NHS Providers position statement on regulation

Both NHS England and Improvement scaled back their regulatory activity during the first wave of COVID-19. Now, as they seek to reconsider their approaches in the new context, with accelerated system working and new innovative models of care, regulatory and oversight frameworks are set to evolve considerably in the years to come. The following text sets out our principles for regulation which will inform how we seek to influence the frameworks on behalf of trusts.

Background

Approach to regulation during COVID-19

During the COVID-19 pandemic, both NHS England and Improvement and the Care Quality Commission (CQC) scaled back their regulatory approach substantially. CQC paused all routine inspections and provider information requests, and introduced an Emergency Support Framework to respond to areas of critical risk or safety concerns. NHSEI also suspended its core oversight activities during the pandemic.

Current status of plans for a future regulatory approach

CQC confirmed in September that its regulatory transition will move away from its previous approach, and function as a 'prototype' model ahead of the implementation of a new strategy from summer 2021. The organisation has made a commitment to placing a greater emphasis 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. The CQC has also been clear that it acknowledges the burden of the inspection regime and plans to move to a leaner approach.

CQC has subsequently indicated its intention to move towards a more proportionate and risk based approach to regulation, and set out in a draft strategy for 2021 onwards how it plans to develop its approach in line with a changing health and care landscape; COVID-19 has accelerated change, with new types of service and increased use of digital channels of care, with restrictions changing how care is delivered. CQC has identified a need to transform and ensure regulation is relevant and fit for purpose in an evolving system.

The draft strategy also sets out plans to adapt its approach to take into account the importance of system working, stating that it is no longer enough to look at how one service operates in isolation, and it is how health and care services work together that has an impact on people's outcomes. CQC also describes how changes to the way care is delivered, including the increased use of technology, artificial intelligence and data analytics, point to a need to regulate these services and ensure they meet people's needs and provide high quality care.

As part of the emphasis on systems, CQC has indicated they are seeking powers to regulate systems as part of new NHS legislation, leading to further questions about the future of ICSs as a potential new statutory layer in the system architecture. The regulator cannot currently inspect local authorities or commissioners, but has used special powers to undertake 'system reviews' of STPs and ICSs and more recently undertaken reviews of provider collaboration using its existing powers. We expect the learning from these approaches to inform its strategy from April 2021.

Longer term, similarly to the CQC, NHSEI is also considering how to adapt its approach to regulation in the context of increased system working. This becomes especially pertinent if forthcoming NHS legislation was to give systems a statutory basis. NHSEI is developing a new system oversight framework, which 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. There remain unanswered questions about the role of systems in managing the performance of local providers, as well as how far systems themselves should have their performance monitored or held to account.

Purpose and principles of an effective regulatory system

The function and purpose of regulation in the NHS

In a high risk sector such as health care, a degree of regulation and oversight will always be necessary to monitor the performance and safety of NHS service for patients and the public, and to provide nationally comparable information to underpin full transparency and accountability and support trusts to drive their own improvement. Regulation, done well, is an important means of monitoring safety and improving services, ensuring people receive safe care, and regulatory activity should provide a valuable feedback loop to providers to help them identify where care can be improved, and as a source of information about performance within their trust.

Regulatory activity in the NHS may be broadly split into three categories and we refer to each as follows:

- Regulation – active intervention directing trusts to take steps towards improving organisational performance or addressing risks to patient safety
- Oversight – An additional layer of assurance to support trusts' own process of monitoring and improving performance
- Performance management – a formal system of collecting data to measure performance and intervene in the process of improvement in trusts.

1. Regulators should provide objective and independent judgement

Objective, independent judgement is an important component of regulation which successfully provides transparent and robust monitoring of the safety and performance of NHS services. Trusts should be measured against a clear and objective framework, which is applied consistently across the country, whether that is by different CQC inspection teams or NHSE/I teams.

An objective and fully independent regulator adds to the assurance carried out internally by trusts offering a complementary function, which is to provide accountability and reassurance to the public, and intervene where necessary to provide additional support. While we acknowledge that NHS England and Improvement cannot achieve complete independence given its relationship to the department of health and social care (DHSC) and its concurrent policy and operational functions, consistency of approach and objectivity is similarly important in underpinning the credibility of their judgements.

2. Regulation should be risk based and proportionate

The degree of oversight and intervention should be proportional to the performance of the trust, and challenges in the system. This should be underpinned by a clear set of metrics and transparent criteria for triggering regulatory intervention. It is important that, as part of this, trusts are empowered to drive their own improvement.

Trusts have pointed out that during a high-risk incident such as COVID-19, 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. There is an argument that this serves as an indication that the current regulatory system risks becoming divorced from its purpose and may not support the provision of safe and high quality care in all possible circumstances. The CQC has tacitly

acknowledged this in its work to refresh its model for next year, and trusts are keen to see a move to a regulatory model which is responsive and proportionate to the needs of the trust, with a real-time awareness of emerging risks and the trusts' own ability to assess and address those risks.

3. Regulation and oversight arrangements should place minimum burden on providers and add value

Feedback from members tells us that the regulatory system prior to Covid-19 was burdensome, time consuming and did not always provide good value for money. As financial and operational challenge has increased, the level of regulatory intervention has increased. This can often be counterproductive in diverting resource away from efforts to manage operational challenges and restore performance. A new regulatory and oversight model should seek to find the appropriate balance of regulatory assurance and intervention, and decisions should be based on transparent criteria.

The information gathered from regulatory activity should be available and accessible to those who would benefit from it. This includes members of the public, STPs/ICSs, national policy makers as well as trusts themselves who can use the data to benchmark and monitor their own performance.

The impact of regulation should be measurable – that is, it should be clear what is being measured and possible to determine whether regulatory activity has contributed to achieving the aim of ensuring safe care is being provided. It should also be possible for regulators to demonstrate accountability for what they do, and ensure they have the appropriate resources and capabilities to deliver their functions, and model the behaviours they seek to encourage in providers.

4. The context within which providers operate should be taken into account in regulatory judgements

Trusts have noted that regulation and oversight does not always align closely with the context in which they work, and they are at times subject to contradictory judgements. For example, trusts may be penalised for the condition and suitability of their estates, in the absence of capital funding to address these issues. While we recognise the need to shine a light on these issues where they arise, the local and national context, and the circumstances leading to any issues identified within a trust, should form a clear part of regulators' judgements.

There are potential benefits to bringing some metrics into system level oversight, including greater recognition within monitoring and support processes of the mutuality inherent in some aspects of

performance. With an increase in system working comes an increase in the complexity of monitoring performance. Fair judgements can only be made if these circumstances are taken into account.

Regulation is a powerful driver of behaviours, and as such can incentivise or discourage trusts to work more collaboratively with partners. There is an opportunity in the current context to achieve greater alignment between national policy objectives related to system transformation, and the regulation and oversight of trusts' contribution towards these objectives. Eighty per cent of trusts agree there is a need to develop new models of oversight to hold systems to account for the collective performance of their component organisations[1], and we fully support better alignment of the regulatory frameworks with the direction of travel towards system working, however there is a need to retain sight of clear lines of accountability.

While a board's openness to collaboration may provide a new focus within a forward looking regulatory approach and may incentivise and enable closer working, providers should not be judged on what is outside of their control, and boards cannot be held accountable for decisions made by other bodies.

5. Accountabilities should be clearly defined

Trusts are designed as board-led organisations with accountability for the delivery of services. This supports the provision of high-quality care and enables local partnerships to develop, as well as ensuring accountability sits as close to the delivery of care as possible.

As the national architecture changes, and the question of how trusts interact with systems and the national bodies develops, the balance of power risks being shifted towards central, rather than local, decision-making, and the government, national bodies and regulators have exerted an increasingly firm grip over foundation trusts. During the pandemic, trusts have demonstrated that they are the most appropriate unit of delivery, with effective corporate governance and assurance processes in place. We continue to support the principle of the unitary board and the benefits of decisions being made by those accountable for the delivery of services.

ICSs can provide a structure in which system partners participate in taking responsibility for the performance of the system as a whole. While many trusts believe this can be achieved without wholesale restructuring of the NHS, others feel that some statutory footing for systems may support

[1] https://nhsproviders.org/regulation-survey-2019/oversight-and-regulation-of-systems-and-new-organisational-forms

closer working between organisations and allow them to go further, faster. However risk management, good governance and clear lines of accountability should sit as close to the front line as possible and trusts should not, and in the current architecture cannot, be responsible for other organisations' performance or for decisions made elsewhere in the system.

Recognition of the implications of system working must be balanced with clarity of accountabilities and the role of the unitary board. It is essential that any move to give ICSs statutory footing is supported by the appropriate governance (i.e. properly accountable boards), but introducing a formal additional tier of oversight is unlikely to be helpful as there is potential to introduce duplication and multiple conflicting judgements. Trusts need the right balance between provider accountability and system performance, either through aggregating organisational performance to a system level, or using separate metrics at the system level to feed into discussions about organisational performance.

Further questions to consider in the context of legislative changes

As the development of new legislation for the NHS progresses, there are a number of key questions which may arise around the implications for a future regulation and oversight model:

- What might a legal merger of NHSE and NHSI mean for regulation and oversight?
- Do we believe the 'improvement support' function in the NHS should be separate from regulation?
  - Should NHSE/I and its regional teams function as a performance manager?
  - Do we support a proposal for systems to have responsibility for performance management in their patch? What might legislative change to place ICS on a statutory footing mean for their functions including with regard to oversight and performance management, and how might this relate to other parts of the regulatory landscape?
  - What would be the correct balance between a top down vs. bottom up improvement process – and what is the correct balance between support and intervention?
- How should NHSE/I and CQC interact with systems? What regulatory powers should/could NHSE/I and CQC have over systems?
  - Could NHSEI look at system level quality without undermining organisation-level oversight?
  - How should a shared definition of quality be created?