Healthcare Improvement Scotland

Clinical Governance

Draft standards

July 2025

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-todate, 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 to notify us of any updates that might require consideration.

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www.healthcareimprovementscotland.org

Contents

Introduction

Background

NHS Scotland has a statutory duty to ensure the quality of care that it delivers. Since 1998, the process that healthcare providers use to measure, report on and improve quality has been referred to as clinical governance. In 2005, NHS Quality Improvement Scotland published national standards for *Clinical Governance & Risk management: Achieving safe, effective, patient-focused care and services.* The aim of the standards was to ensure that NHS boards had clinical governance and risk management arrangements in place to support the delivery of safe, effective, person-centred care and services.

Clinical governance

An effective governance infrastructure is essential to the delivery of high-quality healthcare and continuous improvement. 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. It is the framework of systems and processes that organisations use to assess and improve clinical care.[1]

Clinical governance is an integral and essential part of the NHS Scotland governance framework. It 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, 3]

Details of all current governance requirements for NHS boards are provided in the *Blueprint for Good Governance* (2022).

Quality management in healthcare

Whole system quality management frameworks recognise the complex and person-specific nature of healthcare.[4] They allow continuous learning and adaptation to new technologies, global challenges and increasingly integrated systems.[5, 6] 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.[7] In Scotland, the Scottish Patient Safety Programme recognises the benefits of a staff-led approach to continuous improvement and learning.[8]

Standards are an essential part of a whole-system quality management system. 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.

Population covered by the clinical governance standards

The standards will apply to all clinical services planned, commissioned or delivered 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.

The standards will apply in all settings where people (adults and children) receive clinical care services in Scotland.

Providers responsible for meeting the standards

- healthcare services planned, delivered or commissioned by NHS Scotland
- healthcare 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.

Related guidance and policy

These standards are underpinned by human rights and seek to provide better outcomes for everyone accessing clinical services in Scotland.

The clinical governance standards should be read alongside:

- A national framework for reviewing and learning from adverse events in NHS Scotland: February 2025
- Blueprint for Good Governance (2022)
- Data Protection Act 2018
- Equality Act 2010: guidance
- Health and Care (Staffing) (Scotland) Act 2019: Statutory guidance
- Health and Social Care Standards (2017)
- NHS clinical strategy (2016)
- NHS operational improvement plan (2025)
- NHS Scotland operational improvement plan
- Operating Framework for Healthcare Improvement Scotland and the Scottish Government (2022)
- Patient Rights (Scotland) Act 2011
- Public Sector Equality Duty: guidance for public authorities
- Realistic Medicine
- The Health and Care (Staffing) (Scotland) Act 2019
- The NIS Regulations 2018
- The right to health
- The Scottish Approach to Service Design (SAtSD)
- UK GDPR

Format of the standards

All HIS 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 for the person
- what the standard means if you are a member of staff
- what the standard means for organisations
- examples of what meeting the standard might look like in practice.

Glossary

Wherever possible, we have used generic terminology that can be applied across all health and social care settings. The terms ‘people,’ ‘person’ or ‘individual’ are used within the criteria to refer to the person receiving care or support.

The term **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.

Unpaid carers provide or intend to provide care for an individual and their role is recognised under the Carers (Scotland) Act 2016.[9]

Staff refers to people who are employed to provide health and care support to an individual. It includes but is not limited to those defined in the Health and Care (Staffing) (Scotland) Act 2019.[10]

Organisation refers to all health and social care providers or services that provide or have oversight for clinical care.

How to participate in the consultation process

We welcome feedback on the draft standards and will review every comment received. We are using different methods of consultation, including:

- online and face-to face engagement
- meeting and event attendance to raise awareness and hear feedback
- an online survey.

Submitting your comments.

Responses to the draft standards should be submitted using our online survey: https://www.smartsurvey.co.uk/s/3RRFYJ/

The consultation closes on **2 September 2025**. If you would like to submit your comments using a different format, please contact the project team on his.standardsandindicators@nhs.scot.

Consultation feedback

At the end of the consultation period, all comments will be collated. The Standards Development Group will create a response to each comment received on the draft standards. The response will explain how the comments were considered when producing the final standards.

A summary of the responses to the consultation will be made available on request from the project team at his.standardsandindicators@nhs.scot.

The final standards will be published in March 2026.

Standards summary

Standard 1: Staffing and staff management

Clinical services have effective leadership, oversight and staffing levels.

Standard 2: Clinical audit and quality improvement

Clinical services use data and intelligence to monitor and improve the safety and quality of the service.

Standard 3: Clinical effectiveness

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

Standard 4: Risk management and safety

Clinical services monitor practice and respond to safety concerns, risks and near misses.

Standard 5: Education and training

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

Standard 6: Service user and patient involvement

Clinical services involve people and communities in the design and delivery of services.

Standard 7: Data and information

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

Standard 1: Staffing and staff management

Standard statement

Clinical services have effective leadership, oversight and staffing levels.

Rationale

Leadership at all levels ensures that the organisation's strategic vision is communicated to all staff. This supports effective planning and delivery of services.[11] Leadership and effective strategic planning have a significant effect on all quality practices in healthcare. Leadership has been found to be the main driver of quality and has a significant impact on other quality domains.[12, 13]

Where clinical services are planned or delivered in partnership, clear lines of accountability in partnership structures 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.

The Health and Care (Staffing) (Scotland) Act 2019 provides a statutory basis for the provision of appropriate staffing in health and care services. Statutory guidance has been published to support organisations with duties outlined in the Act to meet the Act's requirements and ensure appropriate staff levels and training. The use of capacity planning tools and data is a key component to the implementation and monitoring of safe staffing levels.

Staff must uphold the professional standards expected of them by their professional regulator or NHS Scotland.[14-17] Staff governance is outlined in the Blueprint for Good Governance (2022).

Criteria

1.1 Organisations have workforce plans to ensure current and future levels of staffing are safe and sustainable.

1.2 Each service has an agreed staffing model, which:

- emphasises values-based practice, including compassion and understanding[18]
- offers the correct blend of skills to ensure timely assessment and appropriate referral where necessary
- enables continuous safe care and support to be provided
- is sustainable.

1.3 Organisations have agreements for the delivery of each service, which cover:

- shared aims, a vision and a culture
- team structure, including clearly-defined roles and responsibilities
- mechanisms for ongoing learning and evaluation to improve joint practice
- resourcing.

1.4 Staff experience leadership at all levels that is:

- compassionate
- inclusive
- positive
- motivational
- visible
- confident.

1.5 Organisations have defined values that are communicated to all staff.

1.6 The organisation has objectives and priorities that:

- reflect its overall vision, strategy and aims
- are driven by what is relevant and important to people who use the services it provides
- 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.

1.7 Staff, including leaders, routinely undertake performance appraisals, including reflection on feedback from all areas of their work.

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

1.9 Staff work within defined clinical competencies and seek specialist advice, second opinion or further clarification where needed.

1.10 Organisations check and validate professional qualifications and registration (where applicable) of all staff:

- prior to their starting work
- throughout the duration of their employment where they are required to maintain or renew their registration.

1.11 Organisations have robust processes in place to identify and mitigate the risk of employing staff who have criminal convictions for, or previous investigations into, abuse, harm or unsafe practice.

What does the standard mean for people?
• You can be confident that the organisation is well led and managed. • The organisation will have appropriate systems and controls in place for recruitment. • 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.
What does the standard mean for staff?
Staff, in line with roles, responsibilities and workplace setting: • experience positive and compassionate leadership • work in adequately-staffed teams and services • understand and act in line with core values • understand their role within a multidisciplinary team.
What does the standard mean for the organisation?
Organisations: • ensure adequate levels of staffing and appropriate skill mix to ensure continuity of care and support in line with the Health and Care (Staffing) Scotland Act 2019 • have workforce resilience plans and implementation monitoring • ensure consistently adequate and sustainable safe staffing levels • support staff through effective leadership • have a clearly communicated vision that is in line with national priorities • provide clear leadership and oversight of healthcare services.

Examples of what meeting this standard might look like
• Evidence of leadership training and development pathways. • Use of staffing tools and workload models to plan required capacity. • Audit of staff vacancies, staff retention and safe staffing levels and action plans. • Board reports on adherence to provisions of the Health and Care (Staffing) Scotland Act 2019. • Evidence of joint and interdisciplinary training and education. • Clear organisational charts describing lines of accountability and defined roles and responsibilities. • Enhanced background checks for staff and compliance with professional regulators. • Evidence of documented roles, responsibilities, accountability and funding structure for multiagency teams and services.

Standard 2: Clinical audit and quality improvement

Standard statement

Clinical services use data and intelligence to monitor and improve the safety and quality of the service.

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.[19] A coordinated and consistent way of managing quality ensures that the organisation prioritises, plans for, measures and improves quality.[5, 20] System-wide quality requires the commitment and capacity to drive continuous improvement.[21] Proactive management of quality requires organisations to identify and plan improvement before performance issues arise.

An effective clinical audit infrastructure is essential for the delivery of high-quality care. This enables organisations to meet changing healthcare needs through continual monitoring, planning, improving and assuring quality. 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 and share good practice.[22]

Criteria

2.1 Organisations undertake routine clinical audit, self assessment and benchmarking as part of reporting quality and safety at board level or equivalent.

2.2 Organisations implement a systematic and evidence-based whole-system quality management approach.

2.3 Organisations participate in national datasets, audit, evaluation and research and they use information from this work to continuously improve care.

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

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

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

- share intelligence and learning
- rolling out good practice.

2.6 Organisations collect demographic data, including ethnicity, when reviewing safety incidents and use this data to reduce health inequalities.

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

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

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

What does the standard mean for people?
• Organisations are always learning to make your healthcare better. • Organisations monitor their own services so they can understand where improvements are needed. • Services share their learning with other services.
What does the standard mean for staff?
Staff, in line with roles, responsibilities and workplace setting: • continuously improve care and treatment • undertake local improvement work and tests of change • understand their role in improving quality across the whole system • provide data and support clinical audit • implement innovative practice and share learning.

What does the standard mean for the organisation?
Organisations: • actively monitor the quality of care they deliver through established governance and oversight forums • use data and intelligence to monitor and improve safety and quality • work collaboratively with other organisations to share learning and improve safety and quality of care • implement a whole-system evidence-based quality management system.
Examples of what meeting this standard might look like
• Implementation of a quality management system at all levels of the organisation. • Use of accessible and intuitive data dashboards, including progress against key indicators for quality reporting at board level or equivalent. • Participation in national forums and informal intelligence sharing networks. • Staff training in quality improvement skills, knowledge and expertise at all levels. • Provision and uptake of staff education and training in quality improvement methodology relevant to their role and responsibilities. • Minutes and actions from forums.

Standard 3: Clinical effectiveness

Standard statement

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

Rationale

Clinical effectiveness is centred on providing evidence-based care with positive outcomes for individuals and populations.[23] Effective 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. 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 the effectiveness of a complex intervention.[24]

Effective clinical care ensures people receive the right care at the right time.[25] 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.[26] Implementing the principle of Realistic Medicine can reduce unnecessary interventions which, 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.[27] Healthcare practitioners should fully explain the situation and options and support people to make decisions about their health and care.[28] Shared decision making can reduce harm and improve the quality of care.[29-31]

To ensure their patient rights are fully upheld, people require timely information in a format and language that meets their communication needs and level of understanding.[32] Inclusive information is sensitive, accessible and clear to meet the differing needs of individuals.[33-36] All communications, including online clinical information, should meet accessibility standards and public sector requirements under the Equality Act (2010).[37, 38] Clinical services must make reasonable adjustments to ensure people who are protected under the Act can access care and participate meaningfully in discussions.

Effective research governance, knowledge exchange and assessment of technology enables health systems to maintain the pace of change. Collaborative efforts, including joint global efforts, ensure that research and data is accurate, equitable, and meaningful.[39] NHS Scotland supports involvement of organisations in multicentre research trials. This requires robust research governance frameworks that support participation of people and communities. Regulated standards from the Medicines and Healthcare products Regulatory Agency (MHRA) must be met.

Criteria

3.1 Organisations monitor their alignment with all relevant standards and benchmark their progress towards full implementation.

3.2 Organisations demonstrate adoption or implementation plans for all relevant clinical guidelines and monitor practice alignment.

3.3 Organisations have the infrastructure to work in partnership with academic, research, third sector and commercial partners to participate in research and develop clinical excellence.

3.4 All staff groups have time, resources and support to participate in knowledge development and exchange and remain up to date with current best practice and clinical evidence.

3.5 Staff develop an understanding of the person they are caring for as an individual, including:

- how they are affected by their condition or conditions
- how the person's circumstances and experiences affect their condition or conditions and treatment
- their goals and outcomes.

3.6 People are actively enabled and supported as appropriate to develop the knowledge, skills and confidence to manage their own care and treatment, where relevant.

3.7 People have timely access to inclusive, relevant and easy to understand information to enable them to make decisions and choices about their health and care.

3.8 People have the information and support to understand the purpose, risks, alternatives and benefits of any treatment or intervention.

3.9 People are:

- asked about what and who matters to them
- supported to set and review personal goals and outcomes.

3.10 Care and treatment plans:

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

3.11 People can discuss results, treatment and care options with appropriately trained staff and are supported to participate as equals in shared decision making.

What does the standard mean for people?
• You will be actively involved in making decisions about your health and care. • 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. • The healthcare you receive will be in line with current best practice and evidence. • You will have access to assessments, tests, treatment and medicines that are effective.
What does the standard mean for staff?
Staff, in line with roles, responsibilities and workplace setting: • work to high-quality clinical and practice guidance • provide personalised and evidence-based clinical care • 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 care • have access to new validated techniques, medicines and technologies • work across different disciplines and organisations to coordinate care • have time to develop and expand their specialist knowledge.

What does the standard mean for the organisation?
Organisations: • ensure people are cared for in the right place at the right time • demonstrate practice alignment with relevant standards and clinical guidelines • work in partnership with research organisations and universities to contribute to knowledge and define best practice • provide opportunities for staff to take part in research • support the development and implementation of evidence-based technology assessments and guidelines.
Examples of what meeting this standard might look like
• Self-evaluation and assessment against national standards and clinical guidelines. • Implementation and knowledge exchange work to translate research into practice. • Existence of formal research partnerships, joint funding bids and research collaboratives. • Research output including publications, new practice and improvement work. • Use of 'What Matters to You' boards, supported conversations and documented individual needs. • Feedback from people and care partners on their experience of shared decision making. • Use of alternative and augmentative communication systems or communication aids. • Use of health passports detailing people's communication needs, adjustments, preferences and adaptations.

Standard 4: Risk management and safety

Standard statement

Clinical services monitor practice and respond to safety concerns, risks and near misses.

Rationale

Enabling and managing risk is a central part of delivering high-quality health and social care services. Organisations have a duty of candour to be open and transparent about clinical risk and how it is managed. Openness and honesty must be central to every relationship between those providing and those experiencing treatment and care.[40]

National statutory inquiries into harm, safety issues or poor performance consistently highlight a lack of 'safety culture.' Learning from incident and inquiries highlights that organisations should listen to people's experience, respond to early warning signs, address staff concerns and prioritise safety.[41-46] Risk management protocols and processes ensure that risks are escalated and mitigated at the right level.[47] National standards outline that processes for whistleblowing should support staff to raise concerns in a psychologically safe way and ensure that staff are adequately protected and supported.[48]

Adverse events and complaints are a key source of intelligence about the safety and quality of a service. Adverse events, near misses, complaints and positive feedback on good practice can help organisations anticipate future risks and prevent or reduce harm.[49] Consistent national reporting ensures that incidents and monitoring and learning from adverse events is shared.[50, 51]

Criteria

4.1 Clinical risk is identified, evaluated and managed according to local protocols:

- at service and ward level (or equivalent)
- at organisational level
- across the system through a consistent national safety reporting mechanism.

4.2 Organisations have a robust governance and reporting structure to support effective oversight and assurance, including:

- clinical leadership and scrutiny of decisions at board level or equivalent
- named responsible officers and deputies
- compliance with regulatory and statutory responsibilities
- proactive management of clinical risk
- oversight of prescribing, supplying and administering medicines.

4.3 Organisations have effective processes for managing complaints, incidents, near misses and adverse events, in line with national policy. This includes:

- standard and consistent approaches to reporting and responding
- systems to ensure an appropriate response is undertaken within nationally recommended timelines
- documented escalation policies for response, investigation and review
- clear lines of accountability for local review and response
- processes to identify and respond to emerging or recurring themes
- systems for monitoring progress against actions and improvement plans.

4.4 Staff use the local adverse event reporting system to report on adverse events, including near misses.

4.5 Organisations are fully transparent and provide timely information to anyone affected by adverse events or near misses, including staff, in line with national guidance.

4.6 Organisations have systems and processes in place to ensure that:

- they learn from each investigation of an adverse event or safety concern
- all learning from safety concerns, including adverse events, is shared and implemented widely
- annual reports are published in line with duty of candour legislation.

4.7 Organisations have processes to support staff who raise concerns about any aspect of service delivery they feel may have a detrimental effect on the quality of services.

4.8 Organisations maintain a confidential record of all staff concerns and the action taken in response to those concerns.

4.9 Organisations have an independent officer at board level or equivalent who is responsible for handling complaints and whistleblowing.

4.10 Organisations have systems and processes in place to demonstrate adherence to national whistleblowing standards.

4.11 Organisations ensure that their complaints process:

- is easy to access, understand and complete
- is outlined in a range of different formats and languages
- includes information for further support, information and advocacy, where appropriate.

4.12 Organisations provide a timely and appropriate response to complaints, including any learning or improvement plans that have been developed as a result.

4.13 Organisations proactively identify, evaluate and manage risks associated with changes to the design or delivery of services.

4.14 Organisations can demonstrate a clear commitment to openness and transparent decision making.

4.15 Information about services is transparent, inclusive and appropriately shared.

What does the standard mean for people?
• You can be confident that services are monitored to make sure they are safe. • You can be confident that services are regularly reviewed to check their quality. • You can be confident that if something goes wrong, the service will find out why it happened and make changes to improve. • You can be confident that if you have been affected by something that went wrong, the service will investigate and contact you with further information.

What does the standard mean for staff?
Staff, in line with roles, responsibilities and workplace setting: • demonstrate responsibility and accountability for their own and others' professional practice • work in a culture of openness, receptiveness and putting learning into action • feel confident that concerns they raise will be listened to and acted on • are supported to raise concerns and address quality issues in their service or area of work.
What does the standard mean for the organisation?
Organisations: • provide assurance and oversight for patient safety in all services they plan, commission and deliver • promote patient safety and encourage a culture of openness and learning • act immediately on concerns, intelligence and early warnings • support staff and people who raise concerns or issues.
Examples of what meeting this standard might look like
• Regular reporting and scrutiny of quality at board level or equivalent. • Risk registers, risk logs, mitigation plans and action plans for clinical risk at board level or equivalent. • Action or implementation plans at board level or equivalent for quality standards, including condition- or population-specific standards. • Evidence of reporting and review of risk, incidents and events, including clear routes for escalation. • Evidence of review and learning from adverse events and safety-critical incidents. • Monitoring the number of adverse events reviews concluded within nationally recommended time frames.

Standard 5: Education and training

Standard statement

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

Rationale

Staff with the appropriate knowledge and training ensure the delivery of clinical care that is safe, effective, high-quality, evidence-based and person-centred. Staff training, education and support should reference relevant local and national protocols, frameworks, guidance and good practice.[52, 53] A healthy and supportive working environment can optimise staff and team wellbeing and performance. This includes time for learning and reflection, support for innovation, provision of breaks and mechanisms for staff to provide feedback to the service using a psychologically safe process.

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. Services should consider barriers experienced by people accessing services, including, but not limited to, people with disabilities, additional language or communication needs, or those living in remote or rural communities.

Criteria

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

- protects learning time
- includes an evaluation 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 frameworks.

5.2 All staff understand their responsibilities and respect the professional competences and contributions of all members of the care team.

5.3 Staff are provided with time, resources and support to access and complete training and education appropriate to their roles, responsibilities and workplace setting.

5.4 Staff who mentor or supervise others receive training on:

- effective and supportive people management
- embedding reflective practice
- how to develop their own skills and knowledge.

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

5.6 Staff have routine access to appropriate clinical supervision.

5.7 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.

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.
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 • attend education and training, including mandatory training, with protected learning time and resources, if required • can access appropriate supervision and support, including support for vicarious trauma if required.

What does the standard mean for the organisation?
Organisations: • provide interdisciplinary and multidisciplinary training, with partners as appropriate • ensure staff have appropriate education, training, supervision, supportive leadership, feedback and time for reflection • ensure all staff are appropriately qualified and trained, and provide assurance of this within national governance structures • provide time, resources and support for staff to access and participate in appropriate education, training, supervision and CPD • 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.
Examples of what meeting this standard might look like
• Training, education and CPD audit and plans. • Evidence of multidisciplinary and interdisciplinary training and education. • Provision and uptake of external and multiagency training. • Partnerships between NHS boards, hospitals or services and higher education institutions.

Standard 6: Service user and patient involvement

Standard statement

Clinical services involve people and communities in the design and delivery of services.

Rationale

Involvement of people and communities helps to ensure that services are equitable, sustainable and rights based.[26] This is outlined in national standards on public involvement.[54, 55] To ensure that clinical services are high-quality, people should be meaningfully involved in the design and delivery of services, assessment of technology and development of clinical pathways, guidelines and standards.[56]

Understanding the barriers to engagement and the context people live in can support meaningful public engagement in the design and delivery of clinical services.[57-62] Approaches should be transparent and involve people as part of the methodology design process.[63-65] Following the principles of the Scottish Approach to Service Design, organisations should work together to understand the system and engage fully with service users and communities to understand where improvements can be made.[66]

Criteria

6.1 Organisations use evidence-based participation models and approaches to understand the practical reality of people's experience of clinical services.

6.2 Organisations use evidence-based user design approaches to support meaningful participation and codesign of new services.

6.3 Organisations:

- use validated tools, data and community engagement methods
- understand barriers in accessing services
- identify underserved communities or locations
- understand the prevalence and impact of health inequalities in their local population.

6.4 Organisations undertake regular local population needs assessments using the routine collection of data on deprivation, rurality, gender, age, disability, race and ethnicity.

6.5 Organisations enable and support people to provide meaningful feedback on their experience of clinical services.

6.6 Organisations can demonstrate where feedback from individuals or communities has resulted in a change.

6.7 Organisations can demonstrate that involvement of people with lived experience is:

- representative
- inclusive
- flexible
- effectively governed through impact assessments and self-evaluation.

6.8 Organisations ensure information about the location, referral mechanism, opening times and performance of services is:

- easy to find
- inclusive
- accessible.

What does the standard mean for people?
• You can be involved in the design and delivery of clinical services, if you wish. • You will be able to give feedback on your experience of services. • Services will be inclusive and accessible.
What does the standard mean for staff?
Staff, in line with roles, responsibilities and workplace setting: • 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.

What does the standard mean for the organisation?
Organisations: • listen to people and communities about the services they provide • have processes in place to facilitate codesign when planning and redesigning services • use data and information to understand and reduce health inequalities • demonstrate compliance with accessibility requirements and standards.
Examples of what meeting this standard might look like
• Communication audit against accessibility requirements. • Use of participation, engagement and public involvement approaches. • Use of Equality Impact Assessments, Islands Community Assessments and evidence of adherence to the Public Sector Equality Duty. • Evidence of patient and community involvement in service design and delivery.

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 records can reduce duplication of work, avoid unnecessary appointments, support safe transfers of care and improve people's experience of the health and social care system. Access to personal health data can support people to better manage their own health and care in line with what matters to them.[67] Compliance with information and data standards supports integration and development of digital systems to improve the quality and safety of clinical care.

The collection, retention and sharing of information is governed by legislation and national guidance.[68-71] The UK General Data Protection Regulation (2021), Data Protection Act (2018) and the Network and Information Systems Regulations (2018) require all public sector organisations 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.

Information about a person's care must only be shared with their consent and in accordance with relevant legislation and guidance.[72-74] In some circumstances, information must be shared without the person's consent if this is deemed necessary to protect them, or other people, from harm.[75-77] National information sharing guidance to support public protection should be up-to-date and rights based.

Data security guidelines require organisations to improve resilience against cyberattacks, data breaches and system errors.[78, 79] Contingency plans reduce harm by ensuring essential networks and systems can continue operating during outages and security risks/threats.

A person-centred approach is essential to the development of safe, secure and ethical data systems and digital tools.[80]

Criteria

7.1 Organisations have robust information management structures and governance processes in place to support the:

- routine sharing of identifiable personal healthcare data, with fully informed consent, and in compliance with information governance requirements
- effective collation and management of anonymised data.

7.2 People are provided with appropriate and accessible information on the collection, use, storage, and sharing of personal data.

7.3 Organisations share and use data in line with legislation and national guidance.

7.4 Organisations take appropriate and responsive measures to mitigate data security risks.

7.5 Organisations have technical and organisational measures in place to ensure continuity of essential network and information systems.

7.6 Organisations have processes in place to provide assurance on the security, efficacy and ethical use of new technology including Artificial Intelligence (AI).

7.7 Staff undertake comprehensive training about cyber security risks and can demonstrate knowledge of how to prevent them.

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. • You can request access to your information and personal data. • Digital systems will be tested and developed to ensure they remain safe and keep improving. • New 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: • share information legally and appropriately • understand their role in keeping clinical systems safe from cyber attacks • test and embed new, proven digital technologies • use digital tools to improve the quality and safety of care.
What does the standard mean for the organisation?
Organisations: • demonstrate compliance with legal regulations related to information, data and digital systems • take appropriate technical and operational measures to ensure clinical data and systems are secure • have contingencies in place to ensure the continuation of essential services • work in partnership to ethically develop and test new digital tools • integrate systems and share data to improve the quality and safety of care.
Examples of what meeting this standard might look like
• Compliance with national information governance and cyber security audits. • Integration of systems to support seamless care as far as possible. • Evidence of routine resilience planning and system testing. • Contingency plans for system-wide issues or network outages. • Data sharing protocols and agreements. • Routine use of Data Protection Impact Assessments. • Protocols for ethical use of technology and digital tools. • Development of a local digital or AI strategy. • Plan-Do-Study-Act cycles to embed and expand the use of new digital tools.

Appendix 1: Development of the Clinical Governance Standards

Healthcare Improvement Scotland has established a robust process for developing standards, which is informed by international standards development methodology. 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 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.

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 his.standardsandindicators@nhs.scot.

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: www.healthcareimprovementscotland.org/

Appendix 2: Membership of the Clinical Governance Standards Development Group

Name	Position	Organisation
Tracey Gillies **(Chair)**	Medical Director	NHS Lothian
Karen Beattie	Senior Inspector	Healthcare Improvement Scotland
Pennie Brankin	Senior Nurse Practice Development	NHS Lanarkshire
Arlene Bunton	Independent Sector Lead	Scottish Care
Line Caes	Associate Professor	University of Stirling
Michael Canavan	Portfolio Lead, Quality Management System	Healthcare Improvement Scotland
Karen Cormack	Director of Quality	NHS Lanarkshire
Caroline Craig	Associate Director Healthcare Staffing and Care Assurance	Healthcare Improvement Scotland
Annamaria De Felice	Comms Manager	JustRight Scotland
David Ejim	Quality Improvement Advisor	NHS Greater Glasgow and Clyde
Kerry Foley	Senior Nurse Quality Assurance and Standards	NHS 24
Dagny Gasking	Public Partner	Healthcare Improvement Scotland
Suzanne Gray	Dementia Nurse Consultant	NHS Tayside
Caroline Gould	Access Auditor	Skye and Lochalsh Access Panel
Emma Hughes	Lecturer in Nursing	Edinburgh Napier University
Jo Hughes	Head of Service Development	Down's Syndrome Scotland

Name	Position	Organisation
Jacqueline Jowett	Reviewer	Healthcare Improvement Scotland
Eleanor Lang	Associate Nurse Director	NHS Golden Jubilee
Adrian MacKenzie	Pharmacy Clinical Lead Medically Assisted Treatment (MAT) Standards	Healthcare Improvement Scotland
Joanne Matthews	Associate Director Improvement and Safety	Healthcare Improvement Scotland
Nirmala Mary	Maternity Lead, Scottish Patient Safety Programme (SPSP) Perinatal programme	NHS Lothian
Paula MacGillivray	Community Development Officer - Scotland	MS Society
Jo McBain	Allied Health Professional Director	Scottish Directors of AHPs (SDAHP)
Gordon McInnes	Engagement Worker	Mental Health Network Greater Glasgow
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
Donna O'Boyle	Professional Regulatory Adviser	Scottish Government
Tracey Passway	Head of Patient Safety, Clinical Governance and Risk	NHS Tayside
Catherine Ross	Chief Scientific Officer	Scottish Government

Name	Position	Organisation
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
Paula Spaven	Director of Clinical and Care Governance	NHS Greater Glasgow and Clyde
Jan Stanier	AHPFS (allied health professions federation Scotland)	SIGN Council
Maureen Stevenson	Patient Safety & Improvement Manager	NHS Dumfries & Galloway
Varshali Swadi	Professional Engagement and Development Lead	Down's Syndrome Scotland
Jo Thomson	Senior Improvement Advisor	Healthcare Improvement Scotland
Lesley Thomson	Nurse Director	South Lanarkshire Health and Social Care Partnership (HSCP)
Lilian Woolfries	Retired	North FoWest Locality Engagement Forum

Appendix 3: Membership of the Clinical Governance Standards 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
Safia Qureshi	Director of Evidence & Digital	Healthcare Improvement Scotland

Name	Position	Organisation
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

References

1. Vincent C, Burnett S, Carthey J. The measurement and monitoring of safety. 2013 [cited 2025 July 08]; Available from: https://www.health.org.uk/reports-and-analysis/reports/the-measurement-and-monitoring-of-safety.
2. Scally G, Donaldson LJ. Clinical governance and the drive for quality improvement in the new NHS in England. Bmj. 1998;317(17).
3. Zahir K. Clinical governance in the UK NHS. 2001 [cited 2025 July 08]; Available from: https://assets.publishing.service.gov.uk/media/57a08d59ed915d622c001935/Clinical-governance-in-the-UK-NHS.pdf.
4. ISO. ISO 7101:2023 Healthcare organization management — Management systems for quality in healthcare organizations — Requirements. 2023 [cited 2025 July 08]; Available from: https://www.iso.org/standard/81647.html.
5. ISO. Healthcare management: Delivering quality to the health industry. 2023 [cited 2025 July 08]; Available from: https://www.iso.org/healthcare/quality-management-health.
6. Burgess N. Six key lessons from the NHS and Virginia Mason Institute partnership. 2022 [cited 2025 July 08]; Available from: https://www.wbs.ac.uk/news/six-key-lessons-from-the-nhs-and-the-virginia-mason-institute-partnership/.
7. Burgess N, Currie G, Crump B, Dawson A. Leading change across a healthcare system: How to build improvement capability and foster a culture of continuous improvement, Report of the Evaluation of the NHS-VMI partnership, Warwick Business School. . 2022 [cited 2025 July 08]; Available from: https://warwick.ac.uk/fac/soc/wbs/research/vmi-nhs/reports/report_-_leading_change_across_a_healthcare_system_22.09.2022.pdf.
8. Healthcare Improvement Scotland. Scottish Patient Safety Programme (SPSP). 2025 [cited 2025 July 08]; Available from: https://www.healthcareimprovementscotland.scot/improving-care/improvement-resources/scottish-patient-safety-programme-spsp/.
9. Scottish Government. Carers (Scotland) Act 2016: statutory guidance - updated July 2021. 2021 [cited 2024 Nov 08]; Available from: https://www.gov.scot/publications/carers-scotland-act-2016-statutory-guidance-updated-july-2021/pages/3/.
10. Scottish Government. Health and Care (Staffing) (Scotland) Act 2019: overview. 2024 [cited 2024 Nov 04]; Available from: https://www.gov.scot/publications/health-and-care-staffing-scotland-act-2019-overview/.
11. ISO. ISO/TS 30431:2021 Human resource management. Leadership metrics cluster. 2021 [cited 2025 July 08]; Available from: https://www.iso.org/standard/68708.html.
12. Parast MM, Golmohammadi D. Quality management in healthcare organizations: Empirical evidence from the baldrige data. International Journal of Production Economics. 2019;216(C).
13. Institue for Healthcare Improvement. Fostering an Improvement Culture: Learning from East London NHS Foundation Trust's Improvement Journey Over 10 Years. 2024 [cited 2025 July 08]; Available from: https://qi.elft.nhs.uk/wp-content/uploads/2024/03/IHI_Fostering-Improvement-Culture-ELFT-10-Years.pdf.
14. Scottish Government. Clinical and care governance framework: guidance. 2015 [cited 2025 July 08]; Available from: https://www.gov.scot/publications/clinical-care-governance-framework/.
15. General Medical Council. Duties of a doctor in the workplace. 2024 [cited 2025 July 08]; Available from: https://www.gmc-uk.org/professional-standards/professional-standards-for-doctors/leadership-and-management-for-all-doctors/duties-of-a-doctor-in-the-workplace.
16. Scottish Government. The Blueprint for Good Governance in NHS Scotland. 2022 [cited 2025 July 08]; Available from: https://www.gov.scot/binaries/content/documents/govscot/publications/advice-and-guidance/2022/12/blueprint-good-governance-nhs-scotland-second-edition/documents/blueprint-good-governance-nhs-scotland-second-edition/blueprint-good-governance-nhs-scotland-second-edition/govscot%3Adocument/blueprint-good-governance-nhs-scotland-second-edition.pdf.

17. General Medical Council. Good medical practice. 2024 [cited 2025 July 08]; Available from: https://www.gmc-uk.org/professional-standards/the-professional-standards/good-medical-practice.
18. Hurst L, Mahtani K, Pluddemann A, Lewis S, Harvey K, Briggs A*, et al.* Defining value-based healthcare in the NHS. 2019 [cited 2025 July 08]; Available from: https://www.cebm.ox.ac.uk/resources/reports/defining-value-based-healthcare-in-the-nhs.
19. Godec S, Hill M. Embedding and sustaining Quality Management Systems. 2025 [cited 2025 July 08]; Available from: https://q.health.org.uk/evidence-and-insights/insight-projects/quality-managements-systems-in-health-and-care-learning-from-examples-in-the-uk-and-ireland.
20. Healthcare Improvement Scotland. Quality Management System. 2024 [cited 2025 July 08]; Available from: https://www.healthcareimprovementscotland.scot/improving-care/improvement-resources/quality-management-systems-qms/.
21. AQUA. Embedding a Culture and System for Continuous Improvement. 2023 [cited 2025 July 08]; Available from: https://aqua.nhs.uk/wp-content/uploads/2023/04/Embedding-a-Culture-and-System-for-Continuous-Improvement.pdf.
22. Centre for Public Impact. Human Learning Systems: A practical guide for the curious. 2024 [cited 2025 July 08]; Available from: https://www.centreforpublicimpact.org/assets/pdfs/hls-practical-guide.pdf.
23. Flint J. The Seven Pillars of Clinical Governance. 2024 [cited 2025 July 08]; Available from: https://www.salford.ac.uk/spd/seven-pillars-clinical-governance.
24. Skivington K, Matthews L, Simpson SA, Craig P, Baird J, Blazeby JM*, et al.* A new framework for developing and evaluating complex interventions: update of Medical Research Council guidance. Bmj. 2021;374.
25. Health Information and Quality Authority. National Standards for Safer Better Healthcare. 2024 [cited 2025 July 08]; Available from: https://www.hiqa.ie/sites/default/files/2017-01/Safer-Better-Healthcare-Standards.pdf.
26. Scottish Government. Delivering value based health and care: a vision for Scotland. 2022 [cited 2025 July 08]; Available from: https://www.gov.scot/binaries/content/documents/govscot/publications/advice-and-guidance/2022/12/delivering-value-based-health-care-vision-scotland/documents/delivering-value-based-health-care-vision-scotland/delivering-value-based-health-care-vision-scotland/govscot%3Adocument/delivering-value-based-health-care-vision-scotland.pdf.
27. Chan SW, Tulloch E, Cooper ES, Smith A, Wojcik W, Norman JE. Montgomery and informed consent: where are we now? Bmj. 2017;357.
28. Giusti A, Nkhoma K, Petrus R, Petersen I, Gwyther L, Farrant L*, et al.* The empirical evidence underpinning the concept and practice of person-centred care for serious illness: a systematic review. BMJ glob. 2020;5(12).
29. General Medical Council. Decision making and consent. 2024 [cited 2025 July 08]; Available from: https://www.gmc-uk.org/professional-standards/the-professional-standards/decision-making-and-consent.
30. NICE. Shared decision making. 2021 [cited 2025 July 08]; Available from: https://www.nice.org.uk/guidance/ng197.
31. SIGN. Shared decision making (NICE guideline NG197). 2021 [cited 2025 July 08]; Available from: https://www.sign.ac.uk/our-guidelines/shared-decision-making-nice-guideline-ng197/.
32. NHS Inform. The Charter of Patient Rights and Responsibilities. 2023 [cited 2025 July 08]; Available from: https://www.nhsinform.scot/care-support-and-rights/health-rights/patient-charter/the-charter-of-patient-rights-and-responsibilities.
33. Realistic Medicine. Working together to provide the care that's right for you. Demonstrating professionalism through approach, behaviour and attitudes of Realistic Medicine. 2024 [cited 2025 July 08]; Available from: https://realisticmedicine.scot/.
34. NHS England. NHS England Accessible Information and Communication Policy. 2017 [cited 2025 July 08]; Available from: https://www.england.nhs.uk/publication/nhs-england-accessible-information-and-communication-policy/.
35. Public Health Scotland. Accessible information policy. 2023 [cited 2025 July 08]; Available from:

https://publichealthscotland.scot/publications/accessible-information-policy/.
36. Inclusive communication. Health and Social Care. [cited 2025 July 08]; Available from: https://inclusivecommunication.scot/all-resources/health-social-care.
37. UK Government. The Public Sector Bodies (Websites and Mobile Applications) (No. 2) Accessibility Regulations 2018. 2018 [cited 2025 July 08]; Available from: https://www.legislation.gov.uk/uksi/2018/952/contents/made.
38. UK Government. Equality Act 2010. 2010 [cited 2025 July 08]; Available from: https://www.legislation.gov.uk/uksi/2018/952/contents/made.
39. Austin CC, Bernier A, Bezuidenhout L, Bicarregui J, Biro T, Cambon-Thomsen A*, et al.* Fostering global data sharing: highlighting the recommendations of the Research Data Alliance COVID-19 working group. Wellcome Open Res. 2020;5:267. https://dx.doi.org/10.12688/wellcomeopenres.16378.2
40. UK Government. Duty of candour. 2020 [cited 2025 July 08]; Available from: https://www.gov.uk/government/publications/nhs-screening-programmes-duty-of-candour/duty-of-candour.
41. Hansen K, Boyle A, Holroyd B, Phillips G, Benger J, Chartier LB*, et al.* Updated framework on quality and safety in emergency medicine. Emerg Med J. 2020;37(7):437-42. https://dx.doi.org/10.1136/emermed-2019-209290
42. Healthcare Improvement Scotland. NHS Greater Glasgow and Clyde Emergency Department Review. 2025 [cited 2025 July 08]; Available from: https://www.healthcareimprovementscotland.scot/wp-content/uploads/2025/03/NHS-Greater-Glasgow-and-Clyde-Emergency-Department-Review-Final-Report-March-2025-.pdf.
43. Scottish Hospitals Inquiry. Summary. 2024 [cited 2025 July 08]; Available from: https://www.pslhub.org/learn/investigations-risk-management-and-legal-issues/investigations-and-complaints/investigation-reports/other-reports-and-enquiries/scottish-hospitals-inquiry-r12030/.
44. House of Commons. Ockenden Report. Findings, conclusions and essential actions from the independent review of maternity services at the Shrewsbury and Telford Hospital NHS Trust. 2022 [cited 2025 July 08]; Available from: https://assets.publishing.service.gov.uk/media/624332fe8fa8f527744f0615/Final-Ockenden-Report-web-accessible.pdf.
45. House of Commons. First interim report of the infected blood inquiry. 2022 [cited 2025 July 08]; Available from: https://www.infectedbloodinquiry.org.uk/sites/default/files/2022-07/Infected%20Blood%20Inquiry%20Interim%20Report.pdf.
46. House of Commons. Second interim report of the infected blood inquiry. 2023 [cited 2025 July 08]; Available from: https://www.infectedbloodinquiry.org.uk/sites/default/files/2023-04/Infected%20Blood%20Inquiry%20Second%20Interim%20Report.pdf.
47. ISO. Risk management – the basics. 2019 [cited 2025 July 08]; Available from: https://www.iso.org/publication/PUB200464.html.
48. NHS Education for Scotland. National Once for Scotland Whistleblowing Standards and training. 2021 [cited 2025 July 08]; Available from: https://www.nes.scot.nhs.uk/news/national-once-for-scotland-whistleblowing-standards-and-training/.
49. Healthcare Improvement Scotland. A National Framework for Reviewing and Learning from Adverse Events in NHS Scotland. 2025 [cited 2025 July 08]; Available from: https://www.healthcareimprovementscotland.scot/wp-content/uploads/2025/02/A-national-framework-for-reviewing-and-learning-from-adverse-events-in-NHS-Scotland.pdf.
50. National Services Scotland. An introduction to IRIC and reporting adverse incidents. 2025 [cited; Available from: https://www.nss.nhs.scot/health-facilities/incidents-and-alerts/learn-more-about-iric/an-introduction-to-iric-and-reporting-adverse-incidents/.
51. Healthcare Improvement Scotland. Adverse events toolkit: April 2025. 2025 [cited 2025 July 08]; Available from: https://www.healthcareimprovementscotland.scot/publications/adverse-events-toolkit-april-2025/.
52. NICE. Healthy workplaces: improving employee mental and physical health and wellbeing. 2017 [cited 2025 July 08]; Available from: https://www.nice.org.uk/guidance/qs147.

53. NHS Education for Scotland. LEARNING AND EDUCATION STRATEGY 2023 - 2026. 2023 [cited 2025 July 08]; Available from: https://www.nes.scot.nhs.uk/media/hwdneqnw/nes_learning_and_education_strategy_2023-2026.pdf.
54. Scottish Government. PLANNING WITH PEOPLE. Community engagement and participation guidance. 2024 [cited 2025 July 08]; Available from: https://www.gov.scot/binaries/content/documents/govscot/publications/advice-and-guidance/2024/05/planning-people-community-engagement-participation-guidance-updated-2024/documents/planning-people-community-engagement-participation-guidance-updated-2024/planning-people-community-engagement-participation-guidance-updated-2024/govscot%3Adocument/planning-people-community-engagement-participation-guidance-updated-2024.pdf.
55. NIHR. UK Standards for Public Involvement. 2019 [cited 2025 July 08]; Available from: https://sites.google.com/nihr.ac.uk/pi-standards/home.
56. Moult A, Baker D, Aries A, Bailey P, Blackburn S, Kingstone T*, et al.* Using the UK standards for public involvement to evaluate the public involvement sections of annual reports from NIHR managed research centres. Res Involv Engagem. 2023;9(1):109. https://dx.doi.org/10.1186/s40900-023-00517-3
57. NHS Research Scotland. Embedding public involvement in health and social care research. 2024 [cited 2025 July 08]; Available from: https://www.nhsresearchscotland.org.uk/public/help-shape-research/page-3.
58. Greenhalgh T, Misak C, Payne R, Swann N. Patient involvement in developing clinical guidelines. Bmj. 2024;387:q2433. https://dx.doi.org/10.1136/bmj.q2433
59. Harrington RL, Hanna ML, Oehrlein EM, Camp R, Wheeler R, Cooblall C*, et al.* Defining Patient Engagement in Research: Results of a Systematic Review and Analysis: Report of the ISPOR Patient-Centered Special Interest Group. Value Health. 2020;23(6):677-88. https://dx.doi.org/10.1016/j.jval.2020.01.019
60. Agyei-Manu E, Atkins N, Lee B, Rostron J, Dozier M, Smith M*, et al.* The benefits, challenges, and best practice for patient and public involvement in evidence synthesis: A systematic review and thematic synthesis. Health Expect. 2023;26(4):1436-52. https://dx.doi.org/10.1111/hex.13787
61. Bardach SH, Perry A, Sturke T, Stevens R, Satcher MF. Evaluation of the Patient Innovation Partner Role: Perceived Benefits, Structures, Supports, and Recommendations for Lived Experience Engagement in Healthcare Innovation Teams. Health Expect. 2025;28(2):e70194. https://dx.doi.org/10.1111/hex.70194
62. Healthcare Improvement Scotland. Quality Framework for Community Engagement and Participation. 2023 [cited 2025 July 08]; Available from: https://www.hisengage.scot/media/2549/quality-framework-for-community-engagement-apr-23.pdf.
63. Butterworth JE, Hays R, McDonagh STJ, Bower P, Pitchforth E, Richards SH*, et al.* Involving older people with multimorbidity in decision-making about their primary healthcare: A Cochrane systematic review of interventions (abridged). Patient Educ Couns. 2020;103(10):2078-94. https://dx.doi.org/10.1016/j.pec.2020.04.008
64. Capobianco L, Faija C, Cooper B, Brown L, McPhillips R, Shields G*, et al.* A framework for implementing Patient and Public Involvement in mental health research: The PATHWAY research programme benchmarked against NIHR standards. Health Expect. 2023;26(2):640-50. https://dx.doi.org/10.1111/hex.13676
65. Healthcare Improvement Scotland. Participation Toolkit. 2024 [cited 2025 July 08]; Available from: https://www.hisengage.scot/engaging-communities/participation-toolkit/.
66. Scottish Government. The Scottish Approach to Service Design (SAtSD). 2019 [cited 2025 July 08]; Available from: https://www.gov.scot/binaries/content/documents/govscot/publications/advice-and-guidance/2019/04/the-scottish-approach-to-service-design/documents/the-scottish-approach-to-service-design/the-scottish-approach-to-service-design/govscot%3Adocument/Scottish%2BApproach%2Bto%2BService%2BDesign.pdf.
67. Scottish Government. Care in the Digital Age: delivery plan 2024 to 2025. 2024 [cited 2025 July 08]; Available from: https://www.gov.scot/publications/care-digital-age-delivery-plan-2024-25/pages/1/.
68. ISO. ISO 24143:2022 Information and documentation. Information Governance 2022

[cited 2025 July 08]; Available from: https://www.iso.org/standard/77915.html.
69. ISO. ISO/IEC TR 38504:2016 Governance of information technology. 2023 [cited 2025 July 08]; Available from: https://www.iso.org/standard/56638.html.
70. Scottish Government. Health and social care - records management: code of practice. 2024 [cited 2025 July 08]; Available from: https://www.gov.scot/publications/records-management-code-practice-health-social-care/.
71. Scottish Government. Health & Social Care Information Sharing - A Strategic Framework 2014-2020. 2015 [cited 2025 July 08]; Available from: https://www.gov.scot/publications/health-social-care-information-sharing-strategic-framework-2014-2020/.
72. Scottish Government. NHSScotland Caldicott Guardians: Principles into Practice. 2011 [cited 2025 July 08]; Available from: https://www.gov.scot/publications/nhsscotland-caldicott-guardians-principles-practice/pages/1/.
73. UK Government. Data Protection Act 2018. 2018 [cited 2025 July 08]; Available from: https://www.legislation.gov.uk/ukpga/2018/12/contents.
74. Digital Health & Care Scotland. Information Sharing (IS) Toolkit. [cited 2025 July 08]; Available from: https://www.digihealthcare.scot/our-work/information-governance-and-assurance-branch/information-sharing-toolkit/.
75. Care Information Scotland. Adult Support and Protection (Scotland) Act 2007. 2023 [cited 2025 July 08]; Available from: https://www.careinfoscotland.scot/topics/your-rights/legislation-protecting-people-in-care/adult-support-and-protection-scotland-act-2007/.
76. Scottish Government. Getting it right for every child (GIRFEC) Practice Guidance 4 - Information sharing. 2022 [cited 2025 July 08]; Available from: https://www.gov.scot/publications/getting-right-child-girfec-practice-guidance-4-information-sharing/pages/14/.
77. Scottish Government. Multi-Agency Public Protection Arrangements (MAPPA):national guidance 2016. 2016 [cited 2025 July 08]; Available from: https://www.gov.scot/publications/multi-agency-public-protection-arrangements-mappa-national-guidance-2016/pages/12/.
78. Irvine G. NISR – Compliance Review – Structure and Reporting. 2022 [cited 2025 July 08]; Available from: https://www.healthca.scot/nisr-compliance-review-structure-and-reporting/.
79. Irvine G. The Scottish Public Sector Action Plan: Cyber Resilience Framework. 2021 [cited 2025 July 08]; Available from: https://www.healthca.scot/the-scottish-public-sector-action-plan-cyber-resilience-framework/.
80. Scottish Government. Health and social care: data strategy. 2023 [cited 2025 July 08]; Available from: https://www.gov.scot/publications/data-strategy-health-social-care-2/.

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