality of care.

2.7 Clinical services use local data and intelligence, including people's experiences of services, to:

- understand their service or system
- identify issues with quality or safety
- address gaps or inconsistencies in data collection
- develop intelligence-led improvement plans
- monitor the impact of improvement plans on quality or safety.

2.8 Staff use appropriate evidence-based tools and improvement approaches to undertake tests of change and demonstrate innovation in their clinical teams and services.

2.9 Organisations have processes in place to support tests of change in clinical services within an agreed quality management system.

What does the standard mean for people?
• You can be confident that organisations and services are always learning to make your healthcare better and more equitable. • Organisations monitor their own clinical services so they can understand where improvements are needed. • You can be confident that services will share their learning with other clinical services.

What does the standard mean for staff?
Staff, in line with roles, responsibilities and workplace setting: • manage quality and safety in a coordinated and interconnected way to plan, improve, maintain and assure high-quality and safe care • continuously improve care and treatment • undertake local improvement work and tests of change • understand their role in improving quality across the whole system • implement innovative practice and share learning.
What does the standard mean for the organisation?
Organisations, in line with their respective governance and delivery structures: • actively monitor the quality of clinical care they deliver through established governance and oversight frameworks • have a system to receive applications for tests of change • use data and intelligence to monitor and improve the safety and quality of their clinical services • work collaboratively with other organisations to share learning and improve safety and quality of care • implement a whole-system evidence-based quality management system.

Benchmarking and measuring performance: Examples of what meeting this standard might look like [linked criteria]

Examples may vary according to the size and scale of the service, NHS board, organisation.

- Identification of GP practice quality lead to prioritise quality improvement activity. [2.1]
- Implementation of a quality management system for all clinical services at all levels of the organisation. [2.2, 2.9]
- Individual GP practice quality audit. [2.3, 2.4]
- Participation in national audits, self-assessment, benchmarking and registries. [2.3, 2.4]
- Evidence of improved outcomes as a result of quality improvement activity. [2.5]
- Locality improvement work though primary care partnerships or clusters. [2.5]
- Participation in national forums and informal intelligence sharing networks. [2.5]
- Evidence of intelligence-led improvement plans. [2.6, 2.7]
- Use of accessible data dashboards, including progress against key indicators for quality reporting at board level or equivalent. [2.4, 2.7]
- Provision and uptake of staff education and training in quality improvement methodology relevant to their role and responsibilities. [2.8, 2.9]
- Minutes and actions from governance and oversight forums evidencing discussion and scrutiny of service and system data to identify signals of safety or quality issues. [2.1, 2.4, 2.7]

Standard 3: Clinical effectiveness

Standard statement

People receive timely, effective, personalised and evidence-based clinical care.

Rationale

Clinical effectiveness is centred on providing evidence-based care with positive outcomes for individuals and populations.[26] Comprehensive clinical care is where interventions are provided to all who could benefit. It includes avoiding interventions when they are likely to provide little or no benefit to a person.[27] Evaluation and outcome frameworks can be used to determine effectiveness. Considering the context and wider impact of a clinical intervention can give a clearer indication of its effectiveness.[28]

Effective clinical care ensures people receive the right care at the right time.[8, 15] Personalised or person-centred healthcare ensures that individual clinical interventions or treatments are based on a person's specific context, values and preferences. Treatment and care tailored to a person may improve their clinical and self-reported outcomes.[8] Implementing the principles of Realistic Medicine can reduce unnecessary interventions that, while clinically indicated, may not be effective in terms of an individual's particular circumstances or choices.

Clinical services are required to ensure that people are fully informed about their individual benefits and risks when consenting to interventions.[29] Staff should fully explain the situation and options and support people to make decisions about their healthcare.[30] Shared decision making can reduce harm and improve the quality of care.[31, 32] Clinical services should make reasonable adjustments to ensure people who are protected under the Equality Act (2010) can access care and participate meaningfully in discussions.

To ensure their human rights and patient rights are fully upheld, people require timely information in a format and language that meets their communication needs and level of understanding.[33] Inclusive information is sensitive, accessible and clear to meet the differing needs of individuals.[27, 34] All communications, including online clinical information, should meet accessibility standards and public sector requirements under the Equality Act (2010).[35]

Effective research governance, knowledge exchange and assessment of healthcare interventions enable organisations to continue to deliver clinical services that reflect changes/improvements in practice and maximise outcomes. Collaborative efforts, including joint global efforts, ensure that research and data is accurate, equitable and meaningful.[36] NHSScotland supports involvement of organisations in multicentre research trials. This requires robust research governance frameworks that support participation of people and communities. Regulated authorisations and assessments from the Medicines and Healthcare products Regulatory Agency (MHRA) should be met for medicines and medical devices where they apply.

Criteria

3.1 Organisations have systems and processes to ensure clinical services are aligned with all relevant national standards and clinical guidance, including benchmarking and monitoring progress towards full implementation.

3.2 Organisations have effective oversight and governance mechanisms for the use of evidence-informed clinical interventions, including but not limited to:

- medicines
- medical devices
- non-pharmacological interventions, including techniques validated or recommended by professional organisations.

3.3 Organisations enable staff to develop their clinical knowledge, skills and understanding through partnership working with other providers and with academic, research, third sector and commercial partners, as appropriate.

3.4 Staff have time, resources and support to:

- participate in knowledge development and exchange
- remain up to date with current clinical best practice and evidence, where relevant.

3.5 Organisations deliver safe and effective healthcare that is:

- personalised
- in the right place at the right time
- informed by current evidence and best practice.

3.6 The clinical effectiveness of care and support is maximised because staff develop an understanding of:

- what and who matters to the person
- the person's circumstances, experiences and any additional support needs
- how the person is affected by their condition(s) or treatment
- the person's goals and outcomes
- the importance of the person's autonomy
- how to support people to uphold their rights to make informed decisions.

3.7 People are actively enabled to develop the knowledge, skills and confidence to manage their own clinical care and treatment, where relevant.

3.8 People are actively enabled to make decisions and choices about their healthcare because they have timely access to:

- inclusive, relevant and easy to understand information
- information on the purpose, risks, alternatives and benefits of any clinical treatment or intervention
- appropriately knowledgeable, trained and unbiased staff to discuss options, including being able to seek a second opinion
- support to set and review personal goals and outcomes
- additional support, including translation services and communication aids, where appropriate.

3.9 Clinical care and treatment plans:

- are based on early discussions about the person's values, needs and circumstances in line with Realistic Medicine
- are developed in partnership with the person and, where appropriate, their care partner
- integrate information and input from all relevant services to put the person at the centre, reduce duplication and support safe transfer of care
- are reviewed and updated as required
- are accessible to all members of the care team, the person and, where appropriate, their care partner.

What does the standard mean for people?

- You will be actively involved in making decisions about your healthcare.
- The healthcare you receive will be personalised and based on what is right for you.
- You will receive information that is right for you to help you make decisions or choices about your healthcare.
- Staff will listen to you, your needs and what matters to you.
- You will have access to healthcare including assessments, tests, treatment and medicines that are effective and are in line with current best practice and evidence.

What does the standard mean for staff?

Staff, in line with roles, responsibilities and workplace setting:

- provide personalised and evidence-based clinical care in line with Realistic Medicine
- consider a person's experiences, values and priorities at all stages of care planning
- recognise the importance of autonomy and the right of the individual to make informed decisions about their healthcare
- work to the relevant legislation, standards, clinical and practice guidance
- have access to evidence-based techniques, medicines and technologies
- work across different disciplines and organisations to coordinate healthcare
- have time to develop and expand their specialist knowledge.

What does the standard mean for the organisation?

Organisations, in line with their respective governance and delivery structures:

- ensure people are cared for in the right place at the right time
- demonstrate alignment of practice with relevant legislation, standards and clinical guidance
- provide staff with adequate time to develop and expand specialist clinical knowledge and skills
- work in partnership with research organisations and universities to contribute to knowledge and define best practice where applicable
- provide opportunities for staff to take part in evaluation and research
- support the development and implementation of evidence-based technology assessments and guidelines.

Benchmarking and measuring performance: Examples of what meeting this standard might look like [linked criteria]

Examples may vary according to the size and scale of the service, NHS board, organisation but not exhaustive.

- Self-evaluation and assessment against national standards and clinical guidelines. [3.1]
- Nominated leads for identification and circulation of new guidelines and standards. [3.1]
- Local protocols for the introduction of new medicines, guidance, standards and technologies within a clinical service. [3.2]
- Minutes from area advisory committees. [3.2]
- Conference presentation or posters outlining multidisciplinary or multiagency improvement projects or practice. [3.3]
- Implementation of multidisciplinary knowledge exchange work to translate research into practice. [3.3, 3.4]
- Existence of formal research partnerships, joint funding bids and research collaboratives. [3.3, 3.4]
- Use of disability passports or key information summaries detailing a person's communication or accessibility needs. [3.6, 3.8, 3.9]
- Use of the Realistic Medicine – National toolkit for professionals. [3.6]
- Access to tools and information to support self-management. [3.7]
- Use of tools to support conversations, shared decision making and document individual needs for example, 'What Matters to You.' [3.5]
- Access to patient advocacy services. [3.8]
- Feedback from people using services and, where appropriate, their care partners, on their experience of shared decision making. [3.8]
- Use of alternative and augmentative communication systems or communication aids. [3.6, 3.8, 3.9]
- Proactive sharing of care plans between organisations and providers. [3.9]

Standard 4: Clinical safety and risk management

Standard statement

Clinical services effectively manage healthcare-related risks, safety concerns, adverse events and near misses.

Rationale

Identifying and managing risk is a central part of delivering high-quality health and social care services. The primary goal of risk management within clinical governance is to minimise risks to patients and prevent harm by ensuring there are appropriate controls in place.[15]

Risks in this context relate to clinical risks. Adopting a risk-based approach to clinical care, including proactive management, ensures that both opportunities and potential threats are considered as part of the decision making process. This approach is supported by structured risk management policies, protocols and processes, to ensure that clinical risks are identified, assessed, managed or mitigated and escalated at the appropriate level within the organisation.[37, 38] These processes also help identify connections, patterns or related factors that may signal increasing risk or systematic failure.

National statutory inquiries into patient harm, clinical safety issues or poor performance in healthcare settings consistently highlight lack of 'safety culture.'[39-43] Learning from adverse events, near misses and inquiries highlights that organisations should listen to people's experience, respond to early warning signs, address staff concerns and prioritise clinical safety. Ongoing monitoring and review of clinical services enables improvements for the safety of everyone using and providing healthcare.[44] This requires a robust system analysis and embedding a learning culture. A learning culture includes the adoption of systems to listen to staff and make changes to systems and processes.

When a clinical risk becomes an issue, adverse event or near miss, robust governance processes are followed.[44] Organisations have a Duty of Candour to be open and transparent when something with the care or services they provide goes wrong and causes harm. Openness and honesty are central to every relationship between those providing and those experiencing treatment and clinical care.[45] Staff also have professional Duty of Candour, which should be followed alongside their respective professional guidance.[46-48]

Adverse events and complaints are a key source of intelligence about the safety and quality of a service. Reviewing and acting on adverse events, near misses, complaints and identifying positive feedback or good practice can help organisations identify risks and prevent or reduce harm.[37, 44, 49-52]

Where there is a concern about unsafe, unethical, or unlawful clinical practice, organisations should ensure these concerns can be raised in a confidential and psychologically safe way. National standards for whistleblowing and supporting processes are in place to ensure that staff are adequately protected and supported.[48, 53]

Feedback from people who experience services is covered in Standard 6.

Criteria

4.1 Organisations have a robust governance and reporting structure to support effective oversight and assurance of clinical safety and risk management.

4.2 Organisations have a framework for managing clinical risks that:

- is aligned to organisational objectives and integrated into decision making arrangements
- clearly defines clinical leadership roles and responsibilities
- proactively identifies and manages clinical risks that could impact on their ability to deliver or maintain services and functions
- proactively identify, evaluate and manage clinical risks associated with service redesign
- review the risks, including control measures, at regular intervals.

4.3 Organisations take active steps to create a safety culture that enables staff to:

- talk openly about errors and raise concerns safely
- act promptly if they think that patient safety is, or may be, seriously compromised, in line with professional guidance
- share and act on learning.

4.4 Organisations publish annual reports covering Duty of Candour legislation requirements.

4.5 Organisations have systems and processes for adverse event reporting (including near misses and complaints) in line with national frameworks, notification processes and recommended timelines, which:[37, 44, 49-52]

- outline standardised and consistent approaches to reporting and responding, while meeting the needs of individuals
- include documented escalation policies for response, investigation and review
- outline clear lines of accountability for local review and response.

4.6 Organisations have robust processes for the reporting and review of clinical risk and patient safety data, including adverse events and complaints investigations, which include:

- identification of emerging or recurring themes
- detailed actions and learning to reduce the likelihood or impact of reoccurrence
- reporting progress against actions and improvement plans
- sharing anonymised, thematic learning with partner multidisciplinary and multiagency teams and governance structures as appropriate
- demonstrating a commitment to openness and transparent decision making.

4.7 Organisations have systems and processes to ensure national learning is reviewed, where applicable, from:

- quality of care reviews and local care assurance processes
- recommendations from national inquiries.

4.8 Organisations are transparent and provide a timely and appropriate response for adverse events (including near misses) and complaints:

- to staff, volunteers and people who experience services
- in line with national guidance and nationally agreed timeframes
- which includes learning or improvement plans that have been developed as a result.

4.9 Organisations have effective feedback processes following adverse events, investigations or complaints, where appropriate, which:

- are easy to access, understand and complete
- are accessible in a range of different formats and languages or can be made more accessible by using online translation services
- include information for further support, information and advocacy, where appropriate.

4.10 Organisations have systems and processes in line with national whistleblowing standards, which:

- outline appropriate reporting and accountability structures, such as an independent officer at board level or equivalent
- maintain a confidential record of all staff concerns and the action taken in response to those concerns.

What does the standard mean for people?
• You can be confident that clinical services are regularly reviewed to check their quality. • You will be able to give feedback, raise concerns or make complaints, and these will be addressed in a timely and fair manner. • The organisation has effective systems to identify and respond to clinical risks. This helps reduce harm and improves the quality of clinical care. • If something goes wrong, the service will find out why it happened and make changes to improve. The organisation will listen to feedback from everyone involved.
What does the standard mean for staff?
Staff, in line with roles, responsibilities and workplace setting: • understand their role to anticipate, identify, assess and manage clinical risk • feel confident that concerns they raise will be listened to and acted on • feel psychologically safe to proactively raise concerns and address clinical safety and quality issues in their service or area of work • follow established escalation pathways for adverse events, whistleblowing and complaints • follow professional Duty of Candour and their respective professional guidance • demonstrate transparency and integrity • are supported to put learning into action with access to the appropriate time and resources.

What does the standard mean for the organisation?

Organisations, in line with their respective governance and delivery structures:

- proactively identify, assess and manage clinical risk
- ensure patient safety and commit to a culture of openness, transparency and learning
- collect, record and act on concerns, intelligence and early warnings
- support staff and people who raise concerns or issues
- have clear escalation pathways, governance and oversight to manage risk, adverse events and whistleblowing
- conduct timely investigations into adverse events, whistleblowing and complaints
- provide resources, including time, for staff to identify, take part in and implement learning from risk
- provide assurance and oversight for patient safety in all services they plan, commission and deliver.

Benchmarking and measuring performance: Examples of what meeting this standard might look like [linked criteria]

Examples may vary according to the size and scale of the service, NHS board, organisation.

- Governance papers and minutes demonstrating discussion and scrutiny of clinical safety and risk management at board level or equivalent. [4.1, 4.6]
- Evidence of implementation of national and local clinical risk management strategies, policies and frameworks as appropriate. [4.2]
- Patient safety huddles[54] or multidisciplinary safety reviews. [4.3]
- Reporting against identified clinical risk key performance or risk indicators. [4.6]
- Reporting and review of clinical risks and patient safety concerns to the appropriate level within the organisation. [4.6]
- Evidence of processes to identify emerging or recurring clinical risk or patient safety themes for improvement and learning. [4.6]
- Evidence of mitigation plans and action plans. [4.6]
- Evidence of compliance with registration and regulatory guidance in regard to Duty of Candour. [4.4]
- Evidence of review and learning from adverse events and implementation of the national adverse events framework. [4.5]
- Monitoring the number of adverse events reviews concluded within nationally recommended timeframes. [4.5]
- Use of technology-enabled translation services or other appropriate adaptations for complaints and feedback processes, such as translation tools. [4.9]

Standard 5: Education and training

Standard statement

Staff delivering clinical services have the skills, competencies, training and support to provide safe, effective and person-centred care.

Rationale

Staff with the appropriate knowledge and training ensure the delivery of safe, effective, high-quality, evidence-based and person-centred clinical care. Staff training, education and support should be underpinned by relevant local and national protocols, frameworks, guidance and good practice. Organisations should enable staff to undertake relevant national core training and role specific training, for example, through NHS Education for Scotland, Scottish Social Services Council and professional healthcare organisations.

A healthy and supportive working environment can optimise staff and team wellbeing and performance.[14, 21] This includes time for learning and reflection, support for innovation and mechanisms for staff to provide feedback to the service using a psychologically safe process. Staff in a clinical supervision role should have the appropriate training and resources to provide supportive leadership, coaching, supervision, assessment and feedback.[55, 56]

Training should be provided to enable staff to understand and respond to factors that matter to people. This includes the impact of culture, relationships and social support on people's experiences of accessing and receiving healthcare. Staff should be provided with training on how to meet the individual needs of people accessing services, including, but not limited to, people with disabilities, learning disabilities, additional language or communication needs or those living in remote or rural communities.[4, 57] Staff should also have training to understand the impact of health inequalities, intersectionality and protected characteristics on people's experiences and outcomes.

Data on training and education should be routinely monitored to provide oversight and assurance that staff have the appropriate skills and competencies to deliver safe and effective clinical services.

Criteria

5.1 Organisations implement a comprehensive and multifaceted education and training programme that:

- includes regular evaluation and audit of staff learning needs
- is responsive to staff roles, responsibilities and workplace settings
- supports continuing professional development (CPD), with opportunities for upskilling to advanced roles
- is aligned to professional development competencies frameworks
- is multidisciplinary and cross-sectoral and provides opportunities for shared learning
- supports formal and informal approaches, including mentoring, shadowing and coaching.

5.2 Staff are provided with time, resources and support to access and complete training and education that includes:

- routine assessment of skills and competencies, including professional development needs
- regular clinical supervision, including restorative clinical supervision,[55] where appropriate
- annual performance appraisals
- reflection on feedback from patients and colleagues
- reviews of wellbeing and support needs.

5.3 Staff in leadership, supervisory or mentoring roles develop skills and knowledge on:

- understanding of psychological safety and trauma-informed practice within teams and services
- effective and supportive people management, including coaching, supervision and assessment
- embedding reflective practice.

5.4 Staff are supported in giving honest and open feedback to their colleagues and leaders to support reflective practice and peer learning.

5.5 All staff are enabled to deliver person-centred and trauma-informed care, which ensures staff:

- treat people with dignity, respect, kindness, compassion, understanding, courtesy and honesty
- respect the person's right to privacy and confidentiality
- support the person to make decisions and shape the care they receive
- respect the person's personal circumstances
- understand their role in improving how people can access and be engaged in services.

5.6 Staff can access information and resources, including online sources and digital tools, to support the consolidation and development of skills and competencies.

5.7 Where organisations deploy volunteers in the delivery of clinical care, they receive appropriate induction, training, and ongoing education relevant to their roles, including safeguarding, confidentiality and trauma-informed care.

5.8 Staff can access training and education that is:

- quality assured and accredited
- underpinned by local and national protocols, frameworks and guidance
- evidence-based and informed by good practice.

What does the standard mean for people?
• You will be supported by staff who are knowledgeable, skilled and non-judgemental. • You will be treated with kindness, compassion, dignity and respect. • Your care will be high-quality, evidence-based and in line with local and national guidance.

What does the standard mean for staff?
Staff, in line with roles, responsibilities and workplace setting are enabled to: • identify their learning needs • participate in appropriate CPD, education and training with time for reflection and feedback • understand people's experience of services and take into account barriers people may face in accessing services, for example learning disabilities or social circumstances • attend education and training, including mandatory training, with sufficient learning time and resources, where required • access appropriate supervision and support, including support for vicarious trauma if required.[14]
What does the standard mean for the organisation?
Organisations, in line with their respective governance and delivery structures: • provide clear leadership and oversight of staff training and education and ensure assurance of this within national governance structures • ensure all staff are appropriately qualified and trained • ensure staff have appropriate education, training, supervision, supportive leadership, feedback and time for reflection • provide time, resources and support for staff to access and participate in appropriate education, training, supervision and CPD • provide interdisciplinary and multidisciplinary training with partners, as appropriate • ensure training, supervision and CPD is provided by appropriately trained, competent and qualified staff • evaluate and respond to the provision, uptake and effectiveness of training, including staff feedback • monitor training uptake and implement training action plans.

Benchmarking and measuring performance: Examples of what meeting this standard might look like [linked criteria]

Examples may vary according to the size and scale of the service, NHS board, organisation.

- Governance papers and minutes demonstrating discussion and scrutiny of staff training and education at board level or equivalent.
- Evidence of multidisciplinary and interdisciplinary training and education. [5.1]
- Provision and uptake of external and multiagency training. [5.1]
- Training, education and CPD records, audit and plans. [5.1-5.3, 5.6-5.8]
- Peer review and support networks for independent practitioners. [5.1, 5.4, 5.6]
- Partnerships between NHS boards, hospitals or services and higher education institutions to deliver multi-disciplinary training. [5.1]
- Training in effective mentoring and clinical supervision. [5.1, 5.3]
- Competency frameworks signed off and uploaded to relevant professional portfolios, such as Turas. [5.1, 5.2]
- Partnerships between national organisations and NHS boards or independent practitioners to develop high-quality learning and training materials. [5.1, 5.8]
- Reviews of staff engagement in annual appraisals. [5.2]
- Ongoing engagement and feedback from service users on their experiences of accessing care. [5.7]
- Induction plans, role profiles or other documentation of a volunteer onboarding process [5.7]
- Use of specific competency frameworks and needs analysis tools relevant to professional groups. For example, the NES development needs analysis tool. [5.1, 5.2, 5.9]
- Improvement plans to increase training uptake. [5.8, 5.9]

Standard 6: Service user and patient involvement

Standard statement

People and communities are meaningfully engaged in the design, delivery and governance of clinical services, in line with statutory duties and national guidance.

Rationale

Effective clinical governance requires routine engagement with people and communities in shaping the services that affect, or may potentially affect, them. Meaningful engagement with people and communities supports quality, promotes equity and helps public sector bodies, including the NHS, meet their legal obligations in line with legislation and national guidance.[51, 57-60] Independent providers can benefit from adopting similar collaborative approaches to improve the quality, relevance and accessibility of their services.

Embedding public engagement within governance and quality systems ensures that services are informed by lived experience, inclusive of diverse voices and responsive to changing population needs.[4, 61] Services should engage proactively, transparently and accountably, using quality assured approaches that demonstrate a clear link between feedback and service improvement.

The Scottish Approach to Change supports services to combine service design, engagement and quality improvement methodologies so that they can fully and meaningfully engage with communities and service users to understand how to improve or design services.

Healthcare Improvement Scotland has a statutory responsibility to support, ensure and monitor the quality of public involvement across health services. NHS boards and Health and Social Care Partnerships should ensure that community engagement is embedded within planning, reporting and governance processes.

Public involvement and engagement activities should be proportionate to the organisation's role, function, size, scope and model of delivery of clinical services.

Criteria

6.1 Organisations demonstrate compliance with relevant national guidance and statutory duties on public involvement and engagement.

6.2 Organisations clinical governance structures should have oversight and assurance of community engagement and include clear lines of accountability, reporting and assurance.

6.3 Organisations use validated engagement approaches and frameworks to ensure engagement is:

- appropriate to the local population
- inclusive
- meaningful.

6.4 Organisations use evidence-based user design approaches to engage people and communities in clinical services in:

- planning
- codesign
- delivery
- monitoring and evaluation
- service change and service development.

6.5 Organisations undertake equality and other impact assessments of clinical services to understand and address:

- barriers in accessing healthcare and services
- the needs of any underserved communities or locations
- the prevalence and impact of health inequalities and intersectionality in their local population.

6.6 Organisations routinely collect and respond to data on deprivation, rurality, sex, gender, age, disability, race and ethnicity to understand and reduce inequalities in engagement and service improvement.

6.7 Organisations provide accessible, inclusive and timely information about services, engagement opportunities and how to participate in decisions that affect clinical care.

6.8 Organisations routinely gather and respond to feedback and publish how this has informed decisions and improvements. Feedback should be actively sought from:

- people who use clinical services and, where appropriate, their care partners
- volunteers
- local communities.

6.9 Organisations review data from complaints and feedback and publish reports that:

- are easily accessible
- include improvement action plans
- demonstrate where learning has led to improvements in clinical services.

6.10 Organisations ensure that involvement of people with lived experience is effectively governed, including appropriate mechanisms to protect confidentiality.

6.11 Organisations ensure staff:

- are supported to understand their responsibilities in engaging people and communities
- have access to training and tools to support high-quality involvement.

What does the standard mean for people?
• You can be involved in the design and delivery of clinical services in your area in a way that works for you. • Information on services will be provided in a way that is easy to understand. • You will be able to give feedback on your experience of services. • You will hear how your feedback has been considered and what has changed as a result. • Services will be inclusive and accessible, having been codesigned with people and communities.

What does the standard mean for staff?
Staff, in line with roles, responsibilities and workplace setting: • are supported to take part in communication, engagement or participation programmes • understand the populations they work with • understand their role in involving people and communities in the design and delivery of services • understand and apply national guidance on involving people and communities • use inclusive and evidence-based methods to involve people in service design and improvement • work collaboratively with engagement specialists and communities to improve quality and safety.
What does the standard mean for the organisation?
Organisations, in line with their respective governance and delivery structures: • listen and respond to feedback from people and communities about the services they provide • have processes in place to facilitate codesign when planning and redesigning services • demonstrate compliance with accessibility requirements and standards • embed service user and community involvement within their governance, quality and planning systems • provide assurance that engagement activity is compliant with statutory duties and best practice • use data, evidence and feedback to identify inequalities and act on these • work with Healthcare Improvement Scotland and local partners to continuously improve the quality of engagement practice • evaluate involvement activities and capture learning to inform future projects.

Benchmarking and measuring performance: Examples of what meeting this standard might look like [linked criteria]

Examples may vary according to the size and scale of the service, NHS board, organisation.

- Review of communications against accessibility requirements. For example, ensuring websites meet accessibility guidance. [6.1, 6.3, 6.7]
- Use of participation, engagement and public involvement approaches and tools. [6.3, 6.7]
- Evidence of active engagement with the local population when setting up, changing and delivering services. [6.3, 6.4, 6.7, 6.8]
- Establishment of patient or public participation groups or forums. [6.4, 6.8]
- Evidence of adherence to Planning with People and use of the Quality Framework for Community Engagement and Participation. [6.1-6.5, 6.7-6.11]
- Governance papers and minutes demonstrating discussion and scrutiny of engagement activity at board level or equivalent. [6.2]
- Equality and other impact assessments and community profiling data used to inform planning and service design and improvement. For example, islands impact assessments or child wellbeing and rights impact assessments. [6.5, 6.6]
- 'You said, we did' reports and case studies published on public platforms. [6.8, 6.9]
- Training records for staff involved in engagement on service planning and improvement. [6.3]
- Active collaboration with Healthcare Improvement Scotland in the design and assurance of engagement approaches. [6.1, 6.3, 6.4, 6.7]

Standard 7: Data and information

Standard statement

Clinical services store and share personal data appropriately and use safe, secure systems and tools.

Rationale

Integrated and readily accessible healthcare records can reduce duplication of work, avoid unnecessary appointments, interventions or medication, support safe transfers of care (including between settings and providers) and improve people's experience of the health and social care system. Compliance with information and data standards supports integration and development of digital systems to improve the quality and safety of clinical care. Access to personal health data can support people to better manage their own healthcare in line with what matters to them.[62] This standard covers all forms of organisational and healthcare records including paper and digital.

The collection, retention and sharing of information is governed by legislation and national guidance, including the UK General Data Protection Regulation (2021), Data Protection Act (2018) and the Network and Information Systems Regulations (2018).[63-65] All public sector organisations are required to ensure appropriate operational and technical protections are in place when they, or their suppliers, process and share personal data. This requires oversight and assurance to protect people's right to privacy and safeguard their personal clinical data. The Public Records (Scotland) Act 2011 governs the use of records management plans and good records management.

Information collected for the provision of health and social care is governed by the eight Caldicott principles. These apply to the use of confidential information and when such information is shared with other organisations and between individuals, both for individual care and for other purposes. Consent should be obtained in line with national policies and procedures. Information should only be shared with consent and in line with legislation and national guidance for example, child and adult protection policies.[66-69] In addition to consent, the eighth Caldicott principle outlines that a range of steps should be taken to ensure that service users understand how and why their confidential information may be shared and what choices they have about this. In some circumstances, information can be shared without the person's consent if this is deemed necessary to protect them, or other people, from harm.[70-72]

Data security guidelines require organisations to improve resilience against cyberattacks, data breaches and system errors.[73, 74] Contingency plans reduce harm by ensuring essential networks and systems can continue operating during outages and security risks.

A person-centred approach is essential to the development of safe, secure and ethical data systems and digital tools.[65]

Criteria

7.1 Organisations have systems and processes in place to ensure personal healthcare data or clinical information is:

- recorded accurately, consistently and timeously in clinical records, care plans and related documentation, including handovers
- anonymised appropriately
- to obtain appropriate consent in line with national policies and procedures
- shared with other services or organisations when it is in a person's best interests or the public's best interests[75]
- managed in line with legislation and national guidance, including records management.[63-65]

7.2 Organisations have accessible policies on the collection, use, storage and sharing of their personal data.

7.3 Organisations use up-to-date technical systems to maximise:

- quality of clinical care
- service efficiency
- data interoperability
- clinical data flow between systems.

7.4 Organisations demonstrate that they meet the Network and Information Systems Regulations (2018) and other relevant legislation and guidance by:

- taking appropriate and responsive measures to mitigate data security risks
- having technical and organisational measures in place to ensure continuity of essential network and information systems.

7.5 Organisations have processes in place to provide assurance on the security, efficacy and ethical use of new and emerging technology, including Artificial Intelligence (AI), while ensuring patients have the opportunity to benefit from innovation.

7.6 Staff and volunteers, where appropriate, undertake training relevant to roles and responsibilities about:

- handling and using clinical data responsibly
- how and when to share clinical data

- cyber security risks and how to prevent them
- data protection and records management.

7.7 Organisations ensure that all clinical records and documentation are accurately and consistently completed with actions recorded. This includes risk assessments.

What does the standard mean for people?
• Your personal data will be kept safe and secure. • Clinical services will be able to access information about you to help you get the right care at the right time. • Information about you and your care, including personal data, will only be shared with your consent unless there are concerns for your wellbeing. This will be explained to you. • You can request access to your information and personal data. • Organisations use the best available digital tools and systems. • Digital systems will be tested and developed to ensure they remain safe. • Organisations have a back-up plan if digital systems fail or are attacked. • All digital tools used in healthcare, including AI, will be ethical, safe and secure.
What does the standard mean for staff?
Staff, in line with roles, responsibilities and workplace setting: • understand the appropriate sharing of clinical information • understand their role in keeping clinical records and information systems safe from unauthorised access • are trained in information governance, including prevention of cyber security risks • test and embed new, proven digital technologies where appropriate • use digital tools to improve the quality and safety of integrated care.

What does the standard mean for the organisation?
Organisations, in line with their respective governance and delivery structures: • demonstrate compliance with national guidelines and legislation related to records management, data and digital systems • implement information management and information governance training for staff, including volunteers and contractors • take appropriate technical and operational measures to ensure clinical data is securely stored and accessed • take appropriate and responsive measures to mitigate information risks, for example data security, data loss, over retention or data breaches • have contingencies in place to ensure the continuation of essential services • renew and assess the digital estate regularly to ensure state-of-the-art digital innovations can be adopted and implemented • work in partnership to ethically develop and test new digital tools • integrate systems and share data to improve the quality and safety of care.

Benchmarking and measuring performance: Examples of what meeting this standard might look like [linked criteria]

Examples may vary according to the size and scale of the service, NHS board, organisation.

- Governance papers and minutes demonstrating discussion and scrutiny of information governance and data management at board level or equivalent. [7.1, 7.2, 7.4]
- Implementation of local records management policies that are aligned with national legislation and codes of practice. [7.3, 7.10]
- Compliance with national information governance and cyber security audits. [7.1, 7.3]
- Data sharing protocols and agreements between services, partnerships or organisations. This may be part of service-level agreements or memorandums of understanding. [7.1, 7.5, 7.9]
- Routine use of Data Protection Impact Assessments. [7.1, 7.3, 7.9, 7.10]
- Provision of information leaflets or signposting to NHS Inform or Care Information Scotland on confidentiality and data protection. [7.2]
- Use of integrated healthcare records or systems to support clinical service delivery, for example MyCare. [7.1, 7.3]
- Implementation and training plans for rollout of new technology or software. [7.5, 7.6]
- Software and technology audits to ensure systems remain up to date. [7.1, 7.2, 7.4]
- Service or organisational Disaster Recovery Plan. [7.7]
- Evidence of routine resilience planning and system testing. [7.7, 7.8]
- Contingency plans for local and system-wide issues or network outages. [7.7]
- Alternative offline processes in case of local system issues. [7.7]
- Routine testing of recovery protocols for digital systems. [7.7]
- System security policies to appropriately risk assess data processing and security. [7.7, 7.10]
- Protocols for ethical use of technology and digital tools. [7.8]
- Development of a local digital or AI strategy with a focus on ethics and governance. [7.8]
- Plan-Do-Study-Act cycles to embed and expand the use of new digital tools. [7.6, 7.8]
- Training programmes and awareness raising sessions on information governance and cyber security. [7.6]
- Organisational chart with named staff for data protection, information governance and business continuity. [7.1, 7.6]
- Annual reports on percentage of staff with completed training. [7.6]

Appendix 1: Development of the standards

Healthcare Improvement Scotland has established a robust process for developing standards, which is informed by international standards development methodology.[76] This ensures the standards:

- are fit for purpose and informed by current evidence and practice
- set out clearly what people who use services can expect to experience
- are an effective quality assurance tool.

The standards have been informed by current evidence, best practice recommendations, national policy and are developed by expert group consensus. The standards have been cocreated with key stakeholders and people with lived experience from across Scotland.

Evidence base

A review of the literature was carried out using an explicit search strategy developed by Healthcare Improvement Scotland's Research and Information Service. Additional searching was done through citation chaining and identified websites, grey literature and stakeholder knowledge. Searches included Scottish Government, Public Health Scotland, NICE, SIGN, NHS Evidence and Department of Health and Social Care websites. This evidence was also informed by equalities impact assessments. Standards are mapped to a number of information sources to support statements and criteria. This includes, but is not limited to:

- government policy
- approaches to healthcare delivery and design, such as person-centred care
- clinical guidelines, protocols or standards
- professional or regulatory guidance, best practice or position statements
- evidence from improvement.

Related guidance and policy

All Healthcare Improvement Scotland standards are mapped to relevant key national legislation, policy and standards (see References section for full list used in these standards). They are aligned to the principles of person-centred and trauma-informed care, human rights and equality.

The standards should be read alongside the following key documents:

- Blueprint for Good Governance (2022)
- Health and Care (Staffing) (Scotland) Act 2019 and Statutory guidance
- Patient Rights (Scotland) Act 2011
- Public Sector Equality Duty: guidance for public authorities

- NHS Scotland operational improvement plan
- NHS clinical strategy (2016)
- Health and Social Care Standards (2017)

Healthcare Improvement Scotland related work programmes:

- A national framework for reviewing and learning from adverse events in NHS Scotland: February 2025
- Excellence in Care
- Healthcare staffing programme
- Quality assurance framework
- Scottish approach to change

Standards development

The development of standards is underpinned by the views and expectations of healthcare staff, third sector representatives, people accessing health and social care and the public. The standards development process included:

- a scoping engagement period of four weeks
- development group meetings held between June and September 2024
- an eight-week consultation on the draft standards
- two development group meetings in September and October 2025.

Format of the standards

All Healthcare Improvement Scotland standards follow the same format. Each standard includes:

- an overarching standard statement
- a rationale explaining why the standard is important
- a list of criteria describing what is needed to meet the standard
- what the standard means if you are a person using clinical services
- what the standard means if you are a member of staff
- what the standard means for organisations
- examples of what meeting the standard looks like in practice. This includes criterion number the example relates to.

The examples provided are intended to support NHS boards in assessing, benchmarking, and evidencing their performance against the criteria. These examples are illustrative only and should not be regarded as an exhaustive or prescriptive list of all possible forms of evidence. Given the variation in scale, service configuration, population needs, and delivery models across NHS boards, the specific examples relevant to each service or organisation may differ.

Examples that NHS boards may use to demonstrate how they are meeting the standards, should reflect their local context including population, configuration of services and partnership working. The same piece of evidence can be used to demonstrate that NHS boards are meeting multiple criteria within these standards.

Consultation feedback and finalisation of the standards

Following consultation, the standards development group reconvened to review the comments received on the draft standards and make final decisions and changes to the standards. More information can be found in the consultation feedback report, which is available on request from the standards and indicators team.

Quality assurance

All standards development group members were responsible for advising on the professional aspects of the standards. Clinical members of the standards development group advised on clinical aspects of the work. The Chair had lead responsibility for formal clinical assurance and sign off on the technical and professional validity and acceptability of any reports or recommendations from the group.

All standards development group members made a declaration of interest at the beginning of the project. They also reviewed and agreed to the standards development group's terms of reference. More details are available on request from the standards and indicators team.

The standards were developed within the Operating Framework for Healthcare Improvement Scotland and the Scottish Government (2022), which highlights the principles of independence, openness, transparency and accountability.

For more information about HIS's role, direction and priorities, please visit: Healthcare Improvement Scotland.

Appendix 2: Membership of the standards development group

Name	Position	Organisation
Tracey Gillies **(Chair)**	Medical Director	NHS Lothian
Karen Beattie	Senior Inspector	Healthcare Improvement Scotland
Penny Brankin	Senior Nurse Practice Development	NHS Lanarkshire
Line Caes	Associate Professor	University of Stirling
Michael Canavan	Portfolio Lead, Quality Management System	Healthcare Improvement Scotland
Karon Cormack	Director of Quality	NHS Lanarkshire
Annamaria De Felice	Communications Manager	JustRight Scotland
Laura Fulton	Chief Pharmacist	Healthcare Improvement Scotland
Dagny Gasking	Public Partner	Healthcare Improvement Scotland
Suzanne Gray	Dementia Nurse Consultant	NHS Tayside
Caroline Gould	Access Auditor	Skye and Lochalsh Access Panel
Katrina Heenan	Chief Risk Officer	NHS Greater Glasgow and Clyde
Jacqueline Jowett	Reviewer	Healthcare Improvement Scotland
Adrian MacKenzie	Pharmacy Clinical Lead Medically Assisted Treatment (MAT) Standards	Healthcare Improvement Scotland
Joanne Matthews	Associate Director Improvement and Safety	Healthcare Improvement Scotland

Name	Position	Organisation
Jo McBain	Allied Health Professional Director	Scottish Directors of AHPs (SDAHP)
Tony McGowan	Associate Director of Community Engagement	Healthcare Improvement Scotland
Marie McKerry	Chief Nurse	Care Inspectorate
Helen Moores-Poole	Professional Advisor Allied Health Professionals	Scottish Government
Phyo Kyaw Myint	Professor of Medicine of Old Age	University of Aberdeen/NHS Grampian
James Niven	Team Leader - Mental Health Standards and Assurance	Scottish Government
Tracey Passway	Head of Patient Safety, Clinical Governance and Risk	NHS Tayside
Lettie Pringle	Risk Manager	NHS Borders
Catherine Ross	Chief Scientific Officer	Scottish Government
Martin Robertson	Public Partner	Healthcare Improvement Scotland
Helen Samborek	Inspector	Healthcare Improvement Scotland
Charlie Sinclair	Associate Director, Nursing, Midwifery and Allied Health Professions	NHS Education for Scotland
Jan Stanier	AHPFS (Allied Health Professions Federation Scotland)	SIGN Council
Maureen Stevenson	Patient Safety and Improvement Manager	NHS Dumfries and Galloway
Varshali Swadi	Professional Engagement and Development Lead	Down's Syndrome Scotland
Jo Thomson	Senior Improvement Advisor	Healthcare Improvement Scotland

Name	Position	Organisation
Lilian Woolfries	Retired	North FoWest Locality Engagement Forum

The standards development group, review and editorial panels were supported by the following members of Healthcare Improvement Scotland's standards and indicators team:

- Stephanie Kennedy – Administrative Officer
- Silas McGilvray – Project Officer
- Rachel Hewitt – Programme Manager (until October 2025)
- Jen Layden - Programme Manager (from October 2025)
- Fiona Wardell – Team Lead

Contributors

The standards development group and project team would like to thank the following people for their contributions to the drafting of the standards:

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- Arlene Bunton, Independent Sector Lead, Scottish Care
- Caroline Craig, Associate Director Healthcare Staffing and Care Assurance, Healthcare Improvement Scotland
- David Ejim, Quality Improvement Advisor, NHS Greater Glasgow and Clyde
- Kerry Foley, Senior Nurse Quality Assurance and Standards, NHS 24
- Ros Fraser, Advanced Practice Speech and Language Therapist, NHS Lothian
- Emma Hughes, Lecturer in Nursing, Edinburgh Napier University
- Jo Hughes, Head of Service Development, Down's Syndrome Scotland
- Eleanor Lang, Associate Nurse Director, NHS Golden Jubilee
- Paula MacGillivray, Community Development Officer – Scotland, MS Society
- Nirmala Mary, Consultant Obstetrician; Maternity Lead; Scottish Patient Safety Programme (SPSP) - Perinatal, NHS Lothian
- Gordon McInnes, Engagement Worker, Mental Health Network Greater Glasgow
- Donna O'Boyle, Professional Regulatory Adviser, Scottish Government
- Paula Spaven, Director of Clinical and Care Governance, NHS Greater Glasgow and Clyde
- Lesley Thomson, Nurse Director, South Lanarkshire HSCP

Appendix 3: Membership of the steering group

The Clinical Governance Standards Steering Group is a high-level, strategic group that:

- agreed the content and wording of a revised scoping report which outlines the title, population, setting, inclusions and exclusions of the standards
- reviewed the membership of the Standards Development Group to ensure it had the relevant expertise
- addressed higher-level risks relating to the delivery of the Clinical Governance Standards
- identified the future governance structure for the Clinical Governance Standards Development Group.

Name	Position	Organisation
Fiona Glen **(Chair)**	Associate Director of Evidence	Healthcare Improvement Scotland
Tracey Gillies	Development Group Chair Medical Director	NHS Lothian
Mhairi Hastings	Associate Director of Nursing and Midwifery	Healthcare Improvement Scotland
Diana Hekerem	Associate Director Community Engagement and Transformational Change	Healthcare Improvement Scotland
Tom McEwan	Professional Lead Midwife- Nursing, Midwifery and Allied Health Professions	Healthcare Improvement Scotland
Adrian MacKenzie	Medically Assisted Treatment (MAT) Standards Clinical Lead	Healthcare Improvement Scotland
Donna McLean	Chief Inspector	Healthcare Improvement Scotland

Name	Position	Organisation
Safia Qureshi	Director of Evidence & Digital	Healthcare Improvement Scotland
Angela Timoney	Chair of Scottish Intercollegiate Guidelines Network (SIGN) Council	Healthcare Improvement Scotland
Simon Watson	Medical Director	Healthcare Improvement Scotland
Fiona Wardell	Standards and Indicators Team Lead	Healthcare Improvement Scotland

Appendix 4: Membership of the editorial and review panel

Name	Position	Organisation
Tracey Gillies **(Chair)**	Medical Director	NHS Lothian
Laura Boyle (final)	Director of Quality Assurance and Regulation	Healthcare Improvement Scotland
Rachel Hewitt (draft)	Programme Manager	Healthcare Improvement Scotland
Jen Layden (final)	Programme Manager	Healthcare Improvement Scotland
Safia Qureshi	Director of Evidence & Digital	Healthcare Improvement Scotland
Fiona Wardell	Team Lead	Healthcare Improvement Scotland

Glossary

Term	Definition
Accessible and timely	ensuring people can access care when and where they need it.
Adverse event	an event that could have caused, or did result in, harm to people, including death, disability, injury, disease or suffering and/or immediate or delayed emotional reaction or psychological harm.
Care partner	refers to any person or representative the individual wishes to be involved in their care. This may be a friend, neighbour, family member or other person who may provide informal help or support.
Clinical risk	refers to the potential for harm which may result from decision making, clinical investigation, treatment or care. Harm includes impact on a person, their wellbeing or healthcare experience. This could arise from gaps in processes, procedures or guidance, failure to provide appropriate staffing and training or failure to comply with clinical care requirements, including regulation.
Clinical supervision	in the NHS, a formal process for supporting the development of registered healthcare professionals through a combination of reflection, case review and feedback. It helps staff manage work-related stress, enhance skills, improve patient care and meet professional requirements for CPD. Supervision is a structured way for staff to discuss their practice, challenges and achievements in a confidential environment.
Effective	providing care based on evidence and which results in positive outcomes.
Equitable	providing care that delivers equity of outcomes for everyone and that recognises the different needs of protected characteristics.
Human rights	Human rights in the UK are protected by the Human Rights Act 1998, which incorporates the rights from the European Convention on Human Rights into UK law. This Act obliges public authorities like NHS Scotland, the Care Inspectorate, government, police and local councils to treat everyone fairly, with dignity and in accordance with these rights. These rights include the right to life, freedom from torture, a fair trial and

Term	Definition
	respect for private life. Anyone in the UK, regardless of citizenship, can use the Act to defend their rights in UK courts. All public sector bodies have duties to respect, protect and fulfil the rights that people have under the Human Rights Act 1998 when carrying out our functions. They also have duties to eliminate discrimination, advance equality of opportunity and foster good relations between different groups under the Equality Act 2010.
Near miss	any event that could potentially have caused harm.
Organisation	refers to all health and social care providers or services that provide or have oversight of clinical care.
Person-centred and personalised	providing care that responds to individual needs and preferences and that ensures individuals are partners in its planning and delivery.
Primary care	is community-based services provided by healthcare staff, including GPs and community nurses.
Quality	in relation to healthcare refers to care that is person-centred, safe, effective, efficient, equitable and timely, in line with the Institute of Medicine's six domains of quality.
Quality management system	is a coordinated and interconnected approach to planning, improving, maintaining and assuring high-quality care applied across all levels of an organisation.
Safe	is when the care people receive does not harm them and people using healthcare services feel safe
Safety	refers to the absence of preventable harm to a patient. It includes the reduction of the risk of healthcare-associated and unnecessary harm to an acceptable minimum.
Skills mix	is the range of competencies possessed by an individual healthcare worker, the ratio of senior to junior staff within a particular discipline and the mix of different types of staff in a team or healthcare setting.
Staff	refers to people who are employed to provide healthcare support to an individual. It includes, but is not limited to, those defined in the Health and Care (Staffing) (Scotland) Act 2019. This includes locum staff, volunteers, contracted staff, those covered by reciprocal work arrangements and students on placement.

Term	Definition
Trauma-informed	is a way of working and delivering services that recognises that a person may have experienced trauma and that understands the effects that trauma may have on them. For healthcare services, it involves adapting processes and practices, based on this understanding of the effects of trauma, and seeks to avoid, or minimise, the risk of exposing the person to any recurrence of past trauma or further trauma. A trauma-informed service will be able to demonstrate the ways in which it has been informed by feedback from people with living and lived experience of trauma. A trauma-informed system also supports workforce resilience and is supported by trauma-informed leadership and systems.
Vicarious trauma	is the emotional and psychological impact that occurs from repeatedly hearing about or witnessing the trauma of others.
Whistleblowing	is when a person who delivers services or used to deliver services on behalf of a health service body, family health service provider or independent provider (as defined in section 23 of the Scottish Public Services Ombudsman Act 2002) raises a concern that relates to speaking up in the public interest about an NHS service where an act or omission has created, or may create, a risk of harm or wrong doing.

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