RECONSIDERING THE APPROACH TO REGULATION
# RECONSIDERING THE APPROACH TO REGULATION

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This year’s regulation survey report reflects the changing context in light of the pandemic, the rapid development of system working, and the intention set out by both Care Quality Commission (CQC) and NHS England and NHS Improvement to develop models of regulation and oversight which take account of new ways of working.

The emergence of new regulatory models from both CQC and NHS England and NHS Improvement provides an opportunity to re-evaluate how regulators interact with providers and ensure a regulatory model which is responsive and proportionate and delivers for patients.

Successive surveys have highlighted the need for better alignment between national policy aimed to advance collaborative working in systems and regulatory requirements which are currently organisationally focused. Importantly, trusts are encouraged by the direction of travel towards more system-focused models of oversight, though some respondents flagged the need for any new role for Integrated Care Systems (ICSs) as a performance manager to be accompanied by a proportionate reduction in oversight from other parts of the system.

Encouragingly, there is strong support among trusts for many of the core proposals in CQC’s new strategy, but trusts are clear that CQC will need to ensure it avoids duplication with other national bodies, does not overstep its core regulatory role, and continues to work with providers to understand the impact of new approaches.

There are clearly lessons for trusts and the regulators to learn from the COVID-19 period. The regulators both implemented welcome changes to their approach at the start of the pandemic, to reduce burden and help trusts to focus on the COVID-19 operational response. While trusts’ experiences of regulation during the first wave were largely positive, this was not reflected uniformly across the sector particularly during the second wave, where many trusts felt reporting requirements and other regulatory activity increased disproportionately once again.

The importance of sustaining dialogue between providers and the two regulators moving forwards underlies all of this year’s findings. We look forward to continuing to work constructively and closely with CQC and NHS England and NHS Improvement colleagues, and our members, at this time of considerable change.
This report outlines the findings of our sixth annual regulation survey, which was carried out in December 2020 to January 2021. The regulation survey usually explores NHS trusts and foundation trusts’ experiences of regulation over the preceding 12 months and their views on the future of regulation, and trends over time. This year’s survey differs from previous years as it covers trusts’ experience of regulation and oversight specifically within the context of the COVID-19 pandemic and looks ahead to shaping the future strategic approach to regulation.

About the survey

This survey was sent to all trust chairs, chief executives and company secretaries in December 2020. This is the sixth annual survey in our series to understand and track NHS providers’ experience of the regulatory and oversight framework in which they operate. Mindful of the operational trusts are facing, we sought to keep our survey short and focused this year, so that we could gain vital insight from trusts to inform important changes to national policy on regulation currently taking place.

In this report, where we refer to ‘the regulators’ and ‘national bodies’, we mean the CQC and NHS England and Improvement, as these are the key regulatory bodies we work with and seek to influence constructively on behalf of trusts.

We received responses from 51 trusts, which represents 24% of the sector. All regions and most trust types are covered in this survey. We did not receive responses from any ambulance trusts this year.

This is a significantly lower response rate than in previous years, reflecting the COVID-19 pressures trusts are working within. This year, our analysis and commentary are also drawn from ongoing engagement and dialogue with trusts - through conversations with trust leaders, roundtable events and our engagement with trusts and foundation trusts on NHS England and NHS Improvement’s recent paper Integrating Care: Next steps to building strong and effective integrated care systems across England.

We are grateful to those trust leaders who responded to this survey during an extremely busy and challenging time, and to CQC and NHS England and NHS Improvement for working with us to develop the survey questions.
The health and care environment has changed significantly in the last 12 months. The COVID-19 pandemic caused an unprecedented level of operational pressure for trusts and their colleagues across the health and care sector – from managing the sheer volume of hospitalisations to maintaining rigorous infection control, while also maintaining non-COVID care and supporting staff in a time of unprecedented operational pressure. However, the COVID-19 pandemic also accelerated positive change in many areas of health and care provision, including the increase in mutual aid, collaborative working in systems and innovation through digital channels.

During the pandemic, particularly in the first wave, both NHS England and NHS Improvement and CQC scaled back their regulatory approach substantially. CQC paused all routine inspections and provider information requests and introduced an Emergency Support Framework (ESF) to respond to areas of critical risk or safety concerns. NHS England and NHS Improvement also suspended its core oversight activities during the pandemic, continuing those which were deemed essential for monitoring the COVID-19 response. This has been welcomed by many given the intense operational pressures trusts faced during the pandemic.

Both regulators have since expressed an intention to reconsider their approaches to regulation within the new context, taking into consideration learning from COVID-19 and a rapidly changing health and care landscape which emphasises greater integration and more established systems, underpinned by the recent Department of Health and Social Care (DHSC) White Paper. The regulators are therefore developing plans to consider system working more strongly in future regulatory models and, as a result, trusts are likely to see substantial changes to the way their performance is measured and assessed.

CQC launched its new strategy for consultation in January 2020, identifying four key areas of focus, which set out how it plans to transform its approach to regulation within this new context. A common thread runs throughout of reviewing health and care systems and their focus on reducing health inequalities. CQC highlights the need for its regulatory approach to be more flexible and dynamic in this period of uncertainty. We cover responses on CQC’s new strategic approach later in the report, but on the whole trusts are supportive of the direction of travel set out in the new strategy but emphasise the need for CQC to be mindful of the current pressures trusts face and avoid duplicating the work of other organisations. We will use the findings of this survey to inform our response to CQC’s consultation.

NHS England and NHS Improvement is also in the process of developing its new system oversight framework, which will be shaped by changes to NHS legislation, and will seek to align system working objectives with oversight arrangements, including looking at local priorities as part of the key oversight metrics and measurement of performance at a system level.

This report highlights the impact of the COVID-19 pandemic on trusts amidst a backdrop of changes happening on a national level. As the regulators continue to adapt and implement new ways of working to align with the move towards integrated care, it is more important than ever that they focus on ensuring regulation is proportionate, coordinated, offers value for money and provides clarity to providers on accountabilities.
Before the COVID-19 pandemic, changes were taking place nationally and regionally across health and care to embed more collaborative ways of working. In our 2019 regulation survey report, we highlighted the fact that this had already created a period of transition in which trusts were often navigating a complex, evolving and sometimes conflicting regulatory framework.

In 2019, we also highlighted the promising development that for the first time since the survey began, trusts did not report an increase in regulatory burden over the previous 12 months. This may well have been due to improvements in joined-up working between the national bodies, having a positive impact in terms of consistency and coordination between the regulators.

This year presents a very different context for the sector, as both CQC and NHS England and NHS Improvement scaled back their regulatory activity significantly to allow providers to prioritise their response to the COVID-19 pandemic. We did not directly compare regulatory burden prior to the start of the pandemic (i.e. before March 2020) to previous years in this survey, but we asked trusts to reflect on how they felt about the regulatory approach before the pandemic began, compared to during the pandemic (i.e. from March 2020 onwards).

Encouragingly, more than four in five (82%, 42 respondents) said NHS England and NHS Improvement understood the pressures before the start of the pandemic, and over half (63%, 31 respondents) said CQC understood the pressures before the start of the pandemic. This suggests that things were moving in the right direction before the pandemic (figure 1).

Figure 1
To what extent did the regulators and national bodies understand the pressures NHS providers faced before the start of the COVID-19 pandemic (before March 2020)?

<table>
<thead>
<tr>
<th>Component</th>
<th>Very good understanding</th>
<th>Fairly good understanding</th>
<th>Neutral</th>
<th>Fairly poor understanding</th>
<th>Very poor understanding</th>
</tr>
</thead>
<tbody>
<tr>
<td>NHS England and NHS Improvement (n=51)</td>
<td>20%</td>
<td>63%</td>
<td>12%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>CQC (n=49)</td>
<td>14%</td>
<td>49%</td>
<td>18%</td>
<td>18%</td>
<td></td>
</tr>
</tbody>
</table>
Two thirds (67%, 34 respondents) thought that reporting requirements from both national bodies were proportionate before the start of the pandemic. This is an improvement from our 2019 survey results where 50% of respondents said they felt reporting requirements of both regulators are proportionate to the level of risk they manage (figure 2).

**Figure 2**

*Do you think the reporting requirements of the regulators are proportionate to the level of risk you manage in your trust?*

<table>
<thead>
<tr>
<th>Date</th>
<th>Yes (n=51)</th>
<th>No (n=84)</th>
<th>Don't know (n=75)</th>
</tr>
</thead>
<tbody>
<tr>
<td>December 2020</td>
<td>67%</td>
<td>27%</td>
<td></td>
</tr>
<tr>
<td>June 2019</td>
<td>50%</td>
<td>43%</td>
<td></td>
</tr>
<tr>
<td>January 2018</td>
<td>36%</td>
<td>56%</td>
<td></td>
</tr>
<tr>
<td>January 2017</td>
<td>40%</td>
<td>55%</td>
<td></td>
</tr>
</tbody>
</table>

*This data reflects trusts’ view of reporting requirements before the start of the pandemic (before March 2020)*
Measures put in place by both regulators at the start of the pandemic were designed to reduce regulatory burden on providers during the peak of the first wave, and the majority have continued in some form throughout the past year. For example, CQC implemented the ESF and is now using a transitional regulatory approach to monitor and respond to risk as the pressures on trusts vary, while it develops its new strategy for 2021 and beyond. Similarly, NHS England and NHS Improvement announced changes to its oversight regime in the first wave with the objective of reducing regulatory burden and freeing up leadership and operational capacity.

**Regulatory burden**

Despite these measures, views from trust leaders about how proportionate both regulators’ approach has been throughout the pandemic are mixed. The majority of respondents (60%, 28 respondents) said that the approach taken by the regulators during the pandemic reduced burden although only four trusts (9%) strongly agreed with this statement (figure 3). Just under half (47%, 22 respondents) felt that the regulators’ (NHS England and NHS Improvement and CQC combined) approach during COVID-19 had been proportionate.
Pre-COVID both CQC and NHS England and NHS Improvement were highly demanding and impatient data hungry beasts. Since the pandemic they have largely been less intense and more understanding of operational pressures, certainly in the first phase. Latterly there has been more regulatory demand, particularly from CQC, NHS England and NHS Improvement local teams have all been redeployed so any return to previous operating models would be less than helpful. Role not specified, acute trust.

Oversight was reduced during the first wave which helped but during the second wave it has been increased and it is a nightmare.

Company secretary, acute trust

A review of qualitative comments throughout the survey, and wider feedback received from our membership suggests that trust leaders’ views on the regulators’ approaches evolved during the year, from a point of greater support in the first wave, to more mixed views as activity picked up over the summer and going into the second wave.

Reporting requirements

Reporting requirements were largely thought to be proportionate before the pandemic, with 67% (34 respondents) saying this was the case, but despite measures taken by the regulators to scale back reporting requirements this fell to 41% (21 respondents) for the period from March 2020 up to December 2020 (figure 4).

Figure 4
Do you think the regulators' reporting requirements are proportionate to the level of risk you manage in your trust?

(n=51)

<table>
<thead>
<tr>
<th></th>
<th>Before the start of the COVID-19 pandemic (before March 2020)</th>
<th>During the COVID-19 pandemic (from March 2020)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>67%</td>
<td>41%</td>
</tr>
<tr>
<td>No</td>
<td>27%</td>
<td>47%</td>
</tr>
<tr>
<td>Don't know</td>
<td></td>
<td>12%</td>
</tr>
</tbody>
</table>

*This data reflects trusts’ view of reporting requirements before the start of the pandemic (before March 2020)*
Regarding my assertion of ‘fairly poor understanding’, this is specifically about the volume of data and information requests both as part of and outside of inspection processes, and the deadlines / timeframes set for these, which can be very unrealistic and disregard reality for most trusts.

Role not specified, acute trust

The amount of information required to be shared with various forums during the extremely busy COVID-19 pandemic period has created more pressure on the organisation.

Company secretary, community trust

The survey results suggest a perception that the regulators do not necessarily have a strong enough understanding of the impact of the COVID-19 pressures. This has manifested in numerous ways, with some trusts feeling that the impact of measures to reduce burden had not been felt as strongly as intended. Feedback also suggests a sense that while many of the regular reporting requirements were helpfully suspended, new requests were onerous or duplicative.

During the pandemic NHS England and NHS Improvement relaxed the reporting arrangements which was very helpful. However, they very quickly reverted to huge amounts of data collection and have not shown that the lessons have been learnt from COVID-19...

Chair, acute trust

The centrally dictated reporting requirements during the pandemic have been onerous, sometimes conflicting, sometimes not fit for purpose, often required within ridiculous timescales and have not been supported by effective IT systems.

Role not specified, community trust

We continue to advocate for the national and regional teams within NHS England and NHS Improvement and CQC to maintain regular dialogue with trusts to understand the pressures they are under. Where this has taken place, trusts are positive about the impact of the support they receive.
After scaling back its approach to regulation to give trusts the space to manage the operational pressures of the pandemic, CQC confirmed that it would move away from its previous approach and introduce a transitional monitoring approach to function as a ‘prototype’ model ahead of the implementation of its new strategy from summer 2021.

CQC has committed to a stronger focus on safety, access, and leadership, and indicated that regulation will be more intelligence led, less burdensome, with more work done offsite than in the prior inspection-led model. CQC has also been clear that it acknowledges the burden of the inspection regime and plans to move to a leaner approach.

This scaled back approach during the pandemic has subsequently been captured within CQC’s new strategy as it reconsiders regulation in the current context and moves towards a more proportionate and risk-based approach. The pandemic has in many ways accelerated change, with providers working more collaboratively within local systems, as well as delivering care in new ways such as through digital channels. CQC has therefore identified the need to transform and ensure its regulatory approach is relevant, flexible, and fit for purpose in an evolving system. As part of this, it has set out an intention to place a greater emphasis on providers’ role in systems, how quality of care is measured across pathways, and the need to tackle health inequalities as part of high quality care.

Regulation in the context of COVID-19

In the survey, we asked respondents to reflect on CQC’s regulatory approach before the start of the COVID-19 pandemic and during the pandemic to explore the impact the scaled back regulatory approach had on trusts. Despite the helpful measures put in place by CQC to allow trusts to respond to the pandemic, views about its regulatory approach over the past year were mixed.

When asked about the level of interaction they had with regulators during the pandemic, respondents reported lower levels of interaction with CQC (high, 17%; medium, 40%) than with NHS England and NHS Improvement (high, 38%; medium, 49%) (figure 5). This is indicative of the different roles NHS England and NHS Improvement and CQC played during the pandemic and reflects CQC’s scaled back approach in which they shifted from routine inspections and provider information requests (PIR) to a more risk-based transitional monitoring.
When asked whether CQC understood the pressures providers face before and during the pandemic, almost two thirds (63%, 31 respondents) of respondents said CQC did understand the pressures providers faced before the start of the pandemic, but this decreased to just over half (55%, 27 respondents) during the pandemic. In addition to this, while three in five (60%, 28 respondents) trusts felt that the scaled back approach reduced burden to allow them to focus on managing COVID-19, the comments and other feedback we received on this showed variable views (figure 6).

It is likely that this variation is due to how CQC adapted its approach between the first and second waves. We received both positive and negative comments about activity undertaken by CQC, and there are indicators that regulatory activity in the second wave created a greater sense of pressure at the frontline than it did during the first wave. For example, trusts have told us that while CQC reduced its regulatory activity quite significantly during the first wave last spring, this was not the case during the second wave, despite the operational pressures being just as intense, and often more intense than in the first wave.
Since the pandemic [the regulators] have largely been less intense and more understanding of operational pressures, certainly in the first phase. Latterly there has been more regulatory demand, particularly from CQC…

Role not specified, acute trust

...we have had more [meetings] during the time period of COVID from both [regulators], but both are proportionate.

Chief executive, acute Specialist trust

The CQC has been reasonable and supportive in its approach. I commend the plans for the new strategy.

Role not specified, acute trust

CQC scrutiny has been totally disproportionate, lacking in any sense of empathy for the efforts Trusts have been going through. In my world, most contact has gone online, but has increased (MHA) rather than decreased. Observations about compliance with regards to leave arrangements for inpatients has shown very little understanding of what we have been managing, staffing pressures and the conditions within our communities.

Chief executive, mental health/learning disabilities trust

The varied experience of trusts also seems to be the result activity undertaken by local CQC teams, rather than CQC’s overall intention set out at a national level. Some have felt that they continued to receive a lot of unnecessary requests from their local team, whereas others felt that their local team could have completed assessments, such as well-led, rather than stopping them midway through the process. This highlights the importance of having strong local relationships between local CQC teams and trusts and echoes previous findings that local relationships and communication is a significant driver of trusts' experience of regulation.

During Wave one, NHS England and NHS Improvement provided clarity on expectations from trusts in terms of reducing the bureaucratic burden…This was not replicated by the CQC whose requirements have not changed which inspections being undertaken in a similar format to those pre-pandemic.

Company secretary, acute trust

"CQC has deferred the Trust's well led meetings and interviews, so we feel part assessed. This was due to COVID-19 so entirely understandable but there did not seem any willingness to undertake Teams interviews with the board, which we found surprising. This has been disjointed and disruptive.

Company secretary, combined acute and community trust
Provider collaboration reviews

Last year, CQC introduced provider collaboration reviews (PCRs) to explore how health and social care providers worked collaboratively in local areas to respond to the pandemic and provide care for particular population groups. The purpose of the reviews was to identify themes and learning that could be used to inform planning over the winter and future waves of the virus, but more broadly to help health and care providers and leaders of local health and care systems plan and work more effectively together.

To date, two phases of the PCRs have been completed. The first review looked to understand how health and social care providers have collaborated to improve care for older people, who are most at risk of COVID-19, while the second looked specifically at how providers are working together to deliver urgent and emergency care services in the context of COVID-19. The remaining three phases of the reviews will focus on cancer services, people with a learning disability and/or autism and mental health services and will take place over spring and summer 2021.

Of the 51 responses to the survey, 11 respondents said their system (i.e. Sustainability and Transformation Partnership or Integrated Care System) took part in a CQC-led PCR since March 2020. Given the low response rate for these questions, the figures in this section should be treated as indicative only.

Of the 11 respondents, two agreed that the review had helped them to understand the effectiveness of their system-wide response to COVID-19, and six (54%) disagreed. Similarly, only two (18%) said they agreed that the review encouraged more collaborative working, and six (54%) disagreed (figure 7).

Only one respondent agreed that the review supported them to improve patient and service user experience, and five disagreed. Similarly, one said they agreed that it supported them to improve patient and service user outcomes in the face of COVID-19, while six (54%) disagreed (figure 7).

Seven respondents disagreed that the review helped them to restore services after the first peak and only one agreed. As for the learning shared from the review, four disagreed that it helped them to respond to winter pressures and further waves of COVID-19, and six disagreed that the review helped them to drive improvement (figure 7).
While some trusts felt that the review preparation itself was helpful, other trusts said the review did not necessarily add value or improve their understanding of how to approach collaborative working across systems. Despite these mixed views, the aggregate findings may still be helpful in highlighting learning and systemic barriers to collaboration at a national level.

While this is a small sample of respondents, the findings highlight the importance of using the insight gathered by these reviews to add value and supports trusts and their partners to work collaboratively across systems, drive improvement and restore services from COVID-19. This will be important if CQC are to use PCRs as a tool to review how well health and social care services work together to reduce inequalities, as outlined in its new strategy. We would encourage CQC to consider how it uses the insights of these reviews to develop a more system-focused methodology in the future.
New strategic approach to regulation

CQC has recently set out plans to change its regulatory approach under four key themes. These themes include regulation that is driven by what people expect and need from services; a smarter approach to regulation that is more flexible and dynamic; regulation that enables stronger safety and learning cultures; and accelerating improvement. Throughout the four themes, a common thread focuses on their ambition to understand how health and care systems are working together to reduce inequalities.

We asked providers to share their views on each of the four themes outlined in CQC’s draft strategy prior to the launch of its formal consultation in January 2021. Respondents expressed very strong support for the direction of travel but raised questions about what the new approach will look like in practice.

Three quarters (75%, 33 respondents) of respondents to our survey said they are supportive of the proposal to ensure regulation is “driven by what people expect and need from services, rather than how providers want to deliver them” (figure 8). Evidently, trust leaders support the principle of planning and delivering care to meet the needs of people using services. The main consideration will be to ensure sufficient flexibility to allow trusts and their partners to determine the most appropriate way of meeting local population health needs while meeting the requirements of a nationally defined framework for performance and quality.

I am strongly in favour of user-driven changes but there does need to be some consideration for providers to be able to deliver services as they feel appropriate for their organisation as a whole… For example, you can’t place a burden such as Cost improvement programmes on trusts and then say they must deliver services as dictated by patients - there needs to be a balance of input and control. And of course, you can’t be everything to everyone, and providers need to be able to have some autonomy in this decision making/planning.

Role not specified, acute trust
Nine in 10 respondents (89%, 39 respondents) are supportive of CQC’s proposal for a smarter approach to regulation, with an ambition to provide an up-to-date, consistent, and accurate picture of the quality of care in a service and in a local area (figure 8). Again, trusts welcome this proposed shift towards regulating more dynamically and proportionately. However, getting the implementation of this ambition right will be crucial to ensuring it has the intended impact.

The devil is in the detail. On paper, the current approach by the CQC seems proportionate. However, in practice the framework is not applied consistently and there is a varied level of quality of regulatory service offered.

Company secretary, acute trust

Almost everyone who responded to this survey (95%, 42 respondents) said they are supportive of the proposal for CQC to focus more on safety and learning cultures, making it the most highly supported of the ambitions on which we sought trusts’ views (figure 8). We know that NHS staff and organisations treat safety as a top priority, so this is expected. Similarly to the smarter regulation proposal, comments from trusts centred on successful implementation.

[CQC] needs to ensure inspectors and assessment tools have the maturity to measure the important elements like culture and emotional intelligence not just weighting inspections to what’s easiest to measure.

Chief executive, acute specialist trust

Others highlighted the need for CQC to ensure it avoids duplication with other national bodies and questioned what role CQC might play in the safety landscape given the work other bodies are doing in this space – a stronger emphasis on safety without adequate coordination with these partners could not only confuse the landscape but also add burden to trusts.

I do not think a stronger approach to safety is applicable to CQC as this cuts across HSIB - only one of these should do this. Focusing more on improvement does not sit well with the current ethos and culture of CQC - to change to this would require a change of direction for the leadership team and new inspectors.

Chair, community trust

I’d like to see a robust and consistent methodology for quality assurance used.

Role not specified, community trust
Two thirds (66%, 29 respondents) of respondents said they are supportive of the proposal to establish and facilitate national sector-wide improvement coalitions to improve the availability of direct, tailored, hands-on support (figure 8). Of the four themes outlined in CQC’s strategy, this had lower levels of support from respondents, raising questions about avoiding duplication and ensuring CQC focuses on its core regulatory role.

**Figure 8**

*To what extent are you supportive of the following proposals as detailed in CQC’s strategy?*

(n = 44)

<table>
<thead>
<tr>
<th>Proposal</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Regulation that is driven by what people expect and need from services</td>
<td>41%</td>
</tr>
<tr>
<td>A smarter approach to regulation</td>
<td>68%</td>
</tr>
<tr>
<td>Expect services to have stronger safety and learning cultures</td>
<td>77%</td>
</tr>
<tr>
<td>Drive improvement through establishing and facilitating national sector-wide improvement coalitions with health and care partners</td>
<td>25%</td>
</tr>
</tbody>
</table>

*It is important that work to develop improvement coalitions does not duplicate arrangements that already exist and therefore not see as the CQC looking to expand their remit. Company secretary, acute trust*

*I am not sure establish/facilitate nationwide improvement coalitions is consistent with the CQC regulator role and this is already a crowded area. Better for a focus on improving the current approach rather than adding another body. Also, with the increase in the number of prosecutions, can you really expect staff to be open in a learning environment with the CQC present? Chair, acute trust*

*I do not see this as a role which sits with a regulation of quality as this is about service improvement - please encourage CQC to stay away from this as this is all about development not regulation - much better for say King’s Fund, NHS Providers and NHS Confederation to support this. Chair, community trust*
Regulation of systems

The COVID-19 pandemic has accelerated the shift towards health and care services working more collaboratively as a system to deliver care. As such, CQC has identified that its ‘single provider service model’ is no longer fit for purpose in the current and evolving landscape. It has therefore outlined its intention to review how well health and care systems are working together.

Trusts are broadly supportive of CQC’s intention to take the system-wide context into consideration when reviewing services. More than four in five (84%, 37 respondents) respondents expressed their support for CQC’s ambition to review how well Sustainability and Transformation Partnerships (STPs) and Integrated Care Systems (ICSs) are working together to improve outcomes for people in their communities. Additionally, three quarters (75%, 33 respondents) said they would be supportive of its proposal to hold STPs/ICSs to account for the quality of care in their area (figure 9).

…Re STP/ICS holding to account, once legislation is approved then the CQC should focus on system but also review work with individual providers so as to avoid duplication. Chair, acute trust

The main concerns trust leaders have noted, including through our broader engagement with them outside of this survey, are around the context of planned legislation to support the shift towards system working. While trusts support this direction of travel, their comments highlight a need to ensure changes to regulating systems are not made too hastily before the full impact of legislative proposals is seen.

Without primary legislation to enable proper governance of any new bodies created by ICPs/ICSs then holding to account these non-legal entities becomes problematic for everyone, time consuming and confusing. Company secretary, combined acute and community trust

In our last regulation survey report, we noted that this shift in the operating environment “serves to highlight that providers, their local partners, and the national bodies are continuing to navigate a complex environment and developing new regulatory models to reflect the changes taking place locally will only grow as a priority.” Trusts have again echoed the complexity of the environment they are operating in and highlight the need for any changes to be flexible, adaptable, and responsive to a changing health and care architecture.
We also asked trusts what changes they felt could be made to CQC’s existing regulatory framework to support the further development of system working and integrated care. Our findings highlight a need to ensure new capabilities and infrastructure are developed to support this shift, as well a focus on ensuring the approach is data driven.

To make the change successfully it’s critical the CQC undertake more robust training and induction of staff so they can understand the complexity of systems. Without extensive experience of working in systems inspectors will struggle to review meaningfully and it will become a checklist/tick box approach, missing the point. Chief executive, acute specialist trust

Much more data driven in terms of overall outcomes for patients and health and wellbeing measures across pathways. Chief executive, acute trust

Trusts also commented on the need for CQC to determine what specific role it will have in regulating and reviewing quality care across systems, but also more widely in assisting in the development of supporting systems to build their own quality management systems.

Figure 9
To what extent are you supportive of the following proposals on reviewing systems as detailed in CQC’s strategy?

(n=44)
On the whole, it is clear that trust leaders experience organisationally-focused regulation as a potential barrier to a more collaborative way of working across a system, and are keen for regulation to support collaboration and take wider system issues into consideration.

**To review services from a whole system perspective rather than just individual organisations. Sometimes there are important inter-dependencies which need to be part of an overall assessment of services that meet the needs of the population in the broadest sense.** Chair, acute trust

**They need to link in with the wider system and not just providers.** Company secretary, combined acute and community trust

**An emphasis on partnership for the benefit of patients and system learning.** Chief executive, acute trust

CQC’s success in effectively reviewing health and care systems will depend in part on the relationships developed between trusts, clinical commissioning groups (CCGs), STP/ICS leaders and other system leaders. As well as working with NHS England and NHS Improvement to design a system level regulatory model that do not duplicate or create additional burdens and where accountabilities are clear. However, if CQC does not take on additional responsibilities for regulating systems, it will be imperative that it provides clarity over how it intends to take system issues into account that are outside of a trust’s direct control.

**… The CQC need to determine whether it is replicating audit functions or whether it is trying to take a more strategic critical friend approach to assist the development of new systems/ ICS, which is the space it should inhabit so it can share other good practice from around the country.**

Company secretary, combined acute and community trust

**ICSs have no quality management systems, no quality assurance, and no quality manual or procedures. CQC should assist the new organisations to build a quality management system and a health and safety system and an environmental management system to bring NHS management up-to-date with all other major enterprises globally.**

Chair, community trust
Coordination with other national bodies

As in previous surveys, this year we asked trusts to describe how well they thought CQC had coordinated its activity with NHS England and NHS Improvement, other regulators, and national bodies over the last 12 months.

Trusts’ opinion was divided as to whether CQC had coordinated its activity effectively with other regulators and national bodies locally (22%/9 fairly effectively, 36%/15 neutral, 21%/6 not very effectively, 7%/3 not effectively at all, 21%/9 don’t know), which is similar to responses received in our previous survey (30% agree, 26% disagree, 35% neutral, 9% don’t know) (figure 10).

Trusts’ opinion in this survey was also largely split as to whether CQC had coordinated its activity effectively at a national level, although more agreed than disagreed (22%/9 fairly effectively, 34%/14 neutral, 12%/5 not very effectively, 5%/2 not effectively at all, 27%/11 don’t know). This is better than the previous survey where more respondents felt CQC had not coordinated effectively than those that did (18% agree, 43% neutral, 23% disagree, 15% do not know).

Given the impact on trusts’ resource and staff time to respond to regulatory requests, particularly during the COVID-19 pandemic, it is important for regulators to coordinate activity effectively to reduce, prioritise and streamline these requests. As most trusts are either uncertain or neutral about the level of coordination CQC has with other regulators and national bodies, this suggests a need for greater alignment.

Both regulation and oversight are out of step and confused. There is, for example, no use of the FT Code of Governance whatsoever since the CQC magicked up the well-led framework.
Role not specified, acute trust

There needs to be a more streamlined and joined-up process so providers are not being asked for the same things (but often in different formats) from different bodies.
Company secretary, combined acute and community trust
The context of COVID-19

At the beginning of the COVID-19 pandemic, NHS England and NHS Improvement issued a letter to providers setting out a series of changes to the way they would oversee trusts' activity by relaxing annual reporting requirements, streamlining national programmes, and reducing the volume of central data collections, including those related to delayed transfers of care, mixed-sex accommodation breaches and figures for operation cancellations.

Trusts reported a moderate level of interaction with NHS England NHS Improvement during the pandemic, with around half (49%, 22 respondents) saying that their level of interaction was 'medium', and 38% (17 respondents) saying it was high. There is likely to be some variation regionally based on the approach taken by regional teams, by sector, and according to the level of pressures faced by the trust related to COVID-19.

The majority (82%, 42 respondents) of trusts said that NHS England and NHS Improvement understood the pressures trusts were facing before the start of the pandemic, with 20% of these saying that they had a 'very good' understanding. During the pandemic, three quarters (73%, 37 respondents) said that NHS England NHS Improvement had a very or fairly good understanding of the pressures they faced in managing coronavirus and other demands (figure 11). Comments suggest that the drop in the number of trusts saying that NHS England and NHS Improvement understood pressures during the pandemic is partly driven by trusts’ experience of the focus on recovering services, and some confusion around lines of reporting with ICSs playing a role alongside the NHS England and NHS Improvement regional teams in monitoring the local situation. Trusts also commented on the impact of a centrally driven response, and the difficulties of keeping up with regular changes to information and guidance, which does not always align with regional messaging.
ICSs have created an additional layer of regulation with confusion about reporting lines from organisations to regional teams and/or ICS and/or ICSs to regional teams. **Chief executive, acute trust**

Regional NHS England and NHS Improvement team has been asking for the impossible in terms of performance on backlogs etc. Lots of sticks and few carrots. Also very centrally driven, so during the pandemic there have been many changes to messaging and requirements. **Company secretary, combined acute and community trust**
Developing new models of system oversight

In previous years of the survey, trusts agreed that NHS England and NHS Improvement would need to develop models of oversight to support system working and hold systems to account for the collective performance of their organisations. Support for this approach increased from 80% in 2019 to 90% in 2020. This likely reflects trusts’ ongoing work to build relationships with local partners and integrate care, and in anticipation of new legislation, further recognition of a need for systems of oversight and regulation to keep pace with work taking place at a local level to work more closely with partners.

As system working and local collaboration progresses, trusts increasingly see a need for organisation-level oversight to take into account the context of system working. However, less than half (48%, 20 respondents) agreed that NHS England and NHS Improvement currently takes the context of local system working adequately into account in this way (figure 12). Trusts feel that this contributes to the challenges they face in contributing to system working, in which decisions made for the good of the system can have a disadvantageous effect on their own performance in the eyes of the regulators. They remain clear that there is a growing need for regulation to keep pace with policy and operational priorities, and NHS England and NHS Improvement’s developing System Oversight Framework is likely to provider a clearer framework in support of collaborative working.

**Figure 12**

**To what extent do you agree that NHS England and NHS Improvement currently takes the context of local system working adequately into account in its support for individual providers and their partners?**

<table>
<thead>
<tr>
<th>Response</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Strongly agree</td>
<td>2%</td>
</tr>
<tr>
<td>Agree</td>
<td>45%</td>
</tr>
<tr>
<td>Neither agree or disagree</td>
<td>26%</td>
</tr>
<tr>
<td>Disagree</td>
<td>21%</td>
</tr>
<tr>
<td>Strongly disagree</td>
<td>2%</td>
</tr>
<tr>
<td>Don’t know</td>
<td>2%</td>
</tr>
</tbody>
</table>

In terms of STPs/ICSs playing an increased role in monitoring performance of their component organisations, again, a large majority agreed that this should be put in place. More than four in five (83%, 34 respondents) agreed that STPs should play a role in holding their component organisations to account, although only 34% (14 respondents) strongly agreed.
However, there remains a diversity of views on how oversight and regulation should be organised in the context of system working.

For example, when asked if STPs/ICSs should take on some oversight and support functions currently held by the NHS England and NHS Improvement regional teams, around three quarters (74%, 31 respondents) agreed. However, some trusts expressed a view that any move towards formalising the role of ICSs as a performance manager, as proposed in the ‘Integrating care’ policy paper, should be accompanied by a proportionate reduction in the level of oversight from other parts of the system, reflecting the ongoing desire among trusts for regulatory bodies to continue to work towards reducing burden and duplication, and the need to avoid introducing ICSs as an additional tier in the system architecture without reducing the level of oversight carried out elsewhere.

The whole has to be greater than the sum of the parts and regulation and oversight needs to reflect the value of partnerships at ICS and place.

Chief executive, acute trust

There is a concern that NHS England and NHS Improvement doesn’t know whether it wants to devolve responsibility/regulation or not. To devolve to systems there needs to be greater clarity about the set up on the ICS. The independence of its AO (not a CCG shoe-in). It would be reasonable to set the system the regulation and oversight responsibilities working to a framework but only if NHS England and NHS Improvement is prepared to step back and work at a strategic level and resist the urge to get into the weeds. This would also require a change of focus for the regional teams. This would support system working.

Chair, acute trust

It seems clear that with the establishment of STPs / ICSs that the role of NHS England and NHS Improvement will need to change. I’m actually not sure what value they currently have other than as the financial regulator. The well-led framework is a good start but has not been particularly helpful to date - I see it as a work in progress and am hopeful it will get better.

Role not specified, acute trust

Trusts describe a different relationship with regulators to the one they have as part of a partnership in an ICS as it currently exists – a coalition of willing partners collaborating around a shared aim. Should systems begin to play a part in local oversight and performance management, trusts anticipate an inevitable change in the relationships they hold with local system leaders as a result.
While system working has rapidly progressed over the past year, and further clarity about the intended future role and purpose of ICSs is emerging, until new legislation is passed, systems will remain voluntary partnerships of health and care organisations with varied levels of maturity, operating contexts and governance arrangements. For this reason, trusts urge caution in how quickly ICSs take on performance management responsibilities. With future clarity about the remit and governance of ICSs emergent, some of these tensions may resolve, but there remains a need to be pragmatic about how quickly system-focused models of oversight will be implemented.

The role of the ICS in self-managing regulation is entirely dependent on the context in which they are operating. It requires high levels of trust and transparency from the AO/chairs of the ICS and a mutual commitment to work together. There is still substantial worry about the lack of robust governance and accountability in the organisation versus the system.

Chair, acute trust
Coordination with other national bodies

As with previous years of the survey, we asked trusts how well they felt NHS England and NHS Improvement had coordinated its activity effectively with other bodies, both locally and nationally. A third (33%, 13 respondents) felt that NHS England and NHS Improvement had coordinated its activity effectively with other bodies nationally, while 37% (15 respondents) felt that NHS England and NHS Improvement had coordinated effectively locally with other bodies (figure 13).

**Figure 13**
*How effectively has NHS England and NHS Improvement coordinated its activity with CQC, other regulators and national bodies over the last 12 months?*  
(n = 41)

As CQC’s strategy sets out its future direction including an intention to look at systems and pathways as they assess quality of care, alongside NHS England and NHS Improvement’s developing its system oversight framework, both NHS England and NHS Improvement and CQC will need to coordinate well to avoid duplicating efforts, metrics and assessment tools. Trusts also cite a centrally-driven model of oversight as a driver of this perceived lack of coordination.
Similarly, as ICSs develop and potentially take on more responsibility for performance management and oversight of their component organisations, trusts have pointed to a need for a concurrent reduction in the activity of both regional and national NHS England and NHS Improvement teams, to streamline activity so that these different functions complement each other. Some trusts have proposed, for example, that if ICSs take on accountability for outcomes and delivery across their patch, there should be a reduction in the amount of organisationally focused performance management from NHS England and NHS Improvement, to help manage the amount of activity taking place, avoid duplication between national, regional and ICS oversight, and between NHS England and NHS Improvement and CQC.

"Needs to be strategic regulator and has been far too operationally driven from the centre. Also issues of overlap with role of CQC.
Company secretary, combined acute and community trust"

"Need to avoid duplicating role with CQC, whatever it does and needs to be less directly involved with the operational issues of individual trusts.
Company secretary, combined acute and community trust"

"There needs to be a more streamlined, joined up processes so providers are not being asked for the same things (but often in different formats) from different bodies e.g. commissioners, ICS, NHS England and NHS Improvement and CQC.
Company secretary, combined acute and community trust"
The NHS White Paper, Integration and Innovation: working together to improve health and social care for all, published in February 2021, sets out far-reaching changes to the legislative landscape surrounding the health and care system. At the heart of these legislative proposals lies an objective to create an enabling framework for local partners to build upon existing partnerships at place and system levels, and to begin aligning services and decision making in the interests of local people. As part of these proposals, ICSs will gain a statutory footing, comprised of an ICS NHS Body taking on commissioning functions and responsible for developing a plan to meet the population health needs in a local area, and securing the provision of healthcare to meet the needs of the system population, and an ICS Health and Care Partnership Board responsible for bringing together health, social care, local government and other partners to develop a plan to meet the wider health needs of the system.

This year, in anticipation of these developments, we asked trusts about their views on how regulatory change could support system working, and many comments referred to proposals to put ICSs on a statutory footing among other legislative changes to support integrated care. In the survey, and other sources of feedback, we explored trusts’ views on legislative change to support system working, and the implications for models of regulation and oversight which currently focus on organisations but will increasingly look across systems.

Implications for regulation and oversight

Trusts are broadly supportive of the strategic direction of travel for system working, with agreement that an enabling, permissive framework to integrate care, will help to support further progress on systems. Mechanisms for reviewing performance and outcomes at a system level are also seen by trusts as an important component of removing barriers to collaborative working and integration. The vast majority (90%, 38 respondents) of trusts support a move towards models of oversight which takes into account system working (figure 14). This has increased since 2019, when 80% agreed with this statement.
However, the process of identifying the right mechanisms for doing this is complex and will no doubt be shaped by proposals to place ICSs on a legislative footing. NHS England and NHS Improvement is developing new metrics to support systems to monitor their progress including measurements around population health, which could well be helpful in bringing together diverse partners around a shared aim, with collective ownership of objectives and outcomes.

The survey also highlighted challenges to tackle around aligning regulatory requirements at system and organisational level. Trusts continue to have reservations about how this would work in practice; two thirds (67%, 28 respondents) agreed that it would be possible to align system oversight with regulatory requirements at an organisational level (14% strongly agree, 52% agree) (figure 15).

**Figure 15**
*To what extent do you agree that it is possible to align system oversight with regulatory requirements at an organisational level?*

(n=42)

<table>
<thead>
<tr>
<th>Strongly agree</th>
<th>Agree</th>
<th>Neither agree or disagree</th>
<th>Disagree</th>
<th>Don’t know</th>
</tr>
</thead>
<tbody>
<tr>
<td>14%</td>
<td>52%</td>
<td>14%</td>
<td>7%</td>
<td>12%</td>
</tr>
</tbody>
</table>

There are also considerations around how system-focused models of regulation and oversight may impact trusts whose work spans multiple systems and places. At worst, these trusts may face multiple conflicting judgements depending which system’s context is being assessed and be subject to performance management from multiple ICS boards. This could prove to be burdensome, duplicative, and confusing for trusts whose services span larger geographies and populations.
…not all organisations will be in a position to fit neatly into one STP/ICS unless it’s well understood.

Company secretary, community trust

Some trusts expressed concern at the impact of system-based regulation on trusts currently performing well on current measures of performance and quality. This underlines the need for a period of testing and evaluation to ensure the new approach does not eliminate recognition and celebration of good work taking place within organisations, alongside good practice in systems.

Finally, trusts highlighted the need for a transition period before the full implementation of system-focused models of oversight, to allow new ways of working to bed in.

I think we need to carefully consider what moving from challenged providers to talking about challenged places (ICPs) and systems means. It is unfair on places and systems to have this put on them without a transition period where this is agreed locally with the relevant provider, place and system

Chair, community trust
This year’s survey highlights some useful lessons to learn from an unprecedented year. Many trusts expressed support for the way regulation and oversight and bureaucracy was pared back during the pandemic, particularly the first wave to allow trusts to focus their efforts on responding to COVID-19. Yet over time, trusts’ sense of whether the regulators related to the pressure they faced at the frontline lessened with slightly less than half of respondents (47%, 21 respondents) agreeing that the regulatory approach taken during the pandemic supported their trust to manage quality and risk.

The fact that key elements of regulatory activity designed to provide assurance of the safety and quality of services were unsuited to the context of the operational response to the pandemic raises interesting questions for the future of regulation, which we look forward to working with CQC and NHS England and NHS Improvement and our members to resolve. The emergence of new regulatory models from both CQC and NHS England and NHS Improvement is an opportunity to re-evaluate how regulators interact with the services they seek to assure, and trusts are keen to see a move to a regulatory model which is responsive and proportionate with greater real-time awareness of emerging risks and local plans to manage risk.

While there are clear examples of where COVID-19 has been the catalyst for positive change in the NHS, there is a need to consider how these changes can be safely and appropriately adapted for longer term reform. We would support a leaner, more streamlined approach to the processes described above with learnings from COVID-19 taken forward, however would emphasise the need to robustly evaluate the impact of such changes and ensure longer term transformation is properly resourced and given time to bed in.

The COVID-19 pandemic – and the new White Paper – offer an opportunity to consolidate a new and constructive dialogue between providers and the bodies that regulate them in the interest of improving services and ensuring people receive safe care.
NHS Providers is the membership organisation for the NHS hospital, mental health, community and ambulance services that treat patients and service users in the NHS. We help those NHS trusts and foundation trusts to deliver high-quality, patient-focused care by enabling them to learn from each other, acting as their public voice and helping shape the system in which they operate.

NHS Providers has all trusts in voluntary membership, collectively accounting for £92bn of annual expenditure and employing more than one million staff.