



Healthcare
Improvement
Scotland

Inspections
and reviews
To drive improvement

Demonstrating Safety, Promoting Improvement: An Overview of the Quality Assurance System

September 2022

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We are committed to equality and diversity. This methodology is intended to support improvements in healthcare for everyone, regardless of their age, disability, gender reassignment, marriage and civil partnership, pregnancy and maternity, race, religion or belief, sex, sexual orientation, socio-economic status or any other status. Suggested aspects to consider and recommended practice throughout the framework should be interpreted as being inclusive of everyone living in Scotland.

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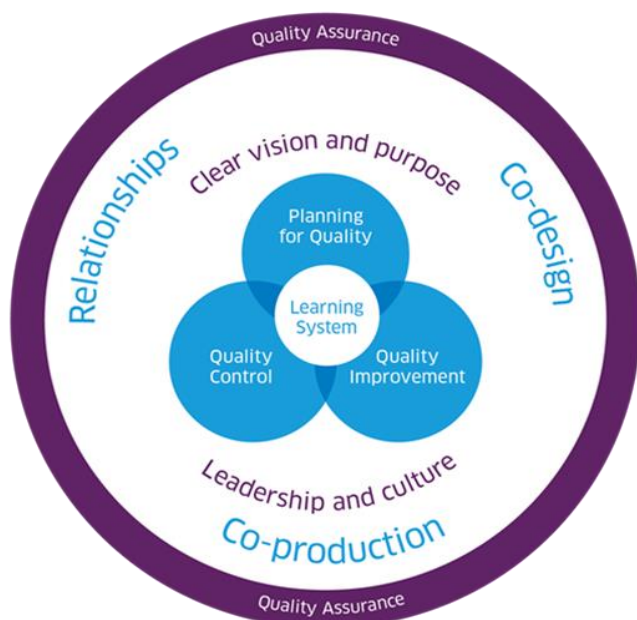
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Introduction

Healthcare Improvement Scotland (HIS) is the national health and social care improvement organisation. The purpose of HIS's Quality Assurance Directorate (QAD) is to enable the people of Scotland to experience the best quality of health and social care. We support healthcare providers by promoting self-evaluation for improvement and delivering external quality assurance.

All of our work fits within the organisation's Quality Management System (QMS) which sets out the main components and functions that support the delivery of high quality care. Quality assurance is one of those components.



The QMS framework defines quality assurance as the independent verification of a system's ability to reliably deliver high quality care.

This document explains how QAD carries out its quality assurance function, in order to offer objective assessments to health and care services about how they are performing in vital areas which can impact on people's care and outcomes. This helps services to understand what they are doing well, and where improvements are needed.

By publishing our findings, we assure the public that health and care services are being independently assessed, and that there is openness and transparency about where improvement is needed.

Background to the Quality Assurance System

Our **Quality Assurance System (QAS)** is designed to support our staff to deliver consistent and high impact scrutiny activity that helps to give people and communities confidence in the services they use. A key aim for the QAS is to support service providers to improve. We started developing this approach in 2017, when it was known as ‘the Quality of Care Approach’.

The evolving approach has been used within QAD to shape regulation, inspections and reviews of services. It has been used in various ways to guide, inform and gain insights through the development and delivery of a range of scrutiny programmes, such as:

- Joint inspections of adult services and of children’s services
- Regulation of independent healthcare
- Prisoner healthcare
- Cancer care
- Ionising Radiation (Medical Exposure) Regulations (IRMER), and
- Responsive reviews, for example, Adult Community Mental Health Services in Tayside.

Particular learning has been gained through test reviews; the work of the Sharing Intelligence for Health and Care Group (SIHCG); and engagement and insights from a wide range of stakeholders. Our scrutiny teams also consider the impacts on equality groups when any methodology changes are required to individual programmes such as prisoner healthcare.

In common with other members of Scotland’s Strategic Scrutiny Group, we have learned a lot from the COVID-19 pandemic. We have learned to work remotely and better apply digital technologies, with our staff developing and embracing new ways of working. The adoption of new technologies, while not without its challenges, has also brought efficiencies and provided opportunities that we can adopt into our standard operating processes as we go forward.

We have reviewed and enhanced the way we gather intelligence about services to assess accurately service quality and any improvements required. This has led to better processes for sharing information and good practice between agencies. We are also using our data and intelligence to help develop risk-based prioritisation for our scrutiny programmes.

COVID-19 has also led us to develop our partnership working with, and gain greater learning from, other scrutiny bodies. For a period during the pandemic, HIS inspectors accompanied Care Inspectorate teams in the inspections of care homes, with our staff providing support in infection prevention and control. We have also sought to appropriately apply new national guidance in related areas, for example: Planning with People¹.

Consequently, we have developed and refined our methodology, based on our experience since 2017, resulting in the QAS.

The QAS is aimed at:

- those staff within HIS who have a role in developing and delivering our external quality assurance (regulation, inspections and reviews of services) programmes
- colleagues who have an interest in the application and development of the overall QMS across the organisation, and
- staff in health and care settings who may:
 - be involved in our external quality assurance programmes for example through contributing to an inspection or review process, or
 - want to self-evaluate the organisation, service/ward or department using the Quality Assurance Framework.

The key components are:

- Core Guiding Principles
- Quality Assurance Framework, and a
- Standard Operating Process (SOP).

¹ <https://www.gov.scot/publications/planning-people/pages/1/>

Core Guiding Principles

HIS reflects the core values of NHS Scotland which are: care and compassion; dignity and respect; openness, honesty and responsibility; quality and teamwork. These values help us maintain and demonstrate high standards in all the work we do.

Centred on the person experiencing care, and their family or carers, our QAS embeds the core values and is underpinned by core guiding principles. These guide our staff in the design and delivery of our quality assurance programmes.

The core guiding principles for all of our inspections and reviews are:



User-focused

We are committed to strengthening how we:

- Ensure that our evaluation of services focuses on the outcomes for service users and carers across the diversity of communities.
- Seek the views and experiences of service users and carers in an inclusive manner, listening and acting on feedback.
- Communicate in ways that are clear, respectful, concise and meet the needs and expectations of service users and carers across diverse communities, and
- Undertake equality monitoring to help us to understand if our engagement has been inclusive; and identify actions to address any potential inequality.

Transparent and supportive, yet independent

We are committed to strengthening how we:

- Are open about our processes and evaluations.
- Work constructively with service providers.
- Support people to participate in our scrutiny work, and
- Undertake evidence-based, independent evaluation of service performance based on all of the pertinent information available.

Intelligence-led and risk-based

We are committed to strengthening how we:

- Work with, and engage in supportive dialogue with, service providers to identify key themes and areas where support may be required.
- Focus our attention and resources on services, or aspects of service provision, where the combined data and intelligence suggests higher levels of risk in relation to adverse impacts on service users and carers (being especially vigilant to the impact on equality groups or on inequalities).
- Apply proportionate, responsive and risk-based approaches that provide appropriate public assurance about the safety and effectiveness of services, and
- Where we can, mutually agree the scope of any interventions required and work with service providers to take these forward.

Integrated and co-ordinated

We are committed to strengthening how we:

- Work with colleagues internally to ensure that we share relevant information appropriately and, where possible, schedule our activity to minimise the impact of our range of work on service providers.
- Work with partners in other quality assurance organisations to share intelligence and reduce duplication of requests for information.
- Work with partners in other quality assurance organisations on the forward planning and scheduling of our programmes of planned activity, and
- Actively seek to enhance and develop, where appropriate, joint activity with other audit, inspection and regulatory bodies.

Improvement-focused

We are committed to strengthening how we:

- Give priority to supporting quality improvement through constructive professional dialogue with service providers.
- Promote a learning system by learning from, sharing and spreading any innovative and effective practice that we identify.
- Use the range of information available to us to make a professional judgement about a service's capacity for improvement, and
- Where necessary, identify recommendations for improvement and engage in follow-up interventions, which may include signposting to, or provision of, practical improvement support.

Quality Assurance Framework

Our Quality Assurance Framework provides guidance to services, and to those externally quality assuring them, about what good quality care looks like and how this can be evaluated. It aligns to the National Health and Social Care Standards² and is based on the HIS QMS with some learning drawn from the European Foundation for Quality Management (EFQM) Excellence Model 2020³. The aim is to help organisations to reflect, evaluate and make decisions about how best to improve outcomes for users of healthcare services.

With a focus on direction, implementation & delivery and results, the revised Quality Assurance Framework is composed of seven areas of focus (referred to as domains), as follows:

² [Health and Social Care Standards: my support, my life \(2017\)](#)

³ [European Foundation for Quality Management \(2020\)](#)

Focus	Domain
Direction	1. Clear Vision and Purpose
	2. Leadership and Culture
Implementation & delivery	3. Co-design, Co-production
	4. Quality Improvement
	5. Planning for Quality
Results	6. Relationships
	7. Quality Control

Each domain is defined by criteria which are outlined in the [Quality Assurance Framework](#). Each criteria has quality indicators, statements to support evaluation of what good care looks like.

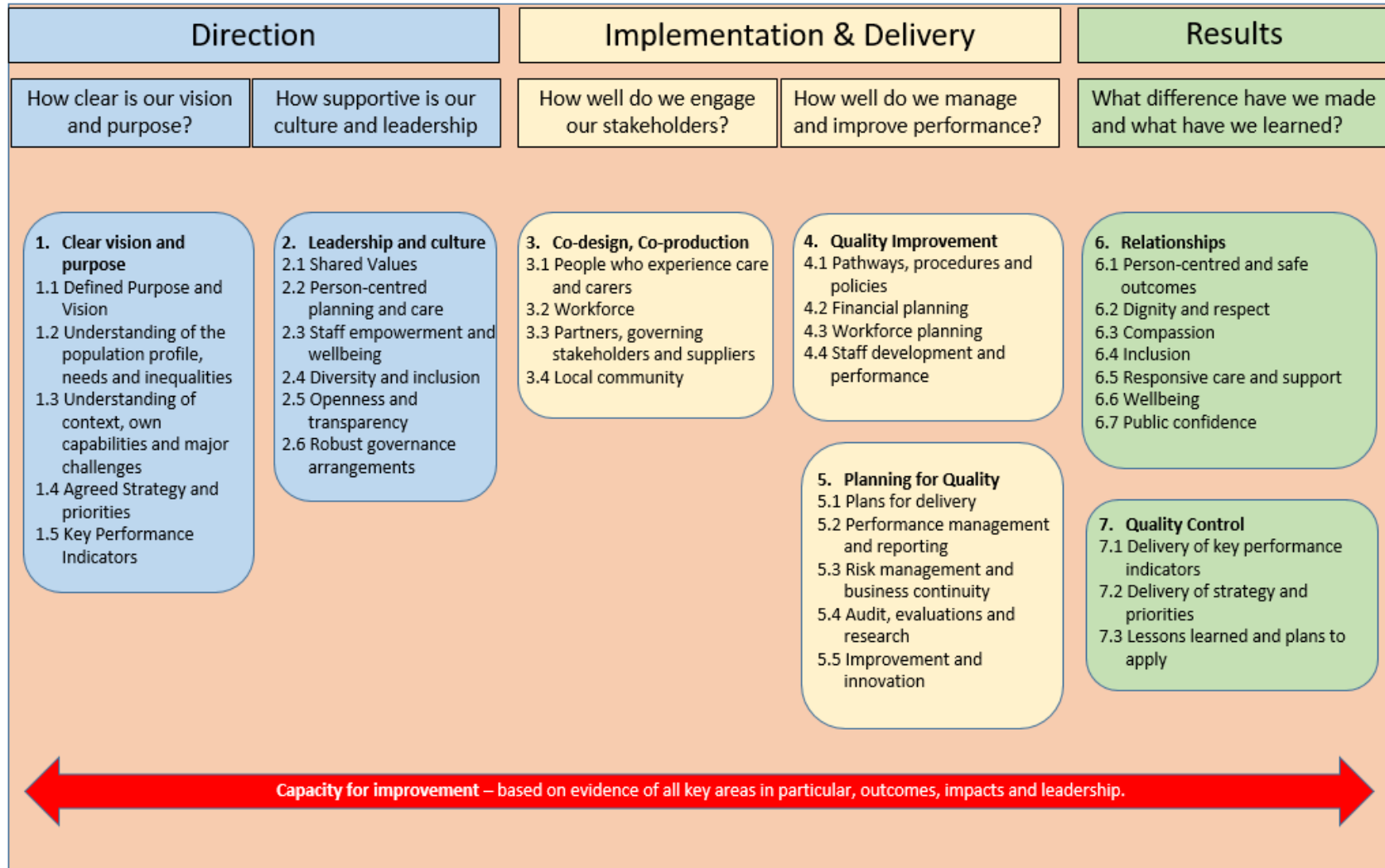
Our Framework allows an assessment of capacity for improvement based on evidence from all or specifically selected domains. This can help inform a proportionate discussion about any follow-up activity or support that may be required. It sets out what good care looks like; and emphasises the importance of leadership and culture; vision and purpose; and the importance of co-designing services with people.

Importantly the Framework is not designed to be a checklist. It is a reference guide to support and inform reflection, evaluation and decision-making about how best to improve outcomes for users of services.

The Framework supports our staff in making challenging judgments in an environment characterised by significant complexities, uncertainties, and pressures. These judgements are based on a combination of evidence and will always be context-specific, reflecting organisational culture, current legislation and history, and the degree of diversity in the evidence. All judgements should be impartial, independent and pragmatic, supported by best available evidence in terms of relevance, robustness, sufficiency and legitimacy.

A regular review of the quality framework by the QAS team will ensure that any links to legislation or guidance are kept up to date and any changes noted.

Quality Assurance Framework



Example of using the Quality Assurance Framework

Example Key line of enquiry:

How well does the organisation include stakeholders and people who use services in strategy and service development?

Include only the quality indicators from the Quality Assurance Framework domains that are specific to the focus for the scrutiny activity. In this example the domains to potentially focus on and which would require evidence are:

- Domain 1 — Clear Vision and Purpose
- Domain 2 — Leadership and Culture
- Domain 3 — Co-design and co-production
- Domain 5 — Planning for Quality
- Domain 6 — Relationships
- Domain 7 — Quality Control

The scrutiny team would decide which of the criteria and quality indicators in each of the selected domains would give them the best evidence to reliably answer the key line of enquiry question. This could be all of the suggested quality indicators or a selection of the ones most likely to give the best evidence and which evidence they will need to request in the first instance. Information from the requested evidence may lead to a request for additional evidence. Some evidence will give information for more than one quality indicator for example minutes of meetings or inspector led focus groups or interviews.

Domain 1 — Clear vision and purpose		
Direction: How clear is our vision and purpose?		
Criteria	Quality Indicator	Potential evidence
1.1 Defined purpose and vision	<p>a) The service has clear vision, strategy, and aims, which are person-focused easily understood by staff, people who experience care, carers and stakeholders.</p> <p>b) The service involves its stakeholders in defining, shaping and communicating its purpose and vision. The strategy clearly defines how priorities and deliverables contribute to the vision.</p>	<ul style="list-style-type: none"> • Organisation strategy documents • Minutes of strategy development meetings involving stakeholders and people who use services • Strategy information leaflets • Website information • Focus groups and interviews
1.2 Understanding of the population profile, needs and inequalities	<p>a) The service involves people experiencing care, carers, the public, staff and local agencies in strategic planning, to identify the needs of the population and plan delivery of equitable, safe, quality care.</p> <p>b) Services are developed and promoted effectively to support understanding and engagement with the people who use or might need the services.</p>	<ul style="list-style-type: none"> • Minutes of engagement meetings • Surveys/questionnaires and analysis of responses including Census data • Delivery plans and minutes of meetings • Focus groups/interviews • Website information • Promotional/engagement materials
Domain 2 — Leadership and culture		
Direction: How supportive is our culture and leadership?		
Criteria	Quality indicator	Potential Evidence
2.1 Shared values	c) Those who experience care, carers and stakeholders easily understand the values	<ul style="list-style-type: none"> • Stakeholder feedback • Minutes of meetings • Interviews/Focus groups • Feedback from Community Engagement groups • Care Opinion website, feedback and follow-up
2.2 Person-centred planning and care	a) The service recognises people experiencing care or their legal guardians as experts in their own experience, needs and wishes, and are fully involved in planning, assessment and decision-making about their care.	<ul style="list-style-type: none"> • Minutes of engagement and planning meetings • Surveys/questionnaires and analysis of responses

	<p>d) The service always considers the needs of people who experience care, and their carers, when developing innovative improvement ideas.</p> <p>i) The processes and culture of the service supports individuals, families and communities to become equal partners in all aspects of care</p>	<ul style="list-style-type: none"> • Interviews/focus groups • Community Engagement Groups feedback • Care Opinion website feedback and follow-up • Strategic planning information
2.4 Diversity and inclusion	<p>g) The service works with stakeholders to contribute to and draw inspiration from the National Health and Social Care Standards, National Performance Framework, Human Rights Approach and United Nations Sustainable Development Goals</p>	<ul style="list-style-type: none"> • Minutes of engagement meetings • Survey/questionnaires and analysis of responses • Discussion groups • Community Engagement Groups feedback
2.5 Openness and Transparency	<p>a) People experiencing care receive a timely response to their requests or complaints and the service seeks their feedback on the handling of complaints or concerns.</p> <p>b) The service implements improvement plans and notifies people of changes made in response to feedback.</p>	<ul style="list-style-type: none"> • Examples of complaint responses • Examples of improvements made in response to feedback • Improvement plans • Examples of notification of changes made in response to feedback • Interviews/focus groups • Action plans
2.6 Robust governance Arrangements	<p>f) The Board routinely receives information on adverse events, complaints, claims, inspections, audits, review findings and feedback from staff and people experiencing care to help gain assurance of appropriate action and shared learning.</p>	<ul style="list-style-type: none"> • Board papers and agendas • Minutes of Board meetings • Focus groups/interviews with Board members

Domain 3 — Co-design, Co-production		
Implementation and delivery: How well do we engage our stakeholders?		
Criteria	Quality indicator	Potential Evidence
3.1 People who experience care and carers	<p>a) The organisation uses a range of approaches to ‘bring people experiencing care into the boardroom’.</p> <p>b) People experiencing care, families or carers have a variety of accessible mechanisms to provide feedback on their experience of care and have support to do so.</p> <p>c) The service involves the public in policy and service design and development.</p> <p>d) The service encourages and empowers communities of interest, third sector organisations and minority groups to be involved in co-producing local health and care services</p>	<ul style="list-style-type: none"> • Examples of approaches used and analysis of effectiveness • Examples of feedback mechanisms and effectiveness data • Minutes of policy and service design engagement meetings • List of co-production partners and contacts • Focus groups/interviews
3.2 Workforce	<p>b) Leaders involve staff in shaping and influencing decisions as well as implementing them</p> <p>d) There is effective communication between management, clinicians, people who experience care and partner organisation</p>	<ul style="list-style-type: none"> • Examples of staff involvement • Focus groups/interviews • Meeting notes
3.3 Partners, governing stakeholders and suppliers	<p>a) The service works with stakeholders and partners in developing and delivering person-focused services.</p> <p>d) The service is able to demonstrate how collaborative working with other agencies, including the third sector, is leading to improved outcomes in a person-centred way.</p>	<ul style="list-style-type: none"> • Examples of services developed with stakeholders and partners • Feedback from service users • Examples of improved outcomes data • Interviews/focus groups • Minutes of meetings and action plans
3.4 Local community	<p>a) The service focuses the design of its services around anticipating need and it plans service delivery and workforce in proportion to this in collaboration with Integration Joint Boards, Community Planning Partnership and relevant</p>	<ul style="list-style-type: none"> • Service delivery plans • Workforce plans • Minutes of meetings • Experience and expectation surveys and analysis • Interviews/focus groups

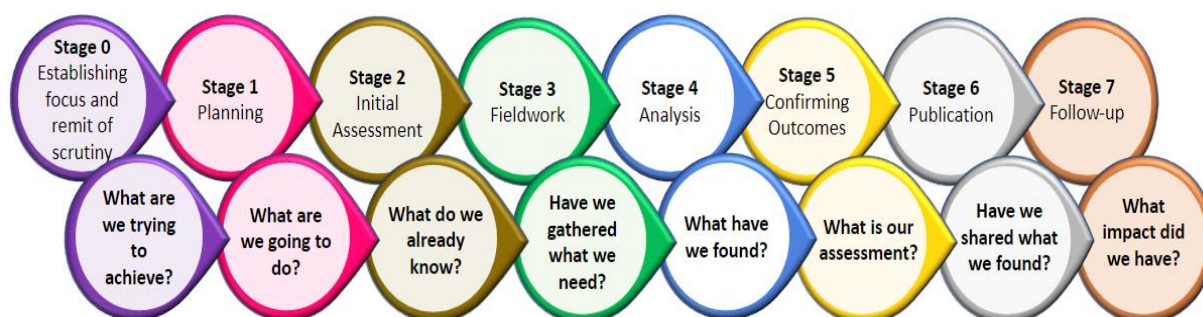
	<p>stakeholders</p> <p>b) The service actively seeks the perceptions of governing stakeholders, partners, suppliers and the wider population regarding their experiences and expectations, and reviews how it is meeting those expectations.</p>	<ul style="list-style-type: none"> • Surveys/questionnaires
<p>Domain 5 — Planning for Quality Implementation and delivery: How well do we manage and improve performance?</p>		
Criteria	Quality indicator	Potential Evidence
5.1 Plans for delivery	b) Quality planning principles focus on understanding the needs and assets from the perspective of those using and delivering the services.	<ul style="list-style-type: none"> • Minutes of Quality planning meetings • User feedback • Interviews/focus groups • Community Engagement feedback
5.5 Improvement and Innovation	<p>b) Leaders encourage and listen to staff ‘voices’ and act upon their feedback.</p> <p>l) The service takes a proactive approach to engaging with people who currently, or potentially might, experience care to identify issues and learning points and to shape improvements.</p>	<ul style="list-style-type: none"> • Minutes of staff meetings and action plans • Focus groups/interviews • Engagement strategy • Minutes of user engagement meetings
<p>Domain 6 — Relationships Results: What difference have we made?</p>		
Criteria	Quality indicator	Potential Evidence
6.1 Person-centred and safe Outcomes	b) The service actively engages people who experience care, members of the public, staff and other key stakeholders using feedback and data to identify trends to inform quality improvement initiatives and improve care.	<ul style="list-style-type: none"> • Minutes of engagement meetings • Examples of feedback and action plans • Trend data • Interviews/focus groups • Community engagement feedback

Domain 7 — Quality Control		
Results: What have we learned?		
Criteria	Quality indicator	Potential Evidence
7.2 Delivery of strategy and priorities	c) The service can demonstrate fulfilment of key stakeholder expectations.	<ul style="list-style-type: none"> • Action plans and outcomes • Key stakeholder meeting minutes • Relevant outcome data • Key stakeholder feedback • Interviews/focus groups
7.3 Lessons learned and plans to apply	e) Lessons learned from people’s care experience, adverse events, improvement and redesign initiatives and staff feedback informs quality improvement activity.	<ul style="list-style-type: none"> • Quality improvement meetings agendas and minutes • Examples of improvement activity and source of lessons learned • Interviews/focus groups

Standard Operating Process

A good practice standard operating process (SOP) underpins our QAS. It particularly supports our organisation's priority of 'safe, reliable and sustainable care' by ensuring that scrutiny teams consistently follow quality assurance processes; and required internal governance policies and procedures. The SOP⁴ has the following stages, to be applied in a manner that best supports the context and outcomes of each specific scrutiny programme.

All scrutiny programmes will be expected to align with the SOP, with the timing, extent and opportunities for doing this based on agreed milestones for each.



The application of the SOP within each scrutiny programme will adapt to take account of the particular aims of the programme; the specific needs of stakeholders; and the work that has been undertaken to date, in order that the approach adds value.

It is recognised that some work programmes may require to undertake specific activities not mentioned in the process; or to follow specific partner-led or external regulatory quality assurance methodology. The process can be applied flexibly, where required.

While the SOP is not designed to be retrofitted to existing scrutiny activity, the iterative nature of its development means that the application of the relevant aspects are already evident within key work programmes.

A digital toolkit of tried and tested templates, procedures, and guidance tools support the application of the SOP to enable staff to develop, deliver and evaluate reviews and inspections in a consistent way. A monthly review of the toolkit will ensure that the tools and templates are kept up to date.

⁴ The SOP is detailed in an accompanying document.

A core element of the QMS is the commitment to a learning system that emphasises the importance of reflecting upon and making decisions about next steps. In keeping with this, our SOP empowers staff to undertake reflection and evaluation activities throughout their scrutiny work in a consistent way.

A suite of audit tools has been developed which will be used to assess how well programmes of work are using the SOP. There is a tool for each section of the SOP which looks at the key processes in that section and suggests evidence which could be used to demonstrate compliance. The data collected from using these tools will also be used to inform the Quality Assurance team where changes may need to be made to keep the QAS up to date.

Our staff and teams consistently applying, learning and valuing our QAS will enhance the impact of our scrutiny activity. This will, in turn, further support safety and quality improvement by providers; and provide greater confidence to service users, carers and the diverse communities across Scotland that those healthcare services are there to serve.

This document provides an overview of HIS's internal QAS.

Further information can be requested from his.qas@nhs.scot.

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