Independent Healthcare Regulation

Inspection Methodology

July 2023

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Introduction

Healthcare Improvement Scotland is the regulator of independent healthcare services in Scotland. We inspect independent healthcare services to ensure they comply with legislation and meet the required standards of care. Registered independent healthcare services include:

- independent hospitals

- private psychiatric hospitals

- independent hospices, and

- independent clinics (including wholly private dental practices).

About this document

This document sets out our methodology for the inspection of independent healthcare services. It also outlines the important principles that guide our inspection process and how we ensure that people who use registered independent healthcare services are at the heart of this process. Our inspection process is informed by:

- assessing compliance with relevant legislation

- evaluating how well providers have applied Healthcare Improvement Scotland's Quality Assurance Framework in their service

- assessing providers' self-evaluations, annual returns and notifications, and

- involving people who use services.

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Quality Assurance System

Our Quality Assurance System (QAS) is an evolving approach to shaping regulation, inspections and reviews of services across Scotland. The Quality Assurance System [Quality Assurance System Overview Document](#) explains how we carry out quality assurance, 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.

Our [Quality Assurance Framework](#) provides a consistent reference point for assessing services. The framework sets out what good care looks like, emphasising the importance of leadership and culture, vision and purpose, and the importance of co-designing services with people.

The QAS drives how we design our methodology and tools, and how we provide external assurance of the quality of healthcare provided in Scotland.

The following principles underpin how we carry out our regulatory function. These are embedded in the design of all our programmes of work, which are:

- user-focused - we put people who use services at the heart of our approach

- transparent and mutually supportive, yet independent - we promote and support a complementary approach to robust self-evaluation for improvement with independent validation, challenge and intervention as required

- intelligence-led and risk-based - we take a proportionate approach to inspection and review which is informed by intelligence and robust self-evaluation

- integrated and co-ordinated - we draw on the collective participation of relevant scrutiny bodies and other partners to share intelligence and minimise duplication of effort, and

- improvement-focused - we support continuous and sustained quality improvement through our quality assurance work.

The QAS (supplemented as required by any relevant legislation and service-specific standards) forms the basis for self-evaluation and any subsequent inspection. See Appendix 1 for further information.

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The Quality Assurance Framework follows the Health Foundation[1] recommendations that Government regulators and national agencies should design their systems for oversight and regulation in a way that allows organisations to demonstrate their safety, rather than their compliance with, prescriptive centrally mandated measures. It provides guidance to services, and to those externally quality assuring them, about what good quality care looks like and how this can be evaluated.

The framework is arranged in seven broad areas of focus referred to as 'domains' that cover all aspects of a healthcare provider's work. Each domain includes quality indicators designed to help with self-evaluation and improving the quality of care provided for all patients (see Appendix 1). These are neither exhaustive nor prescriptive. The framework allows scope for organisations to self-evaluate and develop the narrative about the quality of the care they provide using measures that are meaningful and important to staff locally. The seven domains in the framework can broadly be grouped under three key focus areas related to:

- direction

- implementation and delivery, and

- results.

Using a range of indicators and sources of evidence supports a holistic approach to self-evaluation and allows an organisation to 'tell its story'. Each quality indicator is further broken down into themes to guide and support the process of self-evaluation.

The Health and Social Care Standards

In June 2017, the Scottish Government published the *Health and Social Care Standards: My support, my life*[2]. The standards are applicable to NHSScotland, as well as services registered with the Care Inspectorate and Healthcare Improvement Scotland. The Quality Assurance Framework has been developed to align with these standards. Both documents should be used by providers, patients and by Healthcare Improvement Scotland when considering the quality of the care provided. Like the Quality Assurance Framework, the main objective of the standards is to drive improvement in the care that people receive.

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[1] http://www.health.org.uk/publication/measurement-and-monitoring-safety
[2] http://www.newcarestandards.scot/

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The standards are underpinned by five principles:

- dignity and respect

- compassion

- being included

- responsive care, and

- support and wellbeing.

Services should use the standards as a guideline for how to achieve high quality care. The standards are taken into account by Healthcare Improvement Scotland and other scrutiny bodies for inspections, quality assurance activity and regulation of services. They are written from the point of view of the person receiving support and set out what anyone, irrespective of age or ability, should expect when using health, social care or social work services in Scotland. They seek to:

- provide better outcomes for everyone

- ensure that individuals are treated with dignity and respect, and

- ensure that the basic human rights we are all entitled to are upheld.

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The foundations of our inspections

We monitor independent healthcare services regularly, using announced, unannounced and remote inspection (video communication) methods. The intelligence we gather from self-evaluations, annual returns, notifications, complaints, enforcement activity and other professional bodies helps to inform our risk-based and proportionate approach to regulation.

Our inspection process:

- takes account of relevant legislation that providers must comply with

- is risk based, proportionate and uses information from multiple sources to inform our decision making

- asks providers to evaluate themselves against the Quality Assurance Framework, identify improvements and tell us what actions they are taking to remedy these

- leads to published inspection reports with grades and clear information about the quality of independent healthcare being provided, and

- promotes the principle of involving people.

Who we involve in our inspections

To understand the quality of care delivered, we need to know the views of:

- those receiving care, and

- those delivering care.

During our inspections, we focus on people who use the service and promote ways that providers can improve people's experience of using the service. We talk with patients, carers, their families using the service and those delivering the service.

Our inspections focus mainly on outcomes for patients, such as the care they received and how that care affected their lives. We also evaluate the processes in place to ensure care and treatment is delivered safely. The Quality Assurance Framework helps us to maintain this focus.

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What we look at during inspection

The Quality Assurance Framework contains seven 'Quality Domains' which are grouped into three 'Key Focus Areas'. Under each domain, there are several 'Quality Indicators'. We use these key focus areas, domains and indicators to assess how well care and treatment is delivered.

Requirements and recommendations

A requirement is a statement which sets out what is required of an independent healthcare provider to comply with the National Health Services (Scotland) Act 1978, regulations or a condition of registration. Where there are breaches of the Act, regulations or conditions, a requirement must be made. Requirements are enforceable.

A recommendation is a statement which sets out what a service should do in order to align with relevant standards and guidance.

Ongoing monitoring

We ask providers to submit regular information to us to make sure our inspection process is efficient and effective. This includes self-evaluation, annual returns and notifications.

Inspection frequency

The Service Risk Assessment (SRA) procedure is an operational planning tool that provides us with an ongoing, risk-based and proportionate framework for planning inspections. It helps us target our resources so that we reduce our inspections of services performing well and increase our inspection of services with poorer performance. We regularly update a service's SRA, which means that inspection frequencies flex up and down depending on regulatory activity. Guidance on the frequency of our inspections is set out in Appendix 2.

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Inspection methods and types

We have legal powers to enter and inspect the independent healthcare services we regulate, at any time. Our inspection method may include unannounced, announced or remote inspections and we may carry out one of four inspection types.

Inspection methods		
Unannounced	**Announced**	**Remote**
No prior notice of inspection will be given to the provider and the inspection team will arrive unannounced at the service. Inspections may take place during the day, evening or at the weekend. Inspections of inpatient services (hospitals, hospices, psychiatric services) will generally be unannounced. This is due to the broadly consistent opening hours and staffing levels of this type of service. However, there may be occasions where we may carry out an announced inspection to an inpatient service if we feel this is appropriate. For example, to assess a particular issue or speak with a particular group of staff.	We will normally give the provider 4 weeks' written notice. However, the notice period may be less if we consider it appropriate to do so. We may request the submission of specific documentation to enable us to undertake a desktop review as part of the inspection. Inspections of independent clinics will generally be announced, due to the huge variety of opening hours and lower staffing levels at this type of service. However, we reserve the right to conduct an unannounced inspection of an independent clinic if we feel this is appropriate. For example, a consistently poor performing service or where we receive intelligence that we need to verify.	We will normally give the provider 4 weeks' written notice. However, the notice period may be less if we consider it appropriate to do so. We may request the submission of specific documentation to enable us to undertake a desktop review as part of the inspection. This method of inspection will include a mixture of telephone conversation and video calling, as well as the desktop review of evidence. We may choose this method of inspection for small independent clinics with a remote location, varying opening hours or where our ongoing monitoring identifies a low level of risk.

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Inspection types		
Type	**Description**	**How we will report findings**
Full (announced, unannounced or remote)	We will carry out a full assessment of how the service is performing using: • the HIS (Requirements as to IHC Services) Regulations 2011 • the Health and Social Care Standards, and • the HIS Quality Assurance Framework.	We will report our findings in a 'full inspection report' which includes our grading for our three Key Focus Areas.
Revisit (announced or unannounced)	If we identify an imminent risk to the health, welfare or safety of patients (during a full inspection), we may ask the provider to make immediate improvements. We may revisit the service in the days or weeks that follow the full inspection to check compliance with our request for immediate improvements. Alternatively, we may request the provider meets with us to discuss our concerns and agree an appropriate resolution.	We will include our revisit findings together with our main findings in our 'full inspection report'.
Follow-up (announced, unannounced or remote)	We will only focus on the requirements and recommendations identified in the last inspection report or from a complaint investigation outcome letter. Generally, we will undertake this type of inspection for services with a current 'Very High' or 'High' Service Risk Assessment (SRA) score. *Improved grades awarded as a result of follow-up inspections will be restricted to no more than 'satisfactory'. This is because the focus of our inspection will be limited to the action taken to address the requirements and recommendations we made at the last inspection.*	We will report our findings in a 'follow-up inspection report' which includes our grading for our three Key Focus Areas.

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Focused (announced, unannounced or remote)	In response to special projects, we may undertake focused inspections to assess providers' compliance relating to a particular issue. For example, following any learning identified from our inspection outcomes, upon receipt of relevant intelligence or if we learn of a relevant issue that has been identified nationally. This may involve the use of clinical experts to advise the inspection team and may be announced or unannounced.	We will report our findings in a 'focused inspection report' format, to distinguish it from our other inspection types. We will also include our grading for our three Key Focus Areas.

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The three stages of our inspection process

	Planning	Inspection	Reporting
Stage 1 Planning	**Before each inspection we will:** • decide what method and type of inspection we will undertake • consider technology requirements/capacity (if remote) • normally give the provider 4 weeks' written notice (if announced) • consider the size and type of service, make up of the inspection team and whether a clinical expert is required • check the provider's self-evaluation, annual return, conditions of registration, notifications, enforcement activity and other intelligence • review requirements and recommendations made at previous inspections and at registration • review any complaints received about the service • plan how we will involve patients, and • develop an inspection plan.		
Stage 2 Inspection	**During the inspection we will:** • check the provider's registration certificate and conditions of registration • check compliance with any requirements and recommendations made at registration, previous inspections and recent complaint investigations • assess the provider's compliance with relevant legislation • assess the provider's compliance with the Combined Practice Inspection and Sedation Practice Inspection checklists (dentists only) • evaluate the provider's application of the HIS Quality Assurance Framework • seek feedback from patients and staff, and • provide inspection feedback to the service manager.		
Stage 3 Reporting	**After each inspection we will:** • evaluate our findings and summarise them in a draft report, including any areas for improvement, requirements and recommendations • send the draft report to the provider, requesting a factual accuracy error response form and an improvement action plan is returned to us to address any requirements and recommendations with appropriate timescales • make any amendments necessary and finalise the inspection report (see below for more information about our publication timescales) • review the provider's improvement action plan • update the service's Service Risk Assessment (SRA) score • update the information we hold about a service (if necessary), and • ask services for feedback on how we carried out the inspection process.		

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Reporting

Inspection reports will be finalised once the provider returns the factual accuracy error response form and any necessary amendments have been made to the report. If the provider does not return the factual accuracy error response form within 5 working days of receiving the draft report, we may automatically finalise the inspection report.

The timescales for publication* are:

Publication timescales	
5 weeks after inspection	provider receives draft inspection report to check for factual accuracy
6 weeks after inspection	provider returns the factual accuracy error response form and improvement action plan
8 weeks after inspection	provider receives final inspection report
8 weeks after inspection	inspection report and provider's improvement action plan published on Healthcare Improvement Scotland's website
16 weeks after inspection**	improvement action plan removed from Healthcare Improvement Scotland's website

There may be occasions when we must delay the publication timescales for unexpected reasons. For example, unavailability of inspector/clinical expert or service manager. We will work with the service to agree an updated timescale.

**For services that we grade 'unsatisfactory' for any of the three Key Focus Areas, we will request an updated improvement action plan 16 weeks after inspection. This may be enough evidence to satisfy us that appropriate action has been taken. If so, we will remove the improvement action plan from the website. However, we may need to undertake a follow-up inspection to confirm whether a provider has met the requirements we made.*

Checking compliance

Requirements will remain 'outstanding' until we receive evidence confirming the provider has taken satisfactory action.

Our approach to following up on areas for improvement will depend on the associated risk to the health, welfare and safety of patients and our assessment of the provider's capacity to improve. We will use our Service Risk Assessment (SRA) procedure to help with our decision making about the inspection frequency, method and type of inspection to be carried out. See Appendix 2 for further information.

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Appendix 1: The Quality Assurance Framework Structure

Quality Assurance Framework

Direction		Implementation & Delivery		Results
How clear is our vision and purpose?	How supportive is our culture and leadership	How well do we engage our stakeholders?	How well do we manage and improve performance?	What difference have we made and what have we learned?

1. Clear vision and purpose
1.1 Defined Purpose and Vision
1.2 Understanding of the population profile, needs and inequalities
1.3 Understanding of context, own capabilities and major challenges
1.4 Agreed Strategy and priorities
1.5 Key Performance Indicators

2. Leadership and culture
2.1 Shared Values
2.2 Person-centred planning and care
2.3 Staff empowerment and wellbeing
2.4 Diversity and inclusion
2.5 Openness and transparency
2.6 Robust governance arrangements

3. Co-design, Co-production
3.1 People who experience care and carers
3.2 Workforce
3.3 Partners, governing stakeholders and suppliers
3.4 Local community

4. Quality Improvement
4.1 Pathways, procedures and policies
4.2 Financial planning
4.3 Workforce planning
4.4 Staff development and performance

5. Planning for Quality
5.1 Plans for delivery
5.2 Performance management and reporting
5.3 Risk management and business continuity
5.4 Audit, evaluations and research
5.5 Improvement and innovation

6. Relationships
6.1 Person-centred and safe outcomes
6.2 Dignity and respect
6.3 Compassion
6.4 Inclusion
6.5 Responsive care and support
6.6 Wellbeing
6.7 Public confidence

7. Quality Control
7.1 Delivery of key performance indicators
7.2 Delivery of strategy and priorities
7.3 Lessons learned and plans to apply

Capacity for improvement – based on evidence of all key areas in particular, outcomes, impacts and leadership.

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Appendix 2: Service Risk Assessment / Frequency of inspections

We use our Service Risk Assessment (SRA) procedure to document our ongoing monitoring of services. The SRA procedure drives our inspection frequency and allows us to document our decision making and demonstrate a proportionate and risk-based approach to regulation.

The SRA is an ongoing process that includes our evaluation of five indicators:

	Indicator	Description
1	IHC clinical risk category	We score the service based on the types of treatments and procedures carried out.
2	Annual return outcomes	We assess the provider's responses to the questions in annual returns.
3	Complaint investigation and notification outcomes	We evaluate how well the provider has responded to complaint investigations. We also assess the volume and type of notifications and complaints.
4	Inspection outcomes	We score the service according to its grading, overall performance at inspection and enforcement activity.
5	Significant risk or concern	We add an additional score where we identify an issue that has not been covered by the first four indicators, and is significant enough to bring forward the next inspection.

SERVICE RISK ASSESSMENT OUTCOME KEY		
TOTAL SCORE	OUTCOME	INSPECTION TYPE & FREQUENCY*
250 or above	Very High	FOLLOW-UP inspection within 3-6 months of last report
200 – 245	High	FOLLOW-UP or FULL inspection within 12–18 months
150 – 195	Medium	FOLLOW-UP or FULL inspection within 2 years
100 – 145	Medium/Low	FULL inspection within 3 years
50 – 95	Low	FULL inspection within 4 years
0 – 45	Very Low	FULL inspection within 5 years

*We may undertake focused inspections out with these frequencies if we receive intelligence that highlights a significant risk or concern. We will only undertake a focused inspection if our reason for inspecting is not within the parameters of a full or follow-up inspection. For example, an inspection to focus on how a service is managing the risks from Covid-19 or other infrequent topic directed by intelligence.

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Appendix 3: The quality grading scale and how we apply it

Grading helps to provide a consistent approach to how we report our inspection findings, enables members of the public to clearly determine the standards provided by a service and encourages services to continually improve. In order to provide clarity about our approach to grading, we have developed grading principles that are broad enough to be applied across all services. This gives both inspectors and providers a reference point of what a service should be demonstrating to achieve each grade. The table below illustrates the grading principles.

Generic Grading Principle			
Unsatisfactory	Satisfactory	Good	Exceptional
No evidence of appropriate systems, policies, procedures & processes having been developed and/or implemented.	Evidence of appropriate systems, policies, procedures & processes having been both developed and implemented.	Evidence of appropriate systems, policies, procedures & processes having been both developed and implemented.	Evidence of appropriate systems, policies, procedures & processes having been both developed and implemented.
	AND	*AND*	*AND*
	Evidence of impact and outcomes.	Evidence of positive impacts & good outcomes from these systems, policies, procedures & processes.	Evidence of positive impact and good outcomes from these systems, policies, procedures & processes.
		AND	*AND*
		Evidence of self-directed improvement of systems, policies, procedures & processes and the resulting impacts & outcomes.	Evidence of continuous and sustained self-directed improvement of systems, policies, procedures & processes and the resulting impacts & outcomes.
			AND
			Evidence of involvement in external assurance or benchmarking. Evidence of stakeholders' involvement through different initiatives to improve and develop the service provided.

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	Guidance for 'Exceptional' grading
Strong and transparent leadership	The service is led by passionate, motivated people who always strive to go above and beyond accepted norms and basic standards. Leadership are honest and realistic about the service's performance, understand its strengths and are focused on where improvement is needed.
A positive organisational culture	Staff feel valued and secure and speak positively about leadership. An open/transparent culture is promoted where staff feel happy to speak up and suggest change. Leaders empower staff to take responsibility and invest in their development.
Good oversight of care	Leadership are engaged in the service and have their finger on the pulse of what's going on. They are willing to get stuck in to find out what the real issues are.
Driving change through effective systems and processes	Robust evidence of strong systems and processes that provide effective governance and drive continuous improvement. This not only includes the management of essential functions such as public protection, safety alerts and care plans – but also includes effective workforce planning, staff training & development and implementing/sharing learning from complaints/incidents/adverse events. Results and outcomes from internal processes will be easily demonstrated.
Open to challenge and change	Leaders and staff engage with the inspection process openly and transparently, are honest about their own shortcomings, receptive to constructive feedback and willing to adjust where necessary. They are positive, open and passionate about tackling fresh challenges and will readily change to improve patient care.
Effective collaboration with partners	The service has strong clinical and public engagement (where appropriate) and demonstrates effective collaboration to develop and improve the service provided. Examples of collaboration could be with local authorities, NHS boards, the third sector and/or other stakeholders.
Engaging with those who use the service	Leaders and staff engage well with patients, families and the community. Feedback is used to change and improve the service, e.g. designing care plans, improving facilities and introducing activities that meet people's diverse needs and preferences.
Continuous improvement	Leadership excels at identifying where change needs to happen and taking the time to implement change effectively, for the betterment of patient care and treatment. A culture of continuous improvement and sustainability is evident.

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