

# EVOLVING REGULATION AND OVERSIGHT IN A SYSTEMS WORLD

## Key messages

- In response to the acceleration of system working and the introduction of the Health and Care Bill, the national regulators – CQC and NHS England and NHS Improvement – are adapting their regulatory models to more effectively align with new ways of working. Respectively, NHS England and NHS Improvement has introduced its system oversight framework (SOF) and CQC is implementing its revised regulatory approach as part of its new strategy.
- Regulation is an important driver of behaviours and can therefore incentivise and encourage trusts to work more collaboratively within their system(s) to deliver care. Trusts feel that an enabling framework will help to drive further progress and deliver on the opportunities and benefits of system working. Trusts are also supportive of regulation and oversight which reflects the value of partnership at both ICS and place levels.
- However, there are a complex series of unanswered questions which will need to be worked through carefully as new models of regulation and oversight are rolled out. In particular, trusts are concerned about the impact of system-focused regulation on their accountabilities, whereby holding systems to account for performance risks cutting across their own statutory duties.
- The challenge of meaningfully assessing quality across a system and identifying what contribution an ICS's leadership has made to that picture of quality, is significant. ICSs do not provide care, however their functions do nonetheless contribute to how well services can meet local populations' needs. The link between what is being assessed at system level, and how an integrated care board (ICB) has influenced any fluctuations in local quality or performance, will need to be clear.
- There is still a need for further clarity about how non-NHS bodies outside the reach of the current regime will be considered as part of system-level assessments. Primary care, social care, and services commissioned by local authorities all make meaningful contributions to pathways, patient flow, patient experience and health outcomes, but do not fall within the remit of the SOF. However, CQC does see a role in bringing together insights about wider organisations given its remit to regulate social care, primary care and the independent sector.

- There remains a risk of additional bureaucracy and duplication at trust and system-level as national regulators will need to continue to carry out assurance on how trusts are meeting their duties. Trusts are particularly keen to see a more streamlined approach to regulation.
- Regulation in the context of systems could also become particularly challenging for those trusts spanning multiple ICSs, as they could be subject to multiple judgements and duplicative assessments, particularly as ICSs begin to take on oversight responsibilities. Some trusts which straddle multiple ICS boundaries, such as ambulance trusts, some community service trusts and those providing specialised services, have highlighted the risk that they could be held accountable by more than one ICS, leading to an increased bureaucratic burden, and overlapping data requests and assessments.

## Introduction

The health and care system faces another period of significant change given the acceleration of system working and the introduction of the Health and Care Bill, as integrated care systems (ICSs) are put on a statutory footing with new responsibilities around the planning and co-ordination care. This has created a burning platform for the national regulators – Care Quality Commission (CQC) and NHS England and NHS Improvement – to adapt their regulatory models to more effectively align with new ways of working, taking into account the growing range of collaboration between trusts and non-NHS partners, and the impact of wider system issues when regulating NHS services.

One of two core ambitions running through the proposals outlined in CQC's new five-year strategy, *A new strategy for the changing world of health and social care*, is to assess how care is provided across a local system, rather than just within an individual provider. We expect this to be underpinned by legislative changes proposed by government during the Bill's passage through parliament. There is an increasing emphasis on how CQC can offer transparency to the public about the performance of ICSs, including how ICS leadership and decision-making contributes to quality at place level, and within individual providers.

NHS England and NHS Improvement has also introduced its **NHS System Oversight Framework 21/22**, which reinforces the system-led coordination of integrated care. It sets out for the first time how ICSs will be assessed and held to account for performance and quality ahead of, and in anticipation of, being placed on a statutory footing. ICSs will also play an increased role in the oversight of individual providers, in partnership with regional and national NHS England and NHS Improvement's teams.

This briefing sets out the key implications of the evolving nature of regulation on trusts, outlines opportunities for regulation within this new context, and draws out important unanswered questions regarding the shift towards regulation *within* and *of* systems. It describes some principles for effective regulation that can be applied in a system context, both to individual organisations and to ICSs, as the national regulators develop their future models. For the purposes of this briefing, the term 'national regulators' refers to CQC and NHS England and NHS Improvement as the primary organisations with regulatory influence over trusts.

## Context: strengthening system working and a new statutory framework

# 2

If enacted as planned, the majority of the **Health and Care Bill** will become law in April 2022, including a key focus on developing system working and formalising ICSs as statutory bodies. It will put ICSs on a two-part footing, comprising a new statutory body in the integrated care board (ICB), bringing together the organisations that plan and deliver NHS services within the ICS' geographic footprint, and a statutory committee in the integrated care partnership (ICP), a broader alliance of organisations across health, social care, public health and wider partners. The core purpose of ICSs will be to **improve outcomes, tackle health inequalities, enhance productivity and support social and economic development**.

NHS England and NHS Improvement is rolling out guidance and frameworks to support the development of ICSs, such as its ***Integrated Care Systems: design framework, Interim guidance on the functions and governance of ICBs***, as well as guidance on **place, provider collaboratives, ICS people function, and engagement with communities**, which will serve as key components of system working and ICS delivery. It has also published a **model constitution**, which aims to support the development of ICB constitutions including the composition of the board and appointment processes. NHS England and NHS Improvement recognises the broad and diverse ways in which providers and system partners are collaborating and therefore sets out its intention for a flexible operating model for ICSs and the organisations within them. These guidance documents aim to support trusts, and ICSs, with the shift towards collaborative working arrangements and help partners within ICSs to develop their joint working arrangements at place and ICS level ahead of April 2022.

Critically, trust boards will continue to be **accountable for quality, safety, use of resources and compliance with standards, and in future the delivery of any services or functions delegated to them by the ICS**. Many trusts have already established or are in the process of setting up collaboration arrangements, accelerated by joint working during the COVID-19 pandemic. There is now an expectation for all trusts providing acute and mental health services to be part of at least one provider collaborative, while **guidance** states that other trusts (such as community and ambulance trusts) should be part of one where this 'makes sense'. Given the importance of collaboration to all trust types, we continue to argue for more inclusive wording in national policy guidance.

These changes to the health and care landscape are taking place within the context of the COVID-19 pandemic, characterised by significant additional operational pressure from COVID-19 cases, the need to restore services, tackle backlogs of care, and meet deferred demand across urgent and emergency care, mental health and community health services. This includes a combination of patients with unmet need coming forward for treatment, often in a more advanced clinical position as a result of or exacerbated by the pandemic. Staff burnout is also a key concern, with **48% of trust leaders saying that they had seen evidence of staff leaving their organisation due to early retirement and effects of working through the pandemic**. ICSs, and their constituent organisations, will therefore need to navigate these changes to system working within this challenging context. There will be a need for future regulatory frameworks to be supportive, flexible and reflect an understanding of the level of disruption caused and ongoing challenges brought about by the pandemic.

ICs will be expected to maintain momentum on improving outcomes and support trusts with COVID-19 recovery within a set financial envelope and, under the new **system oversight framework**, to take on some responsibilities for the oversight of trusts. Regulation of provider and system performance and the quality of care will therefore be taking place within a new and rapidly changing architecture. This has the potential to bring with it inherent risks and there remain some unanswered questions about how these risks will be managed.

## Overview of the direction of travel for system regulation

The national regulators are exploring how they can assess the performance of ICSs in the future, take into consideration the system context when assessing individual organisations, and support ICSs as they increasingly take on a role in regulating and overseeing trusts.

Both bodies have now set out how they will balance individual organisational responsibility for quality and performance, with the influence and role of ICSs in care across a patch. There are a number of interrelated elements to this concept:

- how the national regulators will take into account wider system influences, including operational pressures elsewhere, when assessing individual trusts' performance
- how a measure of what good performance looks like will take into account new responsibilities placed on trusts to collaborate with system partners
- how ICSs will play an increasing role in the oversight of their component organisations
- how the national regulators will assess and intervene in the performance of ICSs themselves, on measures such as finances, operational targets, and quality of frontline care and outcomes.

### NHS England and NHS Improvement

In anticipation of the legislative changes proposed in the Health and Care Bill, NHS England and NHS Improvement has implemented its SOF for 2021/22, including a new support programme to replace the old special measures regime, and a segmentation framework for ICSs, trusts and clinical commissioning groups (CCGs). Its intention is to work through ICSs wherever possible and to support ICSs and regional teams to work together to develop locally appropriate approaches, while taking the level of ICS maturity into account. Alongside the SOF, it has also published its supporting oversight **metrics**, detailing what trusts, clinical commissioning groups and ICSs are being assessed against in 2021/22. These align with the deliverables outlined in the **2021/22 planning guidance** and ambitions set out in the NHS Long Term Plan (LTP). They assess:

- **Quality, access and outcomes** – metrics for trusts include operational measures such as overall waiting list size, 52 week waits, ambulance response times and quality indicators such as CQC ratings and mortality. At the ICS level additional metrics include cancer outcomes, neonatal outcomes and antimicrobial resistance.
- **Preventing ill health and reducing health inequalities** – indicators in this domain are primarily measured at ICS and CCG level including vaccination coverage and screening programme uptake. Trusts are assessed on some measures related to reducing health inequalities, including ethnicity and deprivation characteristics across service restoration and NHS LTP metrics.
- **Leadership and capability** – trusts, ICSs and CCGs are being assessed on quality of leadership, and on an aggregate score for NHS staff survey questions that measure perception of leadership culture.

- **People** – trusts, ICSs and CCGs are being assessed against the people promise index, health and wellbeing index, staff experience measures including bullying and harassment, satisfaction with flexible working patterns, staff retention and diversity of leadership.
- **Finance and use of resources** – assessment of performance against financial plan, underlying financial position, run rate expenditure, and overall trend in reported financial position will be made at CCG, trust and ICS level.

NHS England and NHS Improvement also intend for oversight arrangements to reflect an expectation for evidence of effective provider collaboration, and the failure of individual trusts to collaborate in a system context, **may be treated as a breach of governance conditions**. This signals a clear shift in how the national bodies see the relationship between the statutory duties trust boards have towards their organisation and their responsibilities towards system working.

## CQC

CQC is also developing plans, as set out in its **new strategy**, to take the system context into account when it assesses the quality of individual providers alongside its intention to directly assess how systems are performing as a whole. When assessing individual health and care services, it **intends to look at how they work together in an area, as one system, to deliver better and more coordinated care**. CQC has also committed to identifying ways of supporting systems to drive improvement in their local areas, and to assess how well they ensure equal and fair access to care, good experience and good outcomes. A possible amendment in the Bill may provide it with the powers to assess systems, which may include ratings for ICSs, but is unlikely to include powers of intervention.

CQC has also made strategic changes to its regulatory approach, with the aim to be more responsive and flexible to manage change, risk and uncertainty, and ensure assessments reflect the most up-to-date picture of quality. This reflects the current context of a rapidly changing health and care environment, builds on learning from regulation during COVID-19, and enables CQC to ensure its approach remains fit for purpose in the future.

## What are the opportunities of system regulation?

Trusts are broadly supportive of the direction of travel for regulators to take into account wider system factors when overseeing and assessing performance. Our most recent regulation survey report, *Reconsidering the approach to regulation*, found that trust leaders are supportive of CQC's strategic ambition to assess the system-wide context and, similarly, support NHS England and NHS Improvement's intention to develop models of oversight to enable system working and hold ICSs to account for the collective performance of constituent organisations. This reflects the increasing reality that ICSs' decisions may influence outcomes and operational and financial performance, particularly as they take on more functions related to the commissioning and funding of services. Support from trusts for the direction of travel increased between 2019 and 2020, which is likely a reflection of their ongoing work to collaborate with partners across the system and integrate care as well as in anticipation of legislative change.

Regulation is an important driver of behaviours and can therefore incentivise and encourage trusts to work more collaboratively within their system(s) to deliver care. Trusts therefore feel that an **enabling framework will help to drive further progress and deliver on the opportunities and benefits of system working**. They are also supportive of regulation and oversight which reflects the value of partnership at ICS and place level. For example, there is a real opportunity to more effectively explore population health challenges and tackle inequalities in access and outcomes through acknowledging the system-wide effort that is needed to address health inequalities meaningfully.

Refreshing regulatory frameworks also offers an opportunity for regulators, and the trusts they assess, to ensure they are gathering data from the wider range of sources, including perspectives of patients, the public and engaging with governors of NHS foundation trusts. The shift to a system lens can strengthen targeted engagement with experts by experience across a broader spectrum of services.

There have also been long-standing issues when provider-level regulation has fallen short of reflecting the external operational pressures influencing an individual organisation's performance. The changes to regulation and oversight to reflect the context of system working, and the intention to hold ICSs to account for their decisions therefore offer an opportunity to address these concerns and ensure trusts are not held to account for the consequences of decisions that have been taken elsewhere. This shift will, however, bring with it an increase in the complexity of regulating health and care services and monitoring performance. There are many unanswered questions about how the regulators can meaningfully determine the contributions being made to quality and performance at each level of scale, to ensure that providers and systems are only being held to account for decisions and outcomes they have control over.



# Areas for further discussion and development for regulation *within and of ICSs*

# 5

Despite the clear benefits to taking the context of ICS working into account, as well as the need for regulatory frameworks to reflect the changing legislative landscape, there are still areas of uncertainty as new models of assessing and regulating ICSs and trusts are developed. While trusts support the direction of travel, it will be important that issues around accountability and governance, the management of trusts spanning multiple ICSs, and how quality and performance should be defined at a system level, are resolved as new models are tested and refined. Trusts are also worried about an increase in bureaucracy and burden if additional scrutiny of ICS performance is simply layered onto the existing regulatory system without reducing burden elsewhere.

## Accountability and governance

The potential impact of system-focused regulation on trusts' existing accountabilities is a prominent concern for trust leaders. Although NHS England and NHS Improvement states that changes to the governance of ICSs "**will not fundamentally change the core duties and functions of NHS trusts and foundation trusts** to improve quality of care for patients and meet key financial requirements", trusts remain concerned that new regulatory frameworks will create confused and conflicting accountabilities.

For example, the SOF sets out how performance will be assessed across systems as well as at trust and (for 2021/22) CCG level. ICSs will play an increasing role, depending on their level of capability, in overseeing trusts' performance. Local oversight arrangements will be agreed by 'memoranda of understanding' with local priorities forming part of conversations about performance. NHS England and NHS Improvement has set out the expected governance arrangements of ICBs, but it is not expected that all trusts will be represented on this board, and where board members are drawn from local trusts, they will not be expected to act as representatives of either their own organisation or the wider trust sector. Trusts are therefore concerned that, for example, they could be placed in mandated support because the wider system has not delivered outcomes which were agreed in a conversation they were not party to. This demonstrates the need for full consultation and engagement in setting ICS priorities, given the importance of ensuring there is no separation between decision-making and accountability for delivering against those decisions.

ICBs will be expected to distribute funding to local partners, as well as develop plans for how they will meet local population needs. Under the SOF they will then be asked to participate in, or lead, the oversight of trusts' performance against these plans, with allocations they have made. This raises important questions about how conflicts of interest will be managed if a trust is struggling to meet targets with the funding it has been given. The role of the NHS England and NHS Improvement regional teams in helping to resolve disagreements will also need to be made clear.

Similarly, CQC plans to roll out a framework for assessing quality across an area, and is currently developing a model for this. We expect the amendments to be tabled to the Bill to include a proposal for CQC to have powers to regulate and rate ICSs. There appears to be strong political appetite for 'trust-style' ratings for systems. If effective, this may offer increased

transparency for the public, providers and national bodies about ICS performance. However, it is not clear what audiences would find a system level rating helpful, and whether this would be beneficial as giving ratings would imply a level of accountability that does not exist in practice: while CQC may intervene when trusts are rated inadequate, the same powers do not extend to ICBs. While decisions made by an ICB may influence performance and quality in its component organisations, trust boards will remain legally accountable for care. Trusts will need clarity on what outcomes they should expect under a variety of scenarios, with transparent lines of accountability.

Some trust leaders question whether the system has been ‘overcorrected’ from one in which people do not work together to support joined up care for local populations, to one which is beginning to embed multiple conflicting structures of accountability, while simultaneously creating accountability gaps. Despite complex agreements between providers and the introduction of duties to cooperate, when a serious failing in care is identified it will be the trust that provided the frontline care that holds legal accountability for the care they provide.

## Measuring performance and aggregating data

CQC and NHS England and NHS Improvement are setting out how they intend to build a picture of performance and quality across systems. This raises questions around how data collected at provider-level and aggregated to ICS-level can offer a meaningful understanding of the contribution the ICS leadership makes to the operational performance of its component organisations.

The aggregation of data means that if national regulators identify an issue at the level of the ICS, they will still likely need to drill down to organisational level to understand what is driving the issues. There is uncertainty about the utility of using traditionally organisation-level measurements aggregated to system-level as a proxy for a system-wide picture of care. This approach also risks introducing confusion about where intervention would be best placed to drive improvement.

The influences of good performance and quality differ at the system level compared to the organisation-level. The ICB can drive good care and outcomes across its patch through strong leadership, building relationships, enabling collaboration and innovation, and making effective use of resources. However, it is trusts that deliver the frontline services and have a much clearer link to the quality of frontline care.

Despite this, there are clear benefits to striving for a better understanding of the link between local decision-making and leadership and the delivery of care, in recognition of the fact that trusts do not operate in a vacuum. They face decisions and trade-offs in managing their many responsibilities and challenges, with many of these influenced by outside pressures. It will be important that the same data aggregated at different levels is not used to derive conflicting conclusions depending on which organisation is being assessed. National leaders should instead use this process as an opportunity to create a holistic picture of the interrelated factors influencing performance in a place.

Any measurement of performance should bear a clear relation to the actions the organisation being assessed has taken to influence that measure. For example, system-wide performance against urgent and emergency care targets is only a reliable measure for how well an ICB has performed its own duties if accompanied by a clear narrative understanding of how decisions taken by the ICB, including planning and distribution of funding, has influenced the functioning of urgent and emergency care pathways and services.

## The challenge of assessing quality at system level

Currently, CQC has powers to regulate registered providers 'which carry on regulated activities'. As an adjunct to its formal regulatory powers, over the past four years CQC has been carrying out thematic reviews of local systems and reporting on how well system partners are working together to achieve desired outcomes for a defined population group. This has taken place through its system reviews of care for people aged 65 and older in 2018 and 2019, and more recently its provider collaboration reviews, which assessed systems' COVID-19 response with a focus on specific services (such as cancer services and pathways). So far, CQC has not attempted to create an authoritative definition of quality at system level, and these reviews have been intended as informative, supportive assessments for systems to use for local learning and improvement.

CQC now intends to review how well systems are working together to improve outcomes for their populations. Although it does not intend to register ICSs as providers in order to regulate them, there are still unanswered questions about how an assessment of quality at system level can meaningfully reflect the impact of decisions being made at that level. A planned amendment to the Health and Care Bill is likely to introduce more formal mechanisms for CQC to assess ICSs, which will provide welcome clarity on how CQC's role in the regulation of ICSs will look in the future.

ICSs do not directly provide care, but they will, through the ICB, set priorities, agree funding flows, bring together partners, review data to identify population need, and plan for how they will meet these needs. The challenge for CQC will be to draw a clear link between these functions and any future measure of quality at a system level, and create clarity on how ICSs are influencing quality at place and in individual services. Given system level assessments are intended to provide public accountability and transparency, it will be important for regulators to consider how the public relate to their local ICS.

Arguably, if services are challenged due to the leadership and decisions made by an ICB, then accountability should sit with the ICB board. However national leaders have not yet clearly set out how an ICS-level measure of quality would offer better public accountability than assessments of quality at service- and place-level, given that people receive care from services and along pathways often operating at the level of place. A core part of CQC's assessment of systems will be how well they are listening to local communities, which raises a question about whether an ICS is the right level to look at this measure: there may be better opportunities at place for dialogue between providers and the public and a basis for accountability which is meaningful to all parties.

## The role of non-NHS parties

The separation of the ICB and the ICP in the legislative proposals further complicates the task of ensuring accountability when regulating for quality and performance is clear. The purpose of assessing ICSs will be to understand how quality and performance is influenced by all the partners across a system, rather than by individual organisations. By its nature, this includes social care partners and local government, as well as the independent and voluntary sectors, all of which provide services which contribute to the effectiveness of pathways. However, these wider partners will sit on the ICP, rather than the statutory ICB. Given the ICB, which governs the NHS part of the ICS, is the only part of the ICS which will have statutory duties and will be regulated by these frameworks, there is a question about how robustly the wider system partners can be held to account for their contribution to outcomes and care in their patch.

The SOF can only apply to NHS organisations as NHS England and NHS Improvement only has powers to regulate NHS organisations. However, partnerships with non-NHS bodies are a significant part of trusts' role as system partners, and there is a risk of creating an artificial separation between NHS and non-NHS parts of the system as a secondary consequence of the framework. For example, the SOF will assess trusts and ICSs on collaboration and relationships, but it is unclear how it will capture the impact of behaviours in organisations outside its remit, such as local authorities, primary care or social care, and this may leave trusts exposed to judgements on their contribution to system-working based on incomplete information. NHS England and NHS Improvement will need to consider further how to achieve this fundamental aim of system-level regulation within the bounds of available mechanisms of oversight. This is a complex question which has yet to be clearly addressed.

There is also still a need for further clarity about how non-NHS bodies outside the reach of the current regime will be taken into account as part of system-level assessments. Primary care, social care and local authorities and their wider services all make essential contributions to pathways, patient flow, patient experience and health outcomes, but do not fall within the remit of the SOF.

However, CQC does recognise its role in bringing together insights about wider organisations given its remit to regulate social care, primary care and the independent sector. This underscores the need for CQC and NHS England and NHS Improvement to work together in creating a shared understanding of what good looks like in systems despite their differing remits, so that trusts falling under both regulators will not be subject to conflicting judgements. Done well, there is an opportunity for CQC's system-wide regulatory insights to offer helpful context to the SOF.

The need for a clear statement of how the performance and input of non-NHS partners will be included as part of assessments of how well pathways are working for local populations is even more important when considering the level of 'place'. Trusts and other NHS bodies will work alongside social care, local government and independent and voluntary sector organisations as a matter of course at a smaller level of scale than NHS England and NHS Improvement or CQC are planning to review. Trust leaders have expressed concerns that if

resource challenges outside of their control, such as social care market challenges or financial pressures faced by local voluntary sector organisations, hinder progress locally on agreed outcomes, this could impact regulatory judgements made about their own contribution to this work.

## Burden and duplication

Both regulators have stated an intention to avoid duplication in approach and reduce burden on trusts. However, statutory responsibility for the quality of health and care services still lies with trusts. This will continue to be the case after ICSs are placed on a statutory footing, so there remains a risk of overlap and ongoing duplicated intervention at trust and system-level as national regulators will need to continue to carry out assurance on how trusts are meeting their duties.

Trusts are **supportive of greater coordination and alignment between NHS England and NHS Improvement and CQC** to reduce burden and duplication at an organisational level, such as reducing repeated or duplicated data requests and avoiding. As the regulators bring ICSs into their frameworks, and begin assessing how well they are meeting their new statutory duties and contributing to care and outcomes across an area, this will likely become more complex and challenging to avoid.

NHS England and NHS Improvement's SOF describes its ambition to work through ICSs as much as possible and sets out an intention for ICSs to oversee the performance of trusts that sit within their geographical footprint. Trusts have highlighted the risk that this could lead to the creation of a new oversight tier whereby duplication occurs between NHS England and NHS Improvement regional teams and ICSs, particularly if their specific roles are not clear and distinct. This will be particularly applicable to less mature ICSs which will be required to 'jointly conduct' the oversight of trusts with NHS England and NHS Improvement regional teams. It will be important for NHS England and NHS Improvement to clearly define the circumstances in which trusts would work through ICSs and when they would work with regional teams, to ensure duplication is avoided as much as possible.

Regulation *within* and *of* systems could also become particularly challenging for trusts spanning multiple ICSs, which could be subject to multiple judgements and duplicative assessments, particularly as ICSs begin to take on oversight responsibilities. Some trusts straddling multiple ICS boundaries, such as ambulance trusts, some community service trusts and those providing specialised services, have highlighted to us the risk that they could be held accountable by more than one ICS. This could lead to increased paperwork and overlapping data requests and assessments. Establishing a lead ICS working on behalf of the relevant ICSs, or streamlining regulatory activity at ICS level, could help to streamline the approach and reduce burden for trusts. This will require joined up communication between the respective ICSs and between ICSs and the trust in question, and support from NHS England and NHS Improvement where necessary.

With increasing coverage of provider collaboratives, NHS England and NHS Improvement and ICSs will also need to take into consideration the variety and types of arrangements that exist at place level (for example formal alliances or more informal collaborations) and how this will impact on its oversight approach at this level. Practically, this is likely to result in multiple overlapping lines of oversight, as trusts will be operating multiple collaborative arrangements across their patch for different services and populations, all of which will need oversight agreements. This will be extremely complex, and it will be important to consider the practical implications in terms of the resource required to adhere to all monitoring arrangements.

We will continue to highlight the need for greater alignment between NHS England and NHS Improvement and CQC within this new system context, and the commitment from both organisations to continue to align approaches is welcome. This is particularly pertinent as trusts continue to face significant pressure to recover services from COVID-19 while these changes to regulation are taking place. We highlighted **in response to the Bill** that some trust leaders are increasingly concerned about a mismatch between the pace and scale of change, and the sector's capacity to carry out this major transformation at the same time as they grapple with pandemic recovery.

The shift towards regulating systems will require new datasets, regulatory capabilities, processes and assessment frameworks to support, and these will be significant new developments for trusts to adapt to. The regulators will need to take this context into consideration when implementing their new frameworks to ensure it doesn't add burden at a time trusts can least afford it, provide appropriate support to trusts and ICSs and allow time for their approaches to bed in.

## Intervention and improvement

The increasing focus on assessing quality and performance at a system level raises a significant question about how intervention will operate at this level. Meaningful regulation at a system level needs to be focused on improvement at that level, rather than at the levels below it.

If the regulators are using an aggregated measure of quality or operational performance across a geographical area, improvement or deterioration in one provider may alter the overall picture. It will be important that improvements are attributed to intervention or change at the correct level. National regulators will need to build a sophisticated understanding of the drivers of changing performance, so that fluctuation at the provider-level does not disguise ongoing issues or overall improvement across systems, or vice versa.

Similarly, it is unclear how CQC would intervene in the event of finding poor system-wide quality. Realistically, if CQC identified problems across a system, it would take a combination of interventions at ICS level on leadership and relationships, and at provider level on specific quality issues in services. If it does not have intervention powers at ICS level, CQC will likely

seek remedies at the trust level. This risks undermining the purpose of assessing systems and leaves trusts vulnerable to regulatory intervention as a result of issues identified elsewhere in the system.

NHS England and NHS Improvement has set out its desired system-wide approach to improvement through its new 'recovery support programme', a welcome replacement for the previous special measures regime. Under this new programme, struggling providers are expected to receive support from stronger organisations within their ICSs, in recognition of the impact of wider-system pressures. While the direction of travel towards a more supportive, and inclusive response to challenges, is welcome, questions do remain about the practical operation of the new regime: There is a question around what this means for higher-performing trusts, which may be asked to take on additional risk, and whether wider system partners outside of the remit of the SOF could be asked to act differently, receive support or indeed offer support. NHS England and NHS Improvement will be reliant on the strength of relationships between system partners to make the programme work, and while relationships in systems have improved in many places over the past year due to collaboration in the COVID-19 response, there is still a risk that the effectiveness of the programme will be curtailed by strained relationships or differences of culture and governance between NHS and non-NHS partners.

# Principles for good regulation in the context of systems

# 6

## Regulation provides objective and independent judgement

An increased role for ICSs in the oversight of trusts may mean that the partners within an ICS will be held to mutual account for the outcome of decisions they themselves have made. Conflicts of interest need to be avoided. The NHS England and NHS Improvement merger set out in the bill introduces further risks here that need to be managed through the development of safeguards which prevent and give trusts a means of challenging decisions made by their ICB.

## Regulation should be risk based and proportionate

The degree of oversight and intervention should be proportionate to the performance of the trust or system, and wider challenges in the system. Where systems are playing an increased role in oversight it will be important that this does not duplicate work being done by either CQC or NHS England and NHS Improvement national or regional teams. There should be a clear set of metrics and transparent criteria for triggering regulatory intervention. It is important that, as part of this, trusts and systems are empowered to drive their own improvement and that regulation/oversight enables them to do so. Where system-wide issues are identified as part of an ICS-level assessment, the impact on individual trusts should be proportionate to the level of risk as well as the degree to which the trust has influence over the issues in question.

## Regulation and oversight arrangements should place minimal burden on providers and add value

The commitment from CQC and NHS England and NHS Improvement to continue to align approaches is welcome as this has been a longstanding concern for trusts prior to the introduction of ICSs as an additional oversight tier. As systems take on an increasing role in oversight there will be concerns around duplication and additional burden with NHS England and NHS Improvement regional teams particularly as ICSs continue to develop their capability and expertise in oversight. National bodies should articulate the clear purpose and value-add of regulation of ICSs and ensure that this adds to, rather than cuts across, existing provider level regulation, offering new insight into quality and performance rather than simply aggregating or repeating judgements already made at provider-level.

## The context within which providers and systems operate should be taken into account in regulatory judgements

The shift towards regulation *within* and *of* systems provides a clear opportunity to take the wider system context into account when assessing trusts, including understanding how wider partners influence care pathways and performance in individual services. Trusts have noted that in the past, regulation and oversight has not aligned closely with the context in which they work, and this continues to be important particularly within the context



of COVID-19. ICSs are at different stages of development/maturity and are still building capabilities which may have an impact on their performance. All of this context needs to be considered sensitively, but new proposals offer an opportunity for regulatory frameworks to fully consider the broad context within which providers operate.

### Accountabilities should be clearly defined

New regulatory frameworks which attempt to create judgements about how ICSs are performing leave room for conflicting or confused accountabilities, and a risk that organisations will be held accountable for decisions made elsewhere in the system. There should be no ambiguity about where accountability sits for a range of potential issues, with clear routes of intervention, and a means of capturing improvement at the level it takes place.

## Conclusion

Trust leaders agree that regulatory models need to adapt to the evolving health and care landscape, with a particular need for regulation and oversight to take into account the wider system context. CQC and NHS England and NHS Improvement have set out promising new frameworks designed to build a picture of quality and performance across systems, as well as provide an enabling framework for trusts to collaborate with partners. Despite the positive direction of travel, there are clear unanswered questions about how these new models will negotiate existing accountabilities, ensure that intervention is made at the right level, and that ICS level assessments meaningfully add to what already exists.

Over the coming months, the regulators will be developing and refreshing their approach in anticipation of new legislation from April 2022. NHS England and NHS Improvement will be updating the System Oversight Framework for 2022/23 and CQC continues the development of frameworks for reviewing ICSs. This briefing has highlighted some of these questions and risks and detailed a set of principles for a good future regulatory system. As the regulators look to embed their new models, and trusts continue to work through the implications of new legislation on their accountabilities and the role of ICSs, we will look forward to working together to ensure these complexities are addressed.

**Your feedback on this briefing and the development of our wider offer is very welcome – to share your learning so far or offer feedback on our approach, please contact [leanora.volpe@nhsproviders.org](mailto:leanora.volpe@nhsproviders.org)**

For more information:

[www.nhsproviders.org/evolving-regulation-and-oversight-in-a-systems-world](http://www.nhsproviders.org/evolving-regulation-and-oversight-in-a-systems-world)

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