Classification: Official

Publication approval reference: PAR381



NHS oversight

Consultation on a new NHS System Oversight Framework 2021/22

March 2021

Contents

1. Introduction	2
2. Purpose and principles	
3. Role of integrated care systems	4
4. Approach to oversight	6
5. Oversight cycle	8
Monitoring	8
Identifying the scale and nature of support needs	12
Identifying specific support needs	17
Co-ordinating support activity	18
6. Recovery Support Programme	20
7. CCG assessment	23
8. Alignment with partner organisations	24
9. Implementation and next steps	24
Annex A: Intervention and mandated support	
Annex B: Proposed key lines of enquiry for CCG assessment 2021/22	36

1. Introduction

- 1. In recent years it has become increasingly clear that the best way to manage NHS resources to deliver high quality, sustainable care is to focus on organising health at both system and organisation level.
- 2. This document describes NHS England and NHS Improvement's proposed approach to oversight, one that reinforces system-led delivery of integrated care. This reflects the vision set out in the NHS Long Term Plan, Integrating care: Next steps to building strong and effective integrated care systems across England, the White Paper Integration and innovation: Working together to improve health and social care for all, and the 2021/22 Operational Planning Guidance.
- 3. In 2021/22, the NHS will continue to manage the impact of COVID-19 and provide the full range of non-COVID services within an evolving local, regional and national context. The new NHS System Oversight Framework will:
 - a. provide clarity to integrated care systems (ICSs), providers and commissioners on how NHS England and NHS Improvement will monitor performance; set expectations on working together to maintain and improve the quality of care; and describe how identified support needs to improve standards and outcomes will be co-ordinated and delivered
 - b. be used by NHS England and NHS Improvement's regional teams to guide oversight of ICSs at system, place-based and organisation level as well as decisions about the level and nature of delivery support they may require
 - c. describe how NHS England and NHS Improvement will work with the Care Quality Commission (CQC) and other partners at national, regional and local levels to ensure our activities are aligned.
- 4. The new framework introduces a new support programme to replace the 'special measures' regime. The regime was introduced in 2013 to support quality improvement in the most challenged trusts following Professor Sir Bruce Keogh's review of trusts with high mortality rates. Subsequently, a financial special measures programme for trusts and analogous arrangements for CCGs were introduced. These separate programmes no longer provide the breadth of support required in the new system-based approach to the delivery of healthcare and so this document proposes their replacement with a single integrated Recovery Support Programme (RSP).

- 5. The proposals align with the vision set out for ICSs in *Integrating care* and in Integration and innovation. The latter sets out government's proposal to further support the improvement underway in the NHS and the critical role of integrated care co-ordinated at system level. The proposed legislative measures, which include the establishment of new ICS NHS bodies, will support the improvements already underway and are a continuation of the way many systems are already working.
- 6. We will continue to work with ICSs, providers, commissioners and NHS partner organisations over the course of 2021/22 to further develop the approach to oversight set out in this document for future years, as ICSs, placed-based partnerships and provider collaboration arrangements become further embedded. Subject to the parliamentary process, we will introduce a further update to the NHS System Oversight Framework for 2022/23 to reflect the new arrangements for ICSs.
- 7. Responses are invited to the questions asked through this document by Friday 14 May. These can be made via the online feedback portal at https://www.engage.england.nhs.uk/consultation/system-oversight-framework-2021-22.

2. Purpose and principles

- 8. The purpose of the proposed new framework is to:
 - a. align the priorities of ICSs and the NHS organisations within them
 - b. identify where ICSs and organisations may benefit from or require support to meet the standards required of them in a sustainable way, and deliver the overall objectives for the sector in line with the priorities set out in the 2021/22 Operational Planning Guidance, the NHS Long Term Plan and the NHS People Plan
 - c. provide an objective basis for decisions about when and how NHS England and NHS Improvement will intervene in cases where there are serious problems or risks to the quality of care.
- 9. The approach to oversight will be characterised by the following key principles:
 - a. working with and through ICSs, wherever possible, to tackle problems

- b. a greater emphasis on system performance and quality of care outcomes, alongside the contributions of individual healthcare providers and commissioners to system goals
- c. matching accountability for results with improvement support, as appropriate
- d. greater autonomy for ICSs and organisations with evidence of collective working and a track record of successful delivery of NHS priorities, including tackling inequality, health outcomes and access
- e. compassionate leadership behaviours, that underpin all oversight interactions.

Question 1: (a) Do you agree that the proposed approach to oversight set out in this document meets the purposes and principles set out above? (b) If not, how could the proposed approach be improved?

3. Role of integrated care systems

- 10. Integrating care: Next steps to building strong and effective integrated care systems across England describes the role of ICSs in the delivery of integration to serve four fundamental purposes:
 - a. improving population health and healthcare
 - b. tackling unequal outcomes and access
 - c. enhancing productivity and value for money
 - d. helping the NHS to support broader social and economic development.
- 11. The 2021/22 Operational Planning Guidance sets out the headline requirements for all ICSs from April 2021, including the collective management of system resources and performance, clearly defined at system, place-based and organisational level.
- 12. ICSs will therefore continue to be increasingly involved in the oversight process and support of organisations in their system, in partnership with NHS England and NHS Improvement. This is already reflected in NHS England and NHS Improvement's interactions with ICSs and individual organisations in many parts of the country.

- 13. Oversight arrangements will reflect both the performance and relative development of an ICS. The framework will therefore support ICSs and NHS England and NHS Improvement regional teams to work together to develop locally appropriate approaches to oversight linked to the progression of an ICS (Table 1).
- 14. As part of the progressive development of ICSs, provider collaboration arrangements are also playing an increasingly important role in the co-ordination and delivery of joined-up care across populations. The proposed oversight arrangements reflect an expectation for evidence of effective provider collaboration; the failure of an individual provider to collaborate in a system context may be treated as a breach of governance conditions and be subject to enforcement actions.

Table 1: ICS development and oversight approach

Relative level of ICS development and governance arrangements					
By exception		Typical oversight			
ICS	ICS leadership will work in partnership with the regional team, attending and contributing to discussions relating to place-based† systems and individual organisations within the ICS Provide advice and guidance on place-based systems† and individual organisations within the ICS	Jointly conduct oversight and drive improved performance for place-based† systems and individual organisations within the ICS alongside NHS England and NHS Improvement regional teams Participate in any place-based system or organisational support and intervention carried out by NHS England and NHS Improvement, other than in exceptional circumstances	Lead the oversight of place-based† systems and individual organisations in line with the principles of this document Agree and co-ordinate any support and intervention carried out by NHS England and NHS Improvement, other than in exceptional circumstances		
NHS England and NHS Improvement	Lead the oversight of the ICS, and work in partnership on the oversight of place-based systems† and individual organisations in line with the principles of this document Consult the ICS before any escalation action/ intervention is finalised and enacted through a single identified system lead	Lead the oversight of the ICS and contribute to the oversight of all place-based systems [†] and individual organisations alongside the ICS Only engage with organisations with the knowledge, agreement and participation of the ICS through a single identified lead (other than in exceptional circumstances)	Gain assurance of place- based systems [†] and individual organisations through the ICS, other than in exceptional circumstances. Undertake the least number of formal assurance meetings possible with individual organisations		

^{*} Where individual provider or commissioning organisations are subject to formal regulatory intervention, NHS England and NHS Improvement will take a direct role alongside ICSs in enhanced oversight.

[†] Where the ICS is built on more than one place-based system.

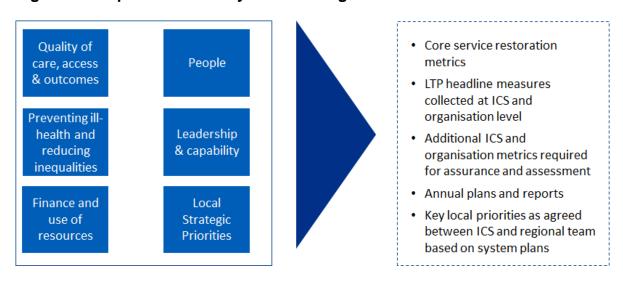
Question 2: (a) Do you agree that oversight arrangements for place-based systems and individual organisations within the ICS should reflect both the performance and relative development of the ICS? (b) If not, please give your reasons.

4. Approach to oversight

- The framework will be built around:
 - a. Five national themes that reflect the ambitions of the NHS Long Term Plan and apply across providers, commissioners and ICSs: quality of care, access and outcomes; preventing ill health and reducing inequalities; people; finance and use of resources; and leadership and capability.
 - b. A single set of metrics across ICSs, trusts and clinical commissioning groups (CCGs) aligned to the five national themes.
 - c. A sixth theme, local strategic priorities, recognises:
 - (i) that ICSs each face a unique set of circumstances and challenges in addressing the priorities for the NHS in 2021/22
 - (ii) the renewed ambition to support greater collaboration between partners in health and care systems, as set out in Integrated care, to accelerate progress in meeting our most critical health and care challenges and support broader social and economic development.
 - d. A description of how ICSs will work alongside regional and national NHS England and NHS Improvement teams to provide effective, streamlined oversight for quality and performance across the NHS.
 - e. A three-step oversight cycle that frames how NHS England and NHS Improvement teams and ICSs will work together to identify and deploy the right delivery support and intervention to drive improvement and address the most complex and challenging problems, respectively.
- 16. Local strategic priorities and oversight arrangements will be developed in partnership with place-based systems (including primary care networks) and organisations. They will be agreed between each ICS and its NHS England and NHS Improvement regional team and reflect the four core purposes of ICSs as set out above. This may involve further development of priorities under the five

- national themes (Figure 1), eg with respect to prevention and reducing health inequalities.
- 17. There will be a need for flexibility in how the oversight role is carried out within the principles of the framework. In some cases, this may involve adjusting the specifics of the approach, for example:
 - a. as the NHS continues to manage the impact of COVID-19 and provide the full range of non-COVID services within an evolving local, regional and national context
 - b. where there is a need to respond quickly and proactively to unexpected issues in individual providers, to national policy changes, the introduction of new service planning or delivery models, or new sector pressures.
- 18. The existing statutory roles and responsibilities of NHS England and NHS Improvement in relation to providers and commissioners remain unchanged for 2021/22. NHS England and NHS Improvement will continue to exercise their statutory powers where necessary to address organisational issues and support system delivery in line with the principles set out above.

Figure 1: Scope of the NHS System Oversight Framework for 2021/22



Question 3: (a) Do you agree that the framework's six themes support a balanced approach to oversight, including recognition of the importance of working with partners to deliver priorities for local populations? (b) If not, how could the proposed approach be improved?

5. Oversight cycle

- 19. The new framework will set out an oversight process which follows an ongoing cycle (Figure 2) of:
 - a. monitoring system and organisation performance and capability under six themes (Figure 1)
 - b. identifying the scale and nature of support needs
 - c. co-ordinating support activity (and where necessary formal intervention) so that it is targeted where it is most needed.

Monitoring

- 20. As part of the oversight of ICSs, providers and commissioners, NHS England and NHS Improvement will monitor and gather insights about performance across each of the themes of the framework (Figure 1). The information reviewed and collected will include annual plans and reports, regular financial and operational information; quality insight, risks and issues; and other exceptional or significant data, including relevant third-party material. Depending on the type of information, the collection and review of data may be:
 - a. in year: using monthly, or quarterly collections and forums as appropriate
 - b. annual: using annual submissions, surveys or other annually published information. In these cases, we expect that systems and NHS England and NHS Improvement regional teams will agree how they monitor progress on a timely basis linked to locally agreed plans and milestones
 - c. by exception: where material events occur or we receive information that triggers our concern outside the regular monitoring cycle.
- 19. Ongoing oversight will focus on the delivery of the priorities set out in the 2021/22 Operational Planning Guidance, including the NHS Mandate, the aims of the NHS Long Term Plan and the NHS People Plan. As part of this, a set of oversight metrics will be used by NHS England and NHS Improvement and ICSs to flag potential issues and prompt further investigation of support needs with ICSs, place-based systems and/or organisations. This will be based on the ongoing review at ICS, place and organisation level of:
 - a. current performance and service quality (based on the most recent data and insight available)

- b. the historical performance trend to identify patterns and changes, including evidence of improvement in reducing clinical variation.
- 20. A key outcome of the successful implementation of the framework will be the early identification of emerging issues and concerns so that they can be addressed before they have a material impact or performance deteriorates further. ICSs, providers and commissioners are expected to engage with regional teams on actual or prospective changes in performance or quality risks that fall outside routine monitoring, where these are material to the delivery of safe and sustainable services.
- 21. Robust quality governance arrangements will support this by ensuring quality intelligence is shared regularly with all key stakeholders; systems consistently monitor quality measures and outcomes and use professional insight to identify risks to the quality of care (including unwarranted variation); risks and issues are appropriately managed and escalated, particularly where they cannot be resolved locally or where the quality risk has wider implications; effective place-based and system solutions are delivered; and quality improvement is ongoing to ensure high-quality care services for patients.
- 22. Ongoing oversight will incorporate review meetings with ICSs, where relevant at place (or relevant local system) level with smaller groups of providers and commissioners and, by exception, with individual organisations. Meetings will be informed by a shared set of information and regional teams will draw on national and other expertise as necessary. Leadership and culture at organisation and system level will form a core part of the oversight conversations.
- 23. Regional teams will work with ICSs to ensure that oversight arrangements at system, place (including community and primary care networks) and organisation level incorporate regular review meetings as appropriate. These arrangements should reflect the local system architecture and governance arrangements. ICSs will agree, and review on a quarterly basis, a memorandum of understanding with regional teams that sets out:
 - a. the delivery and governance arrangements across the ICS, including:
 - i. the financial governance arrangements that will support the effective management of resources within the system financial envelope
 - ii. the role of place-based partnerships and provider collaboratives in delivering the NHS priorities set out in the 2021/22 planning guidance

- b. the oversight mechanisms and structures that reflect these delivery and governance arrangements, including the respective roles of the ICS and NHS England and NHS Improvement regional team
- c. the local strategic priorities that the ICS has committed to deliver in 2021/22 as a partnership and that complement the national NHS priorities set out in the 2021/22 Operational Planning Guidance and align to the four fundamental purposes of an ICS.
- 24. In some cases, oversight arrangements spanning more than one ICS will be required, eg for ambulance trusts and specialised services. Regional teams will work with organisations and ICSs to agree appropriate arrangements in line with the principles of the framework set out in this document.
- 25. Ongoing oversight meetings will be complemented by focused engagement with the ICS and the relevant organisations where specific issues emerge outside these meetings. Regional teams will work with systems to determine an appropriate enhanced associated level of oversight where this is required to monitor improvement alongside a package of support or intervention.

Question 4: (a) Do you agree that the proposed approach will support NHS England and NHS Improvement regional teams to work together to develop locally appropriate approaches to oversight? (b) If not, how could the proposed approach be improved?

Table 2: Ongoing monitoring process – review meetings

	ICS	Place*	Individual organisations/collaboratives
Scope	 Performance against national requirements including the NHS Long Term Plan deliverables at ICS level across the five national themes of the NHS System Oversight Framework Delivery against ICS level 'local priorities' set out in ICS strategic plans and its local people plan Extent to which system partners are working effectively together to deliver and improve 	 Performance against national requirements including the NHS Long Term Plan deliverables at place and organisation level across the five themes of the NHS System Oversight Framework Delivery against place and organisation level priorities set out in ICS plans including primary/community care and population health Any emerging organisational health issues that may need addressing Extent to which place-based partners are working effectively together to deliver and improve 	 Oversight of and support to: individual organisations that span multiple ICSs, or have significant funding flows from outside an ICS, eg ambulance trusts and specialist trusts collaboratives that span multiple places, including for the delivery of specialised services Linked to NHS England statutory duty to annually assess CCGs Occur by exception only for other organisations, with scope determined by the specific issues identified in discussion between the NHS England and NHS Improvement regional team and ICS leadership
Roles and participation	Led by NHS England and NHS Improvement regional team with: ICS leadership team CEOs and AO(s) from system providers and commissioner(s)	Typically led by ICS (with NHS England and NHS Improvement role linked to ICS maturity) with: provider and commissioner leadership team place-based system leaders as appropriate	 NHS England and NHS Improvement, ICS and organisational teams as relevant for cross ICS, provider collaborative and exceptional meetings CCG leadership team, chair and governing body members for CCG assessment-related meetings
Frequency of review meetings	 The default frequency for these meetings will vary according to the governance arrangements agreed between the regional team and ICS, but should be at least quarterly Regional team will engage more frequently where there are material concerns 	 Determined in discussion between the regional teams and ICS based on local system architecture and governance arrangements Regional and/or system team will engage more frequently where necessary, including focused meetings around specific themes (eg quality, finance) and/or with a subset of organisations 	 Frequency determined based on need through discussion between NHS England and NHS Improvement regional team and ICS and organisational leadership Annual meeting linked to CCG assessment process. CCGs are also expected to complete a mid-year self-assessment

^{*} Including integrated care provider or other relevant local system level. For smaller ICSs built on a single overall place, this may form part of the overall ICS review meetings.

Identifying the scale and nature of support needs

- 26. To provide an overview of the level and nature of support required across systems, inform oversight arrangements and target support capacity as effectively as possible, we propose that NHS England and NHS Improvement regional teams will allocate ICSs, trusts and CCGs to one of four 'segments' as described in Table 3. We will adopt a phased implementation to segmentation during 2021/22 that reflects the approach to operational and financial planning set out in the 2021/22 Operational Planning Guidance (see Section 9).
- 27. Segmentation decisions will be determined by the assessed level of support required based on a combination of objective criteria and judgement. For individual organisations segmentation decisions will be taken having regard to the views of system leaders.
- 28. A segmentation decision indicates the scale and general nature of support needs, from no specific support needs (segment 1) to a requirement for mandated intensive support (segment 4). A segment does not determine specific support requirements. These will be identified as set out in the section 'Identifying specific support needs'.
- 29. The principles and approach to oversight will apply across all segments. By default, all ICSs, trusts and CCGs will be allocated to segment 2 unless the criteria for moving into another segment are met.
- 30. In line with the principle of earned autonomy, ICSs, trusts and CCGs in segment 1 will benefit from the lightest oversight arrangements and greater autonomy. Specifically:
 - a. ICSs in segment 1 will be able to request:
 - i. devolution of programme funding, removing the requirement to account for resource deployment in exchange for agreed outcomes
 - ii. greater control over the deployment of improvement resources made available through regional improvement hubs.
 - b. Trusts and CCGs in segment 1 will be able to:
 - i. request access to funding to provide peer support to other organisations
 - ii. be exempt from the consultancy controls/relevant running cost limits
 - iii. benefit from streamlined business case approval.

- 31. Segment 1 ICSs, CCGs and trusts will be consistently high performing and will specifically be expected to meet the following eligibility criteria:
 - a. top quartile across the relevant subset of oversight metrics
 - b. agreed financial plan and forecasting delivery against full year envelope
 - c. CQC rating of 'Good' or 'Outstanding' overall and for well-led (trusts).
- 32. Meeting the eligibility criteria will not lead to automatic entry to segment 1. In considering whether those ICSs, CCGs and trusts meeting the eligibility criteria should be allocated to segment 1, NHS England and NHS Improvement regional teams will take into account trends in performance as well as:

a. For ICSs and/or CCGs:

- i. success in tackling variation across the system and reducing health inequalities
- ii. whether the ICS consistently demonstrates that it has built the capability and capacity required to deliver on the four fundamental purposes of an ICS
- iii. whether the CCG has achieved streamlined commissioning arrangements aligned to the ICS boundary, or is on track to fully achieve these against an agreed implementation plan.

b. For trusts:

- i. evidence of established improvement capability and capacity
- ii. the degree to which the trust plays a strong, active leadership role in supporting and driving key local place-based priorities, provider collaboration arrangements and overall ICS priorities.
- 33. Where ICSs, trusts and CCGs have significant support needs that may require formal intervention and mandated support, they will be placed in segment 3 or 4. They will be subject to enhanced direct oversight by NHS England and NHS Improvement (in the case of individual organisations this will happen in partnership with the ICS) and, depending on the nature of the problem(s) identified, additional reporting requirements and financial controls. Full details are set out in Annex A: Intervention and mandated support.
 - a. Mandated support consists of a set of interventions designed to remedy the problems within a reasonable timeframe. There are two levels depending on the severity and complexity of the issues:

- Mandated support that is led and co-ordinated by NHS England and NHS Improvement regional teams with input from the national intensive support team where requested. This level of support means automatic entry to segment 3.
- ii. Mandated intensive support that is agreed with NHS England and NHS Improvement regional teams and delivered through the nationally coordinated Recovery Support Programme (see Section 6). This level of support means automatic entry to segment 4.
- b. While the eligibility criteria for mandated support will be assessed at ICS and individual organisation (trust and CCG) level, mandated support packages will always be designed and delivered within the relevant system context (eg placebased or provider collaboratives). Where the support need is triggered by an individual organisation, this means that local system partners will be expected to play their role in addressing system-related causes or supporting system solutions to the problem(s).
- 34. An ICS, trust or CCG will be eligible to be considered for mandated support and entry to segment 3 if:
 - a. performance is in the bottom quartile nationally across the relevant subset of oversight metrics

or

- b. there has been a dramatic drop in performance, or sustained very poor (bottom decile) performance against one or more of the relevant oversight metrics or
- c. it is reporting a negative variance against the delivery of the agreed financial plan and/or it is not forecasting to meet plan at year end

or

d. for trusts, there is a CQC rating of 'Requires Improvement' overall and for wellled

or

- e. for CCGs, there are no agreed plans to achieve streamlined commissioning arrangements aligned to ICS boundaries by April 2022.
- 35. Meeting one of the eligibility criteria will not lead to automatic entry to segment 3. In considering whether an ICS, trust or CCG that has met the eligibility criteria

- would benefit from mandated support, regional teams will consider a range of other factors, including whether there is the capability and capacity to address the issues without additional support (see Annex A for full details):
- 36. Systems or organisations placed in segment 4 will typically have longstanding and/or very complex issues that are preventing agreed levels of improvement. Organisations in this segment were previously subject to 'special measures'. We are proposing to replace this with a new support programme that will provide focused and integrated support for the most challenged ICSs and organisations. Further detail is set out in the Section 6 as well as Annex A.
- 37. For ICSs and organisations in segments 1 and 2, overall support needs will be formally reviewed on a quarterly basis by the NHS England and NHS Improvement regional team (in the case of individual organisations this will happen in partnership with the ICS). Where, by exception, ongoing monitoring suggests that the support needs may have changed, this will trigger a review of the segment allocation (see 'Identifying specific support needs' below).
- 38. For ICS and organisations in segments 3 and 4, the agreed exit criteria will need to be met to move to a lower segment (see Annex A).

Question 5: (a) Do you support the proposed approach to segmentation across ICSs, trusts and CCGs? (b) How could the proposed approach be improved to better inform oversight arrangements and effectively target support capacity?

Table 3: Support segments: description and nature of support needs

		Scale and nature of support needs		
	ICS	CCG	Trust	
1	Consistently high performing across the six oversight themes Capability and capacity required to deliver the ICS four fundamental purposes is well developed	Consistently high performing across the six oversight themes Streamlined commissioning arrangements are in place or on track to be achieved	Consistently high performing across the five national oversight themes and playing an active leadership role in supporting and driving key local place-based and overall ICS priorities	No specific support needs identified. Trusts encouraged to offer peer support Systems are empowered to direct improvement resources to support places and organisations, or invited to partner in the co-design of support packages for more challenged organisations
2	This is the 'default' segment un another segment. While ICSs in demonstrate many of the chara is challenged at system, place partners will be in place to addi	Flexible support delivered through peer support, clinical networks, the NHS England and NHS Improvement universal support offer (eg GIRFT, RightCare, pathway redesign, NHS Retention Programme) or a bespoke support package via one of the regional improvement hubs		
3	Significant support needs against one or more of the six oversight themes Significant gaps in building the capability and capacity required to deliver on the ICS four fundamental purposes	Significant support needs against one or more of the six oversight themes No agreed plans to achieve streamlined commissioning arrangements by April 2022	Significant support needs against one or more of the five national oversight themes and in actual or suspected breach of the licence (or equivalent for NHS trusts)	Bespoke mandated support through regional improvement hub, drawing on system and national expertise as required (see Annex A)
4	Very serious, complex issues manifesting as critical quality and/or finance concerns that require intensive support	Very serious, complex issues manifesting as critical quality and/or finance concerns that require intensive support	In actual or suspected breach of the licence (or equivalent) with very serious, complex issues manifesting as critical quality and/or finance concerns that require intensive support	Mandated intensive support delivered through the Recovery Support Programme (see Annex A)

Identifying specific support needs

- 39. Where an ICS, place-based system or individual organisation (trust or CCG) is triggering a specific concern, the NHS England and NHS Improvement regional team will work with, or through, the ICS to understand why the trigger has arisen and if a support need exists. The regional team will involve system leads in this process – both to identify the factors behind the issues and whether local support is available and appropriate.
- 40. Teams will assess the seriousness, scale and complexity of the issues that the ICS, place-based system or individual organisation is facing using information gathered through quality surveillance, existing relationship knowledge and discussions with system members, and information from partners and evidence from formal or informal investigations. As part of this, regional teams will draw on the expertise and advice of national colleagues as required.
- 41. Regional teams, working with the ICS and place-based system leaders (as appropriate), will consider the:
 - a. degree of risk and potential impact
 - b. degree to which the ICS, place-based system or individual organisation understands what is driving the issue
 - c. views of leadership, governance and maturity of improvement approach
 - d. system's or organisation's capability and credibility of plans to address the issue
 - e. previous steps to support the ICS, place-based system or individual organisation to rectify the issue
 - f. extent to which the ICS, place-based system or individual organisation is delivering against a recovery trajectory.
- 42. Based on this assessment, teams will identify whether an ICS, place-based system or individual organisation has a support need and, if so, the specific type and level of support that is required. Support decisions will be taken having regard to the views of the system leadership.
- 43. Where appropriate this may lead to a review of the allocated support needs segment as set out above.

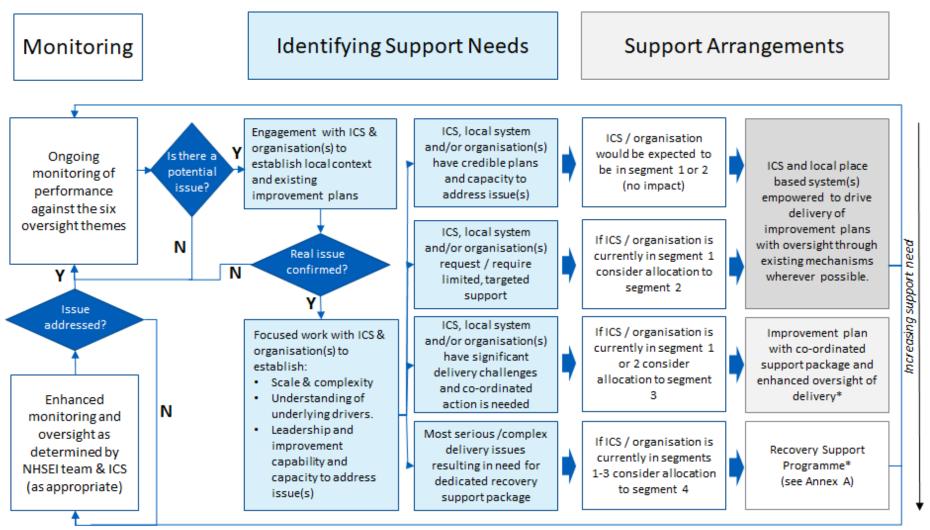
- 44. Specific support needs will be reviewed through regular ICS oversight meetings and additional enhanced oversight arrangements, where these are required to:
 - a. track improvement and understand the effectiveness of the various support measures
 - b. ensure support is targeted where it has the greatest impact.

Co-ordinating support activity

- 45. Regional system improvement teams will work flexibly with ICSs to deploy the right support through this ongoing cycle, drawing on the expertise and advice of national colleagues as appropriate. We will explore with ICSs the future role peer review could play in the oversight model.
- In line with the principles governing the framework, regional system improvement teams will work with and through ICS leaders, wherever possible, to tackle problems and ensure that the oversight process is both proportionate and co-ordinated across ICSs.
- 47. Support requirements for ICSs, place-based systems and individual organisations will be considered in parallel so that any support activities (and where necessary interventions) are mutually reinforcing and can be deployed at the right level, eq where concerns affect multiple organisations a system-wide approach may be needed.
- 48. Where the operation of the ICS itself is deemed to be a causal part of the identified issue(s), this could result in a change to the oversight approach normally associated with that system's previously assessed maturity level.

Question 6: (a) Do you have any additional suggestions that could improve the proposed approach to oversight, support and intervention?

Figure 2: Oversight, diagnosis and support and intervention process



^{*}may involve use of relevant regulatory powers

6. Recovery Support Programme

- 49. For systems, trusts and CCGs allocated to segment 4, we are proposing that a new national Recovery Support Programme (RSP) will provide focused and integrated support, working in a co-ordinated way across the system, regional and national NHS England and NHS Improvement teams.
- 50. The programme of special measures for trusts experiencing significant quality concerns has been in place since 2013, and for those with significant financial concerns since 2016. A parallel programme for CCGs has been in place since 2016. Having these separate programmes no longer fits with the much more integrated approach to healthcare and it is now time to focus on an integrated system approach to improvement.
- 51. The new RSP will differ from the special measures programmes in a number of important ways (details of the operation of the RSP as part of the overall approach to mandated support are set out in Annex A). It will:
 - a. be system oriented, while still providing focused, intensive support to individual organisations
 - b. focus on the underlying drivers of the problems that need to be addressed and those parts of the system that hold the key to improvement
 - c. be nationally led by a credible, experienced system improvement director (SID) jointly appointed by the system, region and national intensive support team
 - d. involve team-based support via an expert multidisciplinary team co-ordinated by the SID
 - e. be time limited with clear exit criteria
 - f. focus on system resilience with knowledge and skills transfer, providing sustainable capability within the system following exit.
- 52. Where entry to segment 4 and the RSP is triggered by an individual organisation, local system partners will be expected to play their role in addressing systemrelated causes, or supporting system solutions to the problem(s).
- 53. On entering the RSP a diagnostic stocktake involving all relevant system, regional and national partners will:

- a. identify the root cause(s) of the problem(s) and the structural and strategic issues that must be addressed
- b. recommend the criteria that must be met for the system or organisation to exit mandated intensive support (exit criteria).
- 54. NHS England and NHS Improvement will review the capability of the ICS's, trust's or CCG's leadership. This may lead, if necessary, to changes to the management of the system/organisation to ensure the board and executive team can make the required improvements. Where changes are required, this will happen as soon as is practical and the necessary support will be provided to help facilitate this.
- 55. At the same time as helping to address the specific issues that triggered mandated intensive support, NHS England and NHS Improvement will consider whether long-term solutions are needed to address any structural issues affecting the ICS's, trust's or CCG's ability to ensure high quality, sustainable services for the public.
- 56. The SID will be jointly appointed by the system, NHS England and NHS Improvement regional and national intensive support teams, and will normally report to the system lead, with a reporting line to the existing Director of Intensive Support to ensure sufficient independence. Specific arrangements will need to be agreed in each situation to ensure appropriate governance and independence.
- 57. The SID will support the ICS or relevant organisations with the development of the improvement plan, which will include an indicative timeline for exit from the RSP and segment 4 of the framework.
- 58. The SID will work with the trust, CCG and/or ICS to co-ordinate the necessary support from the system, NHS England and NHS Improvement teams, the broader NHS or, when no NHS provider is available, an external third party. This could include:
 - intensive support for emergency and elective care
 - intensive support to deliver the national programmes focused on reducing clinical variation across clinical pathways
 - intensive support for workforce and people practices

- financial recovery support including specialist support, eg to reduce agency use, implement cost controls
- drivers of deficit review
- governance review
- governance and leadership programme for improvement in challenged organisations and systems
- tailored delivery of a range of improvement programmes such as 'Well led', 'Better tomorrow' and 'Making data count'.
- 59. Exit from the RSP and segment 4 of the framework will be decided by the NHS England and NHS Improvement System Oversight Committee on the recommendation of the relevant region and on the basis that the agreed exit criteria have been met in a sustainable way. Progress against the improvement plan will be reviewed on a six-monthly basis to ensure improvement is being achieved. Where entry into the RSP was on the recommendation of the CQC, then exit will also require CQC recommendation.
- 60. When a system or organisation exits the RSP, a package of support will be agreed to ensure that the improvement is sustained.
- 61. Key elements of the proposed RSP have been successfully tested, with positive feedback from organisations and systems. This includes the approach to the diagnostic stocktakes, role of the SID, deployment of multidisciplinary support teams and approach to integrated improvement planning.

Question 7: (a) Do you agree that the current model of special measures for individual organisations should be replaced by a more system-focused support programme? (b) If not, please give your reasons.

Question 8: (a) Do you support the proposed approach to the Recovery Support Programme? (b) How could the proposed approach be improved to better support systems, trusts and/or CCGs to address complex and/or longstanding challenges?

7. CCG assessment

- 62. NHS England has a legal duty to annually assess the performance of each CCG. The assessment must consider the duties of CCGs to improve the quality of services; reduce health inequalities; obtain appropriate advice; involve and consult the public; and comply with financial duties.
- 63. From 2015/16 to 2019/20, this was done first under the auspices of the CCG Improvement and Assessment Framework and for 2019/20 the NHS Oversight Framework. This provided an approach whereby CCG performance was assessed in key areas that covered leadership, financial management and performance in priority areas. On the basis of this performance, NHS England provided each CCG with an overall assessment rating using the CQC rating terminology of 'Outstanding', 'Good', 'Requires Improvement' and 'Inadequate'.
- 64. For 2020/21, a simplified approach to the annual assessment of CCGs' performance will be taken as a result of the differential and continued impact of COVID-19. It will provide scope to take account of the different circumstances and challenges CCGs face in managing recovery across the phases of the NHS response to COVID-19 and focus on CCGs' contributions to local delivery of the overall system recovery plan. A narrative assessment, based on performance, leadership and finance, will replace the ratings system previously used for CCGs.
- 65. We propose that the approach is adapted for 2021/22 as this will provide greater flexibility to reflect both the continued uncertainty faced by the NHS in light of COVID-19 and the increasingly significant differences between the size and nature of CCGs with the delivery of streamlined commissioning arrangements aligned to ICS footprints. The annual assessment will be based on:
 - a. performance against the oversight metrics
 - b. the key lines of enquiry set out in Annex B
 - c. an assessment of how CCGs work with others (including their local health and wellbeing boards) to improve quality and outcomes for patients.
- 66. This will inform an end-of-year meeting between the CCG leaders and the NHS England and NHS Improvement regional team, and result in a narrative assessment identifying areas of good and/or outstanding performance, areas of

improvement, as well as areas of particular challenge across: quality (including reducing health inequalities), leadership, and finance and use of resources.

Question 9: (a) Do you support the proposed approach to CCG assessment? (b) If not, how could the proposed approach be improved?

8. Alignment with partner organisations

- 67. As well as working with and through ICSs wherever possible to tackle problems, we recognise that the challenges facing the health and care system also require a joined-up approach and increased partnership with other organisations at national, regional and local levels. This is most evident for the purposes of quality oversight; the National Quality Board (NQB) has recently issued Shared Commitment to Quality on the importance of having a common approach to quality and of organisations coming together to share intelligence though quality surveillance group (QSG) structures.
- 68. Over the course of 2021/22, NHS England and NHS Improvement will publish further detail on quality and safety function requirements for systems working with us. This includes working with ICS and system partners to develop effective escalation of quality risks and issues to NHS England and NHS Improvement regional teams, and regulators to share intelligence and address issues where they cannot be managed locally or where the quality risk has wider implications.
- 69. NHS England and NHS Improvement will also continue to work alongside key regulators, CQC, Health Education England, General Medical Council and the Nursing & Midwifery Council through the Joint Strategic Oversight Group (JSOG) function to provide a dedicated space for regulators to share intelligence and develop aligned approaches to support organisations.

9. Implementation and next steps

70. We will separately set out the oversight metrics for 2021/22. These will reflect the priorities set out in the 2021/22 Operational Planning Guidance, including the NHS Mandate, the aims of the NHS Long Term Plan and the NHS People Plan.

- 71. Following consultation on the approach described in this document, the new NHS System Oversight Framework for 2021/22 will be issued at the end of June.
- 72. We intend to adopt a phased and risk-based approach to implementation of the segmentation proposals in recognition of the continued pressures on systems. The initial focus will therefore be on segments 3 and 4, including the introduction of the new Recovery Support Programme.
- 73. During 2021/22 we will continue to work with ICSs, providers, commissioners and NHS partner organisations to further develop the approach to oversight set out in this document for future years.

Annex A: Intervention and mandated support

Introduction

- 1. Mandated support applies when ICSs, NHS trusts and foundation trusts ('trusts'), or clinical commissioning groups (CCGs) have serious problems and where there are concerns that the existing leadership cannot make the necessary improvements without support.
- 2. Mandated support consists of a set of interventions designed to remedy the problems within a reasonable timeframe. There are two levels depending on the severity and complexity of the issues:
 - Mandated support that is led and co-ordinated by NHS England and NHS Improvement regional teams with input from the national intensive support team where requested. This level of support means automatic entry to segment 3 of the NHS System Oversight Framework.
 - Mandated intensive support that is agreed with NHS England and NHS Improvement regional teams and delivered through the nationally co-ordinated Recovery Support Programme (RSP). This level of support means automatic entry to segment 4 of the NHS System Oversight Framework.
- 3. While the eligibility criteria for mandated support will be assessed at ICS and individual organisation (trust and CCG) level, mandated support packages will always be designed and delivered within the relevant system context (eg placebased or provider collaboratives). Where the support need is triggered by an individual organisation, this means that local system partners will be expected to play their role in addressing system-related causes or supporting system solutions to the problem(s).
- 4. Mandated support involves the use of our enforcement powers:
 - a trust considered to be in need of mandated support will be subject to enforcement action that requires the trust to carry out specific actions as part of the intervention
 - a CCG that is failing or is at significant risk of failing to discharge its functions may be subject to directions

in the case of an ICS, this may involve enforcement action at the level of individual organisations (trusts and CCGs) where appropriate.

5. This annex explains:

- how NHS England and NHS Improvement determine the requirement for mandated support and the level of support
- what happens to an ICS or organisation when mandated support applies
- the roles and responsibilities of other key organisations involved, specifically the CQC
- how an ICS or trust exits from mandated support.
- 6. This annex supersedes the previously published policy described as 'special measures' and should be read in conjunction with the 2021/22 System Oversight Framework.

How NHS England and NHS Improvement determine the need for mandated support

7. NHS England and NHS Improvement determine which ICSs, trusts and CCGs require mandated support with reference to a set of objective criteria, but we also take into account other appropriate considerations. Any ICS, trust or CCG meeting the objective criteria set out below is eligible to be considered for the relevant level of mandated support, but may also be excluded from this in light of other relevant considerations.

Mandated support (segment 3)

- 8. An ICS, trust or CCG is eligible to be considered for mandated support and entry to segment 3 if:
 - performance is in the bottom quartile nationally across the relevant subset of oversight metrics

or

there has been a dramatic drop in performance, or sustained very poor (bottom decile) performance against one or more of the relevant oversight metrics

or

- it is reporting a negative variance against the delivery of the agreed financial plan and/or it is not forecasting to meet plan at year end or
- for trusts, there is a CQC rating of 'Requires Improvement' overall and for wellled

or

- for CCGs, there are no agreed plans to achieve streamlined commissioning arrangements aligned to ICS boundaries by April 2022.
- Where there are material concerns about a system's and/or organisation's 9. governance, leadership, performance and improvement capability arising from intelligence gathered by or provided to NHS England and NHS Improvement (eg delivery against the national and local transformation agenda), this may also trigger consideration of mandated support. In these circumstances regional teams will also consider the extent to which the above eligibility criteria are met.
- 10. Meeting one of the eligibility criteria does not lead to automatic entry to segment 3. In considering whether an ICS, trust or CCG that has met the eligibility criteria would benefit from mandated support, regional teams will consider whether:

For all:

- there is the capability and capacity to address the issues without additional support, eg where there is clarity on key issues with an existing improvement plan and a recent track record of delivery against plan and/or of agreed recovery actions
- there are other exceptional mitigating circumstances.

For ICSs:

- there is evidence of collaborative and inclusive system leadership across the ICS, eg where the system is not in financial balance, whether it has been able to collectively agree credible plans for meeting the system envelope
- there is clarity and coherence in ways of working and governance arrangements across the system.

For trusts and CCGs:

- whether the trust or CCG is working effectively with other system partners to address the problems.
- 11. Foundation trusts will only be placed in segment 3 where there is evidence of their being in actual/suspected breach of their licence conditions (or equivalent for NHS trusts).

Mandated intensive support (segment 4)

or

- 12. An ICS, trust or CCG is eligible to be considered for mandated intensive support and entry to segment 4 if, in addition to the considerations for mandated support above, any of the following criteria are met:
 - longstanding and/or complex issues that are preventing agreed levels of improvement for ICSs, trusts or CCGs in segment 3
 - a significant actual or forecast gap to the agreed financial plan or
 - a catastrophic failure in leadership or governance that risks damaging the reputation of the NHS or for trusts:
 - a recommendation by the CQC.
- The CQC, through the Chief Inspector of Hospitals, will normally recommend to NHS England and NHS Improvement that a trust is mandated to receive intensive support when it is rated 'Inadequate' in the well-led key question (ie there are concerns that the organisation's leadership is unable to make sufficient improvements in a reasonable timeframe without extra support) and 'Inadequate' in one or more of the other key questions (safe, effective, caring and responsive).
- 14. The evidence provided by the CQC will include the reasons why it is recommending the trust is mandated to receive intensive support, the specific areas of improvement where actions need to be taken, and what improvements in quality need to be achieved.

15. Based on the full range of information, NHS England and NHS Improvement will decide, following national moderation, whether the trust will be placed in segment 4 and receive intensive support through the RSP.

What happens when NHS England and NHS Improvement mandate support for an ICS, trust or CCG

Mandated support (segment 3)

- 16. NHS England and NHS Improvement will communicate their decision to the ICS, trust or CCG and work with them to develop and deliver a bespoke mandatory support package through the relevant regional improvement hub, drawing on system and national expertise as required.
- 17. The NHS England and NHS Improvement regional team will agree the criteria that must be met for the ICS, CCG or trust to exit mandated support (exit criteria) and the ICS, CCG or trust will develop an improvement plan with an indicative timescale for meeting the exit criteria.
- 18. Typically, the following additional interventions will be put in place:
 - enhanced monitoring and oversight of the ICS, CCG or trust by the NHS England and NHS Improvement regional team
 - NHS England and NHS Improvement advisory role for senior appointments including shortlisting and as external assessor on interview panels.
- 19. Depending on the nature of the problem(s) identified and the support need, further interventions may include enhanced:
 - scrutiny/assurance of plans
 - reporting requirements
 - financial controls including lower capital approval limits.

Mandated intensive support (segment 4)

20. NHS England and NHS Improvement will communicate their decision to the ICS, trust or CCG and then make a formal public announcement through a press release.

- 21. Mandated intensive support will be agreed with the region and delivered through the nationally co-ordinated RSP. The RSP has been developed to provide intensive support either at organisation level (with system support) or across a whole system health and social care system.
- 22. A diagnostic stocktake involving all relevant system partners will:
 - identify the root cause(s) of the problem(s) and the structural and strategic issues that must be addressed
 - recommend the criteria that must be met for the system or organisation to exit mandated intensive support (exit criteria).
- 23. NHS England and NHS Improvement will review the capability of the ICS's, trust's or CCG's leadership. This may lead, if necessary, to changes to the management of the system/organisation to make sure the board and executive team can make the required improvements. Where changes are required, this will happen as soon as is practical and the necessary support will be provided to facilitate this.
- 24. At the same time as helping to address the specific issues that triggered mandated intensive support, NHS England and NHS Improvement will consider whether long-term solutions are needed to address any structural issues affecting the ICS's, trust's or CCG's ability to ensure high quality, sustainable services for the public.
- 25. NHS England and NHS Improvement will appoint an improvement director who will act on their behalf to provide assurance of the ICS's, CCG's or trust's approach to improving performance. The improvement director will support the ICS, trust or CCG to develop an improvement plan with an indicative timescale for meeting the exit criteria (typically within 12 months).
- 26. The improvement director will work with the trust, CCG and/or ICS to co-ordinate the necessary support from the system, NHS England and NHS Improvement teams, the broader NHS or, when no NHS provider is available, an external third party. This could include:
 - intensive support for emergency and elective care
 - intensive support to deliver the national programmes focused on reducing clinical variation across clinical pathways

- intensive support for workforce and people practices
- financial turnaround/recovery support including specialist support, eg to reduce agency use, implement cost controls
- drivers of deficit review
- governance review
- governance and leadership programme for improvement in challenged organisations and systems
- tailored delivery of a range of improvement programmes such as 'Well led', 'Better tomorrow' and 'Making data count'.
- 27. Typically, the following additional interventions will be put in place:
 - regular formal progress and challenge meetings with national-level NHS England and NHS Improvement oversight
 - board vacancies filled on the direction of NHS Improvement (trusts).
- 28. Depending on the nature of the problem(s) identified and the support need, further interventions may include:
 - NHS Improvement-appointed board adviser
 - enhanced reporting requirements
 - enhanced financial controls including:
 - NHS Improvement control of applications for Department of Health and Social Care financing (trusts)
 - peer review of expenditure controls
 - reduced capital approval limits (trusts)
 - rapid roll out of extra controls and other measures to immediately strengthen financial control, including those set out in NHS England and NHS Improvement guidance (including the 'Grip and Control' checklist).
- 29. Where a trust is deemed to require mandated intensive support on the recommendation of the CQC, there will be close dialogue between the CQC, NHS England and NHS Improvement, the trust and ICS, which will include what improvements in quality would give assurance of progress being made. These

- improvements form the basis of joint reviews of progress during the mandated intensive support period, as well as the existing regular information exchange between the CQC and NHS England and NHS Improvement regional leads.
- 30. This process of information exchange and review will enable extra support or intervention to be considered as needed. These decisions need not wait until the next re-inspection.
- 31. NHS Improvement will ensure that the trust addresses any urgent patient safety and quality issues identified as a priority. The CQC will continue to monitor quality at the trust. If at any time patients are at immediate serious risk of harm, the CQC can use its urgent powers to safeguard them. In some circumstances, the Chief Inspector of Hospitals may proceed to use CQC's strongest enforcement powers including:
 - Imposition of conditions: this can mean the provider may no longer provide certain aspects of its services in certain of its locations. Contingency planning would be needed to ensure that appropriate alternative provision is in place for service users.
 - Cancellation of registration: this means the provider can no longer lawfully provide the health and care services for which it is registered in any of the sites it operates. Contingency planning would be needed so that another provider can ensure continued access to services.
- 32. The expectation is that the CQC will reinspect the trust within 12 months of the start of mandated intensive support. It will judge if the quality of patient care and the trust's leadership have improved.

How ICSs, trusts and CCGs exit from mandated support

Mandated support (segment 3)

33. To be considered for removal from mandated support, an ICS, trust or CCG must demonstrate that the exit criteria have been met. In deciding whether to accept a recommendation to approve exit, the NHS England and NHS Improvement regional team will also consider whether a targeted and time-limited post-exit support package is needed to ensure the improvement is sustained.

Mandated intensive support (segment 4)

- 34. To be considered for removal from mandated intensive support, an ICS, trust or CCG must demonstrate that the exit criteria have been met. In deciding whether to accept a recommendation to approve exit, the NHS England and NHS Improvement will also consider the proposed post-exit support package that will be needed to ensure the improvement is sustained.
- 35. Where a trust is in receipt of mandated intensive support at the recommendation of the CQC, NHS England and NHS Improvement will only approve exit following a recommendation from the Chief Inspector of Hospitals. The Chief Inspector will usually recommend this where there is no reason on grounds of quality why a trust should remain in receipt of mandated intensive support – that is, if the quality of care is showing sufficient signs of improvement, even if it is not yet 'good', and if the trust leadership is robust enough to ensure that the trust will sustain current improvements and make further improvements. NHS England and NHS Improvement must also be confident that improvements will be sustained.
- 36. Before the CQC makes its recommendation, it will carry out an inspection which will include a well-led assessment. This will include taking account of the trajectory of improvement where there are broader improvement plans across a health economy.
- 37. Sufficient improvement will normally be demonstrated when:
 - all 'Inadequate' ratings across the five key questions at trust level, together with the overall trust rating, have improved to at least 'Requires Improvement'
 - for a trust with a single major site, no core service remains 'Inadequate' overall
 - for multi-site trusts, no core service remains 'Inadequate' or exceptionally – one or more core services remain 'Inadequate' but there is significant evidence of an ongoing trajectory of improvement across the organisation.
- 38. There may be specific extra improvements required by the CQC which reflect the trust's individual circumstances. The CQC may also need to take into account

- structural problems in the local health economy, if they have contributed to the requirement for mandated intensive support.
- 39. Typically, an ICS, trust or CCG will exit with a mandated support package and automatically be allocated to segment 3.
- 40. Where NHS England and NHS Improvement are not satisfied that the exit criteria have been met, mandated intensive support will be extended for a short period to allow the ICS, trust or CCG to make the improvements needed. This might occur, for example, where there have been changes to the leadership team and more time is needed for the new team to bring about change. In the case of an extension, the ICS, trust or CCG will prepare a revised improvement plan that lists actions to address any outstanding or new concerns.
- 41. NHS England and NHS Improvement will inform the ICS, trust or CCG in question of their exit decision once their formal decision-making processes are complete. NHS England and NHS Improvement will then communicate their decision formally and publicly in a press release on its website.

Annex B: Proposed key lines of enquiry for CCG assessment 2021/22

Quality of care, access and outcomes

How has the CCG contributed to ensuring delivery of health services in the priority areas set out in the 2021/22 Operational Planning Guidance?

How has the CCG monitored oversight of quality and patient experience?

How has the CCG supported the system to respond to emergency demands and manage winter pressures?

Preventing ill-health and reducing inequalities

How has the CCG supported actions to address inequalities in NHS provision and outcomes?

Does the CCG have effective systems and processes for monitoring, analysing and acting on a range of information about quality, performance and finance, from a variety of sources, including patient feedback, analyses of access to services and experiences of service users, so that it can identify early warnings of a failing service?

How does the CCG identify and engage with deprived communities, ethnic minority communities, inclusion health populations and people with disabilities (people with learning disabilities, autism or both, people experiencing mental ill-health and people experiencing frailty) and the full diversity of the local population?

How has the CCG taken account of lessons from managing COVID-19, in a way that locks in beneficial changes and explicitly tackles fundamental challenges, including support for staff, and action on inequalities and prevention?

People

How can the CCG evidence that it has supported the health and wellbeing of its workforce?

How has the CCG contributed to the delivery of the priorities for the NHS workforce set out in the NHS People Plan and 2021/22 Operational Planning Guidance, and the implementation of Our NHS People Promise?

Leadership

Has the CCG demonstrated effective system leadership and progressed partnership working, underpinned by governance arrangements and information-sharing processes, including evidence of multiprofessional leadership?

Finance and use of resources

Evidence that the CCG has delivered its break-even target in-year and contributed to the reduction of system deficits.

Evidence that the CCG has delivered the Mental Health Investment Standard.

NHS England and NHS Improvement Skipton House 80 London Road London SE1 6LH

This publication can be made available in a number of other formats on request.

© NHS England and NHS Improvement 2021

Publication approval reference: PAR381