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NHS England

Risk assessment framework and reporting manual for independent sector providers of NHS services

Consultation on the proposed revision

January 2023

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Introduction

1. Under the Health and Care Act 2022, NHS Improvement (Monitor and the NHS Trust Development Authority) has been abolished and NHS England has assumed responsibility for carrying out NHS Improvement's statutory functions, including the licensing and regulation of independent sector providers of NHS services. Independent sector providers of NHS services must hold an NHS provider licence (unless exempt) and must comply with its conditions.

2. Section 1 of this consultation document proposes changes to the Risk assessment framework and reporting manual for independent sector providers of NHS services (IPRAF), including a new part on how NHS England will oversee standards of quality governance for some independent sector providers.

3. Section 2 introduces the concept of mandated support for independent sector providers when significant failings put strategically important services at risk.

4. Section 3 sets out the policy for 'hard to replace' providers, a second mechanism of applying the continuity of service (CoS) licence conditions to those independent sector providers NHS England determines would be 'hard to replace' if they failed for financial or quality reasons. Changes to the provider licence, including to incorporate 'hard to replace' providers, are currently also subject to consultation.

5. This consultation is therefore aimed mainly at licensed independent sector providers that are subject to the CoS licence conditions (including those likely to be determined to be 'hard to replace'), but also contains important information for all other licensed independent sector providers, including NHS-controlled providers that have been told they will be regulated under the IPRAF. The proposed changes have no implications for our oversight of NHS trusts or NHS foundation trusts.

6. Providers will be subject to the CoS licence conditions in Section 5 of the provider licence if they have been formally told by a commissioner that they are a provider of commissioner requested services (CRS) and/or by us that they are a 'hard to replace' provider.

7. Historically, providers subject to the CoS licence conditions have been under financial oversight by Monitor and then NHS Improvement, with the aim of reducing their risk of failing financially and the impact on NHS patients if a provider does fail. Proposed changes to the provider licence (subject to consultation) include a new requirement within the CoS conditions for providers to have standards of quality governance that are appropriate, and to provide reasonable safeguards against not being able to deliver services due to quality stress, with the aim of reducing the risk of service closure.

Rationale for the proposed changes

8. Since 2014 Monitor's and now NHS England's regulation of the independent healthcare sector has focused on financial risk. However, the effectiveness of quality governance at an independent sector provider is also an important factor in ensuring sustainable care for patients, particularly given the increasing level of quality-related concerns at some of those providing 'hard to replace' NHS services.

9. The revised IPRAF therefore describes the general approach we will take to assessing whether the standards of quality governance at a provider provide reasonable safeguards against closure of services either by the Care Quality Commission (CQC) or the provider themselves.

10. In instances where other methods of intervention have not improved quality governance, we will consider whether mandating that support is received or taking regulatory action is appropriate. Action will only be considered where we have significant concerns and other methods of intervention are either deemed to be inappropriate or have been unsuccessful.

11. This consultation document also outlines how we will apply the 'hard to replace' provider policy, including the criteria for determining which providers are 'hard to replace'. This policy allows us to apply CoS licence conditions irrespective of existing CRS designations by commissioners, thereby enabling us to ensure that these conditions are applied appropriately across the sector to those services or providers in need of oversight for the protection of services to NHS patients.

12. In designing the changes, we remained cognisant of the need not to put excessive or unwarranted burden on providers and only put in place additional regulation where it delivers clear value. We have done this by:

- focusing information requirements where they add most value to a risk-based assessment of standards of quality governance
- streamlining regulation by having a more joined-up approach across regulators
- ensuring that we can have holistic conversations with providers, with a focus beyond finance
- collecting as much information as is practicable from other regulators and stakeholders such as the CQC and regional quality forums in order to avoid additional reporting burden
- where necessary, supporting providers to improve their quality governance for the benefit of their NHS patients.

Summary of proposed changes for providers subject to the continuity of services (CoS) conditions of the provider licence

13. Under the current IPRAF, we determine a CoS risk rating (CoSRR) score for each provider subject to the CoS licence conditions, using three financial metrics and a set of overriding rules. A CoSRR score of 1 represents the highest level of financial risk and of 4 the lowest. No changes are proposed to how we calculate and assess financial risk.

14. Financial risk and quality governance risk are often linked and as such a single team will monitor both, to form a holistic view of the provider. However, we have deliberately opted to rate risk associated with finance and quality governance separately, meaning we will determine two risk ratings for each provider.

15. We will determine a second quality governance risk rating (low, medium or high risk) but like the financial risk rating it will not be published. We will use information from providers, the CQC, commissioners, and national and regional quality forums to consider the overall level of quality governance risk to reach a risk rating. Providers will move between quality governance risk ratings in response to new information such as CQC inspections or following routine monitoring

conversations. The quality governance risk rating will inform the level of engagement that the provider has with us.

Table1: Summary of proposed changes

Section 1: Introducing requirements for standards of quality governance for some independent sector providers	
Collecting information to reach a quality governance risk rating	We will take a risk-based approach to collecting information (see Section 1) that includes: • in the first year of oversight and then on any material changes (eg as a result of a transaction) collecting information that helps us understand a provider's governance of quality • collecting information direct from the CQC • collecting intelligence from national and regional quality forums • exception reporting based on individual circumstances. There may be additional reporting requirements where we have significant concerns regarding the quality of care at an individual provider.
Defining risk ratings and how they will influence the monitoring approach	Establishing the risk rating definitions: • high: significant concern • medium: emerging or ongoing concern • low: no apparent concerns. More detail on the risk ratings is given in Section 1.
Setting out monitoring timescales	Routine monitoring of quality governance will be incorporated in the existing timescales for monitoring of financial risk. Timescales are described in Section 3.
Responding to quality stress	Where there are concerns regarding quality stress, NHS England will either informally engage with the provider or, if necessary, use some combination of mandated support and/or regulatory action. More detail on these actions is given in Section 1 and 2.
Section 2: Mandating support	

Mandating support	The NHS England Independent Provider team will determine whether action to address shortcomings is required; this could include enforcement undertakings to rectify a potential breach of the provider license or mandating support is received. This action is intended as a last resort and will only be used once other methods of intervention have not resolved quality governance concerns. If we incur costs in ensuring a provider puts this support in place, we may look to recover these costs.
Section 3: Introducing the 'hard to replace' provider policy	
Introducing the 'hard to replace' provider policy	The application of our 'hard to replace' provider policy allows us to apply the CoS licence conditions irrespective of existing CRS designations by commissioners. The NHS England Independent Provider team will use the criteria detailed in Section 3 to identify 'hard to replace' providers that are not currently designated as CRS. This will allow them to ensure that the CoS licence conditions are appropriately applied to all 'hard to replace' providers.

Section 1: Introducing requirements for standards of quality governance for some independent sector providers

Collecting information to reach a quality governance rating

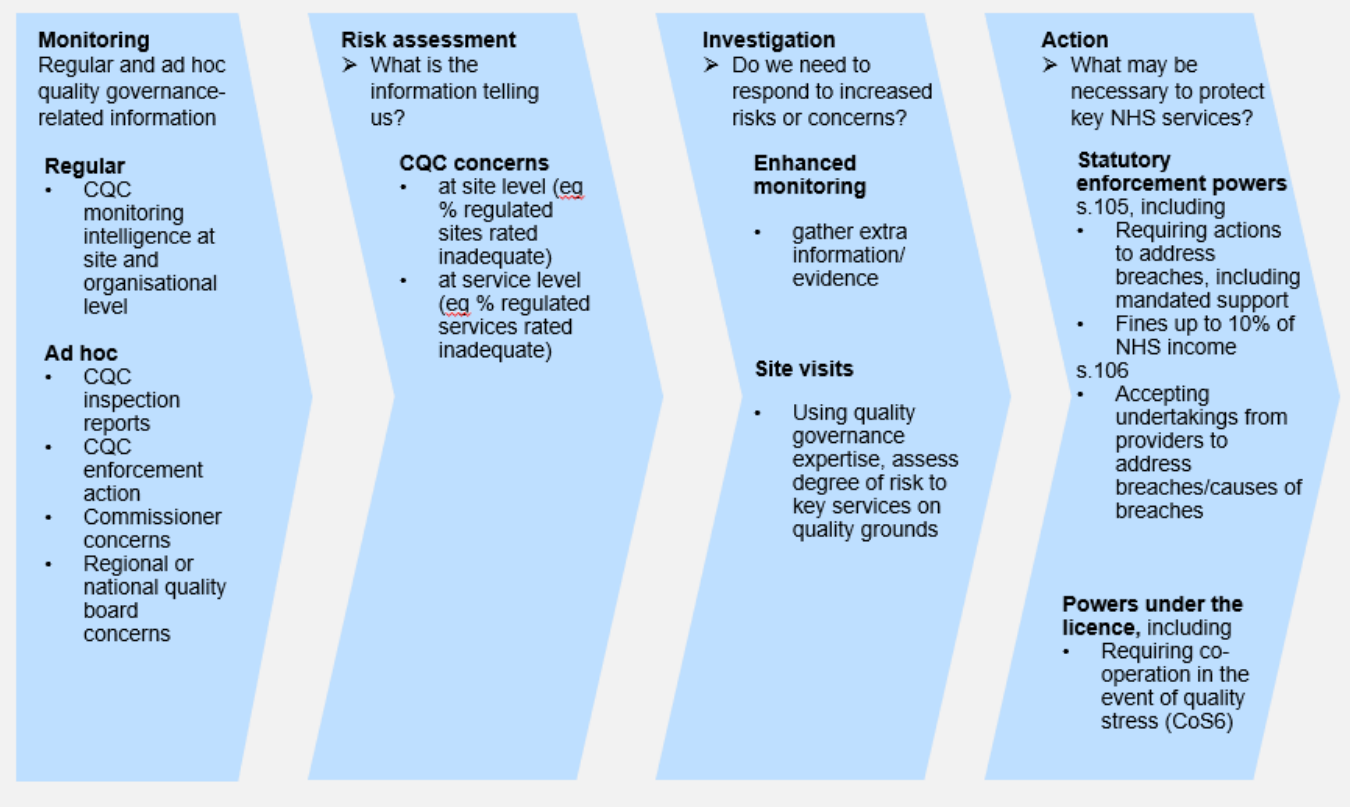
Overview of changes

16. Our overarching objective is to ensure NHS patients can continue to access key services. We will take a risk-based and proportionate approach to identify and investigate quality concerns and take appropriate action if shortcomings in standards of quality governance are indicated that may put services at risk.

17. The CQC has the power to suspend services where it has significant concerns regarding the quality of care. Where this occurs at providers subject to the CoS licence conditions and there are no obvious alternatives to these services, suspension could result in access being limited or even terminated for NHS patients. Suspension would have the same practical effect on commissioners and patients as a provider insolvency.

18. Our risk-based monitoring will minimise reporting requirements for most providers, with additional requirements only placed on providers demonstrating signs of quality stress. Our overall approach to overseeing and protecting key services from quality governance risks will have four stages shown in Figure 1 below.

Figure 1: NHS England's regulatory approach to overseeing quality governance risk and ensuring continuity of services for independent sector providers subject to the CoS licence conditions



19. This section sets out the information we will collect to determine provider risk ratings, as part of business as usual monitoring or under enhanced monitoring where there is indication of significant deterioration in quality.

Business as usual monitoring

20. In the first year of monitoring, providers that are subject to the CoS licence conditions will be required to provide us with information that describes their approach to quality governance and sets out how they are assured of the quality of services they provide. After this, providers will be asked to inform us by exception of material changes to their system for quality governance, eg in response to a major transaction or a governance review.

21. We will also consider intelligence provided by other relevant sources that collect data on independent sector providers and form a view on risks to patients and services, such as the CQC. Consequently, we will look at information including, but not limited to:

    a. % of sites or % of services rated inadequate by the CQC
    b. trends in CQC views of a provider's sites and services
    c. CQC enforcement actions
    d. NHS England regional clinical quality teams
    e. national quality forums
    f. commissioners' views.

22. In addition to the above, we may require ad-hoc or exception reporting depending on individual circumstances and risk factors. Providers must report any material in-year changes in their finances and other circumstances that may have significant implications for the provision of high-quality care. These include, but are not limited to:

    a. CQC warning notices or other regulatory requirements that can require healthcare providers to spend significantly more to meet safety/quality requirements, or see services reduced
    b. CQC triggered reviews and their outcomes
    c. risk of CQC finding a service or site 'inadequate'
    d. risk of failure to maintain registration of any service with the CQC
    e. proposals to vary CRS provision
    f. serious clinical incidents
    g. significant adverse media
    h. transactions, including the acquisition and disposal of sites providing care
    i. governance reviews.

Enhanced monitoring

23. We will always look to respond in a proportionate fashion to any potential concerns arising through our oversight, and only apply enhanced monitoring to providers where we have significant concern regarding deterioration in care quality, arising from our business as usual monitoring as outlined above. Given the level of risk and the associated issues driving this, we will generally consider several factors before judging the appropriate response to any potential concern. These include:

a. the extent to which management teams at site and/or organisational level were/are aware of the issues and the drivers behind them

b. the length of time the issues have been apparent (continuously or otherwise)

c. the quality of management's plans for addressing issues and their ability and capacity to implement them

d. over time, management's track record of addressing quality issues.

24. We are likely to require additional information for enhanced monitoring, and the actions we may take where we suspect a breach of the quality governance criteria in the provider licence include:

a. requiring additional information

b. site visits to discuss issues with management at site or organisational level

c. engagement with senior resource (eg leadership or clinical governance expertise).

Consultation question 1

Do you agree that we should take a **risk-based approach** to monitoring that largely relies on CQC and commissioner oversight but gives us powers to intervene when key services are at risk due to failings in quality governance?

Please answer: strongly agree / agree / neither agree nor disagree / disagree / strongly disagree

Please explain your answer or provide any other comments you have about this proposal.

Consultation question 2

Do you agree that the information we identify in paragraph 21 is the relevant information for us to collect to identify any shortcomings in standards of quality

governance that may put services at risk? What other information would be appropriate?

Please answer: strongly agree / agree / neither agree nor disagree / disagree / strongly disagree

Please explain your answer or provide any other comments you have about this proposal.

Defining our risk ratings and how they will influence the monitoring approach

Overview of changes

25. Based on our assessment of data collected as set out in Section 2, we will determine which of three quality risk ratings should be assigned to each provider, but we will not publish this rating.

Risk rating	Description of consequences
Low	**No apparent concerns** Ongoing monitoring based on CQC and third-party information
Medium	**Emerging or ongoing concern** Where there is either a heightened quality governance risk or an emerging quality stress at the provider, action may be needed to prevent significant issues. NHS England is likely to maintain or initiate additional levels of monitoring and may consider opening an investigation to assess whether there has been a breach of the CoS licence conditions. If any investigation finds that a breach has taken place NHS England may take action to require a provider to put remedies in place. In some cases, NHS England may also start taking an active role in ensuring continuity of services using provisions in the relevant licence conditions, eg requesting the co-operation of the provider to assess and address quality stress and fix governance issues that may be negatively affecting the care provided to patients.

	NHS England may use the KLOEs in the appendix to identify the issues and inform the course(s) of action required.
High	**Significant concern** Providers in this category are highly likely to be exhibiting quality stress sufficient for NHS England to open an investigation and consider using formal enforcement powers to take an active role in addressing governance issues and ensuring continuity of services as set out under CoSRR2. Providers exhibiting this level of risk may be subject to monthly monitoring. NHS England may use the KLOEs in the appendix to identify the issues and inform the course(s) of action required.

26. There is likely to be an element of learning when this rating process is introduced to define relevant triggers that will determine the ratings applied to individual providers. We will define these as we gain a deeper understanding of the factors critical to ensuring the sustainability of 'hard to replace' services.

Consultation question 3

Do you agree that the categories set out in the table in paragraph 25 are appropriate risk categories for overall quality governance?

Please answer: strongly agree / agree / neither agree nor disagree / disagree / strongly disagree

Please explain your answer or provide any other comments you have about this proposal.

Setting out monitoring timescales

Overview of changes

27. Our approach to collecting quality information is integrated with the existing timescale for reporting financial information, to minimise burden on providers. Risk to continuity of services will then be assessed at three stages:

1. **Annually**, when we receive historical and forward financial information from providers. Providers must provide their annual quality accounts unless exempt at this time as described in Part 1 of the revised IPRAF.[1]
2. **In-year**, when we receive year-to-date financial information from providers.
3. **By exception**, if a provider subject to the CoS licence conditions informs us of a material quality-related event, or we receive relevant information from another source that raises concerns regarding the provider's ability to continue providing key services to NHS patients. Examples of exception triggers are provided in Part 1 of the IPRAF.

Consultation question 4

Do you agree that we should collect additional information to clarify any quality governance issues in instances where providers experience quality-related stress?

Please answer: strongly agree / agree / neither agree nor disagree / disagree / strongly disagree

Please explain your answer or provide any other comments you have about this proposal.

Responding to quality stress

28. For more information on the process of investigation and regulatory action, please refer to the NHS England enforcement guidance. Where there are concerns regarding quality stress, we will either informally engage with the provider or, if necessary, use some combination of mandated support and/or regulatory action

Informal engagement

29. Where there are concerns regarding quality stress, but these are insufficiently material to merit mandated support or regulatory action, or we are seeking more

[1] Organisations are required under the Health Act 2009 and subsequent Health and Social Care Act 2012 to produce quality accounts if they deliver services under an NHS Standard Contract, have more than 50 staff and NHS income greater than £130,000 per annum.

information to ascertain the severity of the situation, we may engage informally with the provider. This may involve discussions with management, requesting the ad-hoc provision of information and/or referring providers to the key lines of enquiry in the appendix.

Regulatory action

30. Where appropriate, eg when providers are either unwilling to take the necessary actions to address risks or are not doing so with sufficient urgency, or where we need to set formal requirements on them to safeguard key services, we will use our statutory powers. The enforcement guidance sets out how these may be used.

Mandated support (also see Section 2)

31. In situations where there is material quality stress or providers are in breach/potential breach of the quality governance criteria in the provider licence, or where there are clear and serious failings in quality governance with material risks to patients, we may consider using powers to require the provider to receive mandated support. Note: we may where possible seek to recover costs incurred by NHS England in accessing this support.

Consultation question 5

Do you agree with our proposals about how we will respond to quality stress?

Please answer: strongly agree / agree / neither agree nor disagree / disagree / strongly disagree

Please explain your answer or provide any other comments you have about this proposal.

Consultation question 6

Does the risk assessment framework for independent sector providers clearly explain how we will oversee quality governance?

Please answer: strongly agree / agree / neither agree nor disagree / disagree / strongly disagree

Please explain your answer or provide any other comments you have about this proposal.

Section 2: Mandating support

32. In most cases use of formal regulatory tools is a last resort once other methods of intervention (enhanced monitoring, regional support, CQC interventions and contract levers) have not resolved quality governance concerns. We are still developing how we will operationalise this, but it will likely be situation dependent.

33. The NHS England Independent Provider team will determine if a provider we rated high risk is experiencing quality stress and whether action is likely to be required because any of the following criteria are met:

    a. failure to intervene will likely lead to loss of strategically important services

    b. there is evidence that the independent sector provider does not have the capability and capacity to manage sustainable improvements without intervention

    c. there will be interdependent risks such as contagion risk to the independent sector provider and/or other providers in the system if the services close

    d. there is evidence of catastrophic quality and/or safety failures.

34. In most cases we will expect providers to identify and procure their own support and agree this with us. If we incur costs accessing this support, we may where possible seek to recover these costs from the provider. We will develop the process for cost recovery in these rare circumstances in the coming months.

Consultation question 7

Do you agree that the indicative criteria set out in paragraph 33 should be part of our considerations when determining if a provider is in quality stress and action is likely to be required? What other things should we consider?

Please answer: strongly agree / agree / neither agree nor disagree / disagree / strongly disagree

Please explain your answer or provide any other comments you have about this proposal.

Section 3: Introducing the 'hard to replace' provider policy

35. The CRS policy was introduced and applied to independent sector providers in 2014. Since then a number of commissioner designations of local and national services has led to these independent sector providers being subject to NHS England (formerly Monitor or NHS Improvement) financial oversight via the CoS licence conditions and, where necessary, interventions to ensure the continued delivery of these services.

36. We know that some independent sector providers that either have no or very few services designated as CRS by a commissioner would be 'hard to replace' due to the scale of services they provide regionally or nationally; but our ability to act would be limited.

37. The application of our 'hard to replace' provider policy will allow us to apply the CoS licence conditions of an independent provider's licence irrespective of existing CRS designations by commissioners.

38. The policy complements and does not replace the CRS policy; commissioners should continue to consider what services are CRS and make designations appropriately as the CRS policy imparts additional safeguards for commissioners.

39. To identify potential 'hard to replace' providers, the NHS England Independent Provider team will consider one or more of the following factors:

    a. previous and existing CRS designations by commissioners

    b. known reliance on the independent sector for delivery of significant amounts of activity

c. known fragilities in the sector such as staff shortages and adverse trends in CQC ratings

d. regional reliance on a large independent sector provider that does not currently have services designated as CRS

e. likely 'market response' to provider failure – that is, there may be no alternative organisations with access to external finance that could acquire or replace a failing competitor.

40. This means that some independent sector providers that do not have services designated as CRS will be identified as a 'hard to replace' provider, and as a result will be subject to the CoS licence conditions and monitoring under the IPRAF.

41. We will keep the list of 'hard to replace' providers under review and it may change as providers enter or leave oversight in response to changes in markets and sector pressures. We will also maintain a published list of independent sector providers that are subject to the CoS licence conditions.

42. Providers will be able to appeal their status as a 'hard to replace' provider once this status has been assigned by NHS England, on the basis that they do not meet any of the criteria set out above. The review process following appeal will be similar to (in terms of the timeframe and information gathering) a CRS designation review.[2] However, 'hard to replace' providers will be subject to the CoS licence conditions from the time they are notified of this status and until an NHS England board sub-committee determines otherwise following a provider appeal.

Consultation question 8

Do you agree with the factors we will consider to identify a 'hard to replace' provider (factors are outlined in paragraph 39)?

Please answer: strongly agree / agree / neither agree nor disagree / disagree / strongly disagree

[2] ToPublishFinalCRSGuidance28March13.pdf (england.nhs.uk)

Please explain your answer or provide any other comments you have about this proposal.

Consultation question 9

Do you agree that once notified of their status as a ‘hard to replace’ provider, these providers will be subject to the CoS licence conditions until an NHS England board sub-committee determines otherwise?

Please answer: strongly agree / agree / neither agree nor disagree / disagree / strongly disagree

Please explain your answer or provide any other comments you have about this proposal.

Responding to the consultation

We look forward to receiving views on the questions above. You can respond to the consultation via our survey https://www.engage.england.nhs.uk/consultation/draft-updated-risk-assessment-framework-and-report. The consultation closes at midnight on 22 February 2023.

Please email england.iprafconsultation@nhs.net if you have any difficulty accessing the survey.

Please let us know if your response (or part of it) is confidential so that we can exclude this from our published summary of responses. We will do our best to meet all requests for confidentiality, but because we are a public body subject to the Freedom of Information Act, please note we cannot guarantee that we will not be obliged to release your response, or part of it, even if you say it is confidential.

Appendix: Independent sector provider quality governance domains

These draft key lines of enquiry show the proposed areas of focus in instances where NHS England has identified an elevated quality risk concerning a ‘hard to replace’ provider or a provider of CRS. These areas will allow NHS England to better understand the nature of the risk and therefore make an informed decision on whether further action is appropriate.

Independent sector provider quality governance domains	Key line of enquiry	Supporting prompts
1. Capability and culture	QG1.1 – Do you promote a quality-focused culture?	Does the leadership have the necessary skills and knowledge to maintain and improve the quality of all clinical services?
		Does your leadership/executive comprise the appropriate mix of skills and capabilities in relation to delivering good quality governance?
		Do you have a systematic process to assess the training needs of new and existing board members and provide access to training as needed? Please explain.
		Does your organisation take proactive steps to listen to patients and staff and involve them in all aspects of service monitoring, design and improvement? Please illustrate with examples?
		Is there a strong culture of reporting and learning from evidence in your organisation without fear of retribution, and is this evidenced by an increase in incident reporting and continuous learning?

Independent sector provider quality governance domains	Key line of enquiry	Supporting prompts
		Do you effectively communicate quality success and areas for improvement across your organisation? If so, can you illustrate this with an example?
	QG1.2 – Do you actively engage patients, staff and other key stakeholders on quality?	Do you systematically involve patients, carers, staff, local authorities and the wider community in defining the quality strategy and framework for monitoring outcomes and developing plans for quality improvement? If so, what are your processes for this?
2. Structures, processes and systems of accountability	QG2.1 – Are there clear responsibilities, roles and systems of accountability to support good quality governance?	Do leaders understand and acknowledge their ultimate accountability for quality and the responsibility for delivering quality performance throughout all levels of the organisation? Please demonstrate how they do this.
		Are there assigned leads for quality governance that oversee risk and performance, and ensure quality is managed throughout your operations?
		What steps do you take to ensure all staff understand their responsibilities for governance within their individual, team or divisional role? How do you ensure that they maintain a good understanding of effective quality governance?
	QG2.2 – Do you have clearly defined, well-understood processes for identifying opportunities for maintaining and driving quality improvement? Including identifying the potential risks to	Does your organisation make effective use of processes to identify opportunities for maintaining and delivering quality improvement? Can you point to examples in which these processes have resulted in demonstrable improvements in line with national best practice? Please describe the internal process for staff reporting quality concerns.
		Are there effective structures, processes and systems of accountability to support the delivery of the quality/clinical strategy and good quality, sustainable services? Are these regularly reviewed and improved? How are they performing against core indicators?

Independent sector provider quality governance domains	Key line of enquiry	Supporting prompts
	quality, and for escalating and resolving issues?	Does the organisation ensure that performance and risk issues are escalated and challenged using the most appropriate structures and processes, eg quality governance committees? Does this enable the board/executive to challenge effectively?
		How are you ensuring that services are fully engaged with their systems/wider NHS stakeholders in meeting the needs of the local health populations? How are risks managed within this engagement approach? How do you ensure that information is escalated within the system?
		For those entering the enhanced level of monitoring only – How do you approach the processes for identifying Serious Incidents? How do you ensure that structures and processes support effective and efficient resolution and quality improvement?
3. Data and reporting	QG3.1 – Is appropriate quality information analysed and challenged in the organisation?	As a leadership team do you consider what information is routinely available to you across all the domains of quality, and whether this is appropriately aligned with integrated care board (ICB)/regional strategic quality goals and assessment of the key risks to quality where services are located? What information do you review and how often?
		How comprehensive is the quality information you receive to support decision-making? Are there obvious risks associated with not considering specific outcome measures (and associated process measures) that your organisation is responsible for? If so, are you taking steps to address the gap? Do the chosen indicators readily identify where there is the greatest need/potential for improvement?
		Do you have access to the relevant information for benchmarking your performance? If so, how does this inform your quality strategy?

Independent sector provider quality governance domains	Key line of enquiry	Supporting prompts
		How do you ensure that quality metrics are seen as routine business throughout the organisation, from board level to staff delivering care? Is the information you review supported by more detailed information in the organisation?
	QG3.2 – Do you consistently assure the robustness of all information relating to quality?	How do you continually assure ongoing information, accuracy, validity, timeliness and comprehensiveness?
	QG3.3 – Do you look to monitor and understand current and future risks to quality and take steps to address these?	Do you ensure that quality information is used to maintain and drive improvement in quality performance?
		Is there an effective and comprehensive process to identify, understand, monitor and address current and future risks? If so, how often is this reviewed and updated?
		What processes, systems and mechanisms does the organisation have to manage current and future performance and to highlight risks when they arise? Please illustrate with examples.
		Does the organisation ensure that clinical and internal audit processes function well and have a positive impact on quality governance, with clear evidence of action to resolve concerns and maintain the improvement?
		When considering transactions and developments to services or efficiency changes, how is the impact on quality and sustainability assessed and monitored? Do you have examples of where financial pressures have compromised care?

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