The PDA's response to the Care Quality Commission's Consultation on "Changes for more flexible and responsive regulation"

March 2021

Summary:

The Care Quality Commission (CQC) is consulting about making changes to its Inspection process and the manner in which ratings are generated and published. The CQC is proposing to move away from comprehensive on-site inspection visits and will instead rely on other tools and techniques to assess quality. The CQC proposes to make inspection visits but on a targeted basis. The CQC states that it will further develop its assessment frameworks and publish information to explain how often it will update ratings.

It is also making proposals to publish ratings without having made a site visit. The proposals also include changes in the way it publishes ratings for both GP practices and NHS Trusts.

The consultation document also states changes to the way CQC will consult and engage with stakeholders and the public on regulatory changes. It states that there will be fewer large scale formal consultations and believes that it can satisfy its statutory duties under the Health and Social Care Act 2008 by publishing a statement that explains how they will assess the performance of health and care service providers.

The consultation closes on the 23rd of March 2021.

About the Pharmacists' Defence Association

The Pharmacists' Defence Association (PDA) is a not-for profit defence association and trade union for pharmacists. It is the only organisation that exclusively looks after the interests of employee and locum pharmacists across all sectors of pharmacy, currently with a membership of more than 32,000, the PDA is the largest representative membership body for pharmacists in the UK. Our members increasingly work in settings regulated by the CQC including GP surgeries, NHS Trusts, Prisons, Hospitals and within care homes.

There is an increase in the number of pharmacists who are independent prescribers and over recent years there has been a significant increase in pharmacists joining GP practices leading to a greater proportion of our profession finding themselves practicing in CQC regulated settings, and hence we expect to be a stakeholder more regularly engaged by the CQC.

We also take the opportunity of this consultation to reiterate that practice in this area continues to evolve and that the regulation of the CQC alongside GPhC and others must keep pace with that development. For example, the CQC must ensure the regulation of such premises and relevant healthcare professionals takes the activities of pharmacist prescribers into consideration and clear guidance should be in place which sets out the responsibilities of GP practices, care home owners and hospital trusts, for example, in relation to pharmacist prescribers."

Our response is informed by the experiences of our members and the knowledge garnered whilst representing them.

Preamble

We appreciate that the CQC, like all regulators, has had to modify its processes in light of the Covid-19 pandemic. Some of these changes may ultimately result in more proportionate and better quality regulation but this is not a given.

Certainly, the pandemic has shone a light on the inequalities **(1)** that persist both for patients and healthcare workers within the healthcare system and there are many lessons here for the CQC.

We also need to take into account the political perspective and the wider Government agenda to reduce regulation which is increasingly being seen as just cumbersome bureaucracy. **(2)**

In between this lies a way forward with changes that promote fair and proportionate regulation of individuals, whilst also holding to account poor systems authorised by unregulated and poor quality managers and leaders.

Our response is based on the overarching concept that it would be unwise for the CQC to make such radical changes without having an evidence base to support the changes. This is even more important as the coming together of health and social care within Integrated Care Systems will mean that a multitude of providers may be providing care and have responsibility and accountability within the care pathway.

The alignment of weakness (the holes in swiss cheese effect) of each provider will be much more likely unless there is granular assessment of the weakness within each provider in the system. The risk to patients of falling through the hole increases in the absence of an assessment with granular details for care providers. Whilst we appreciate that the CQC is seeking a greater role in regulating systems (which is subject to a separate linked consultation) it should not do so at the expense of the existing rating and inspection process.

We also have concerns about the second part of the consultation which outlines how the CQC will engage with stakeholders without undertaking a full scale consultation process. Whilst we appreciate that consultation and engagement is a burdensome requirement for regulators, it should also be seen as an absolute necessity and not as an optional extra.

If the CQC is minded to go forward with this measure, then it must as a minimum engage with stakeholders in a meaningful manner. This process would include allowing any party to register as a stakeholder, having open and accessible stakeholder engagement sessions, publishing the full details of all the parties that were engaged with (and detailing steps taken to reach hard to reach groups like travellers) before the final “thing” the CQC is altering is put into effect. An independent competent entity should oversee the whole comprehensive engagement process which culminates in a full publication of all the details.

We answer the questions as posed but these should be seen in the overarching context that we disagree with the underlying changes, as proposed to inspections and to the future consultation process.

1. Assessing quality

We propose to assess quality and rate services by using a wider range of regulatory approaches – not just on-site or comprehensive inspections.

Question 1a. To what extent do you support this approach?

The question could be misinterpreted as the consultation document (the document) clearly states the intention of the CQC, following this consultation:

> ***"..we won't return to using the current inspection frequencies .. and the type of large inspections associated with this approach."***

We support the concept of using a wider range of approaches to inform the frequency of full onsite inspections but cannot support the total abandonment of periodic comprehensive or large inspections as is detailed in the body of the consultation document.

The document also states the CQC is already testing ways of assessment without visiting premises. However, the CQC must publish the outcome of these tests and the underlying assumptions / data it has used before progressing the proposed abandonment of inspections any further. Until such time as the outcome of the tests is published we cannot know whether the proposed approach may be fit for purpose.

Question 1b. What impact do you think this proposal will have?

We think the proposal will have a negative effect on enhancing safety. The capacity for comprehensive on-site inspections has taken a considerable amount of time to build. Many GP surgeries are closing and many are merging resulting in large patient lists. GP surgeries are also increasingly becoming a hub for multi-disciplinary teams providing more extensive services and these professionals are regulated by a number of different regulators. We are also seeing many GP

surgeries coalescing as “supersurgeries” with some having in excess of 300,000 patients.

This reconfiguration of the GP surgeries and the further significant changes planned with the creation of Integrated Care Systems (ICSs) means the need for comprehensive physical inspections as part of an overall assessment process is now greater than ever. Systems have to be seen and witnessed on-site as working SOP documents may be perfectly written but in practice redundant as no one follows them. The bigger the system the bigger the risk.

The consultation document informs us that the CQC already

> ***“ …. use information from a wide range of sources to support our judgements”.***

The proposal in the document is that the whole assessment process will be generated as a desk-based computer generated report which has been totally reliant on the quality of the input information. The document states that on-site assessment would occur

> ***“.. where we have information about significant risks to people’s safety, ... ”***

The CQC strategy consultation revealed that artificial intelligence and data analysis would underpin the methodology to rate premises and also as a basis to decide on whether a targeted inspection was necessary. We have commented in that consultation that there is a real risk of embedding inequality as a result of poor AI algorithms. There is a growing body of data that suggests that many AI systems result in discriminatory practice and embed existing biases. **(3)**

2. Reviewing and updating ratings

Rather than following a fixed schedule of inspections, we propose to move to the more flexible, risk-based approach set out in this section for how often we assess and rate services.

Question 2a. To what extent do you support this approach?

We cannot support the proposed approach as it is vague and lacks detail.

The document states clearly that this CQC proposal will result in the abandonment of comprehensive on-site inspections. It is proposed that ratings would be created

and updated without on-site inspections. These ratings would be created using inputs that have not been clearly detailed or weighted. There should be total transparency of the underpinning methodology which would generate ratings.

The document does clearly state:

> ***"For all these changes to happen we'll need to further develop our assessment frameworks and publish information to explain how often we'll update ratings in a consistent and proportionate way. This work will sit alongside wider changes in how we assess quality …"***

We are also concerned that further changes may not be subject to full consultation.

Question 2b. What impact do you think this proposal will have?

We have concerns that reliance on feedback and factors that cannot be seen and witnessed during an on-site visit could lead to inappropriate ratings. We have significant concerns about diversity issues that the proposed model could lead to and we detail this in later sections.

3. Rating GP practices and population groups

We propose to stop providing separate and distinct ratings for the six population groups when rating GP practices.

Question 3a. To what extent do you support this approach?

The consultation document merely states that there is little variation in ratings between different groups of patients. We ask if the CQC has considered commissioning research to consider why this may be so? Without having an understanding as to why the ratings between population groups are so similar it would be unwise for the CQC to discontinue monitoring this even if it chooses not to publish the data.

Question 3b. What impact do you think this proposal will have?

We cannot comment on the impact as the CQC has not shared any information to explain why there is little variation in the ratings provided by different population

groups. The CQC has the data and presumably it has used this data to make the proposal so it is incumbent upon it to share why there is little variation so we can make an informed response.

4. Rating NHS trusts

We propose to remove aggregation for NHS trust level ratings and replace with a single trust-level rating, based on a development of our current assessment of the well-led key question for a trust.

Question 4a. To what extent do you support this approach?

We cannot support this approach as it does not recognise that detailed breakdown of performance can target resource on areas where improvement is needed. It may also tease out patient concerns as patients may otherwise think that they alone had a poor experience. A single trust-level rating would be a retrograde step in context of identifying and isolating poor process that could harm patients.

We are also concerned that systemic Trust wide failure could be masked by removing aggregation. Systemic problems such as poor leadership at Trust level may be masked by exceptional leadership at individual location level. Separate Trust level ratings are really important as public inquiry after public inquiry has shown that poor quality governance and leadership has been at the heart of many cases of patient harm.

> ***"Once we implement this approach, we will no longer publish separate trust-level ratings for the safe, effective, caring and responsive key questions. We will continue to publish those ratings at service and location level."***

Following the publication of the Francis report, Sir David Nicholson, the then Chief Executive of the NHS, wrote to every single NHS Trust asking them to

> ***"…review your standards, governance and performance.."*** **(4)**

The Bristol Royal Inquiry of 2001 **(5)** recommended the statutory regulation of senior managers but this has still to be taken forward. A surgeon in a 2021 paper published in the BMJ commented:

> ***"Almost all the senior managers who were responsible for clinical and professional failures simply melted away just before or after the tribunal and reappeared a few months later, often with accolades and/or promotions in other trusts."*** **(6)**

It should be of note that there is a marked under-representation of BAME persons as senior managers in the NHS and this is a marked variation to the diversity seen within the overall NHS clinical workforce.

Question 4b. What impact do you think this proposal will have?

This proposal will have a negative effect on both being useful for patients and also in helping to drive up standards and especially the quality of leadership within the NHS.

5. Measuring the impact on equality

Question 5. We'd like to hear what you think about the opportunities and risks to improving equality and human rights in our draft equality impact assessment. For example, you can tell us your thoughts on:

- **Whether the proposals will have an impact on some groups of people more than others, such as people with a protected equality characteristic.**
- **Whether any impact would be positive or negative.**
- **How we could reduce or remove any negative impacts.**

Any regulatory activity has to be proportionate, fair and free of bias for all parties. It is alleged that the CQC has struggled to achieve that with its Inspection process.

This issue is of such concern that the Council of the Royal College of General Practitioners has on the 1st of March 2021 called for an Independent commission to look into the CQC Inspection process and its impact on BAME GPs. **(7)**

It is acknowledged that a disproportionate number of BAME GPs work in challenging neighbourhoods with multiple indices of deprivation. These GP practices struggle to recruit and retain not only GPs but any healthcare staff.

Despite our reservations around the alleged bias in the CQC Inspection process we still support retention of the overall concept of rigorous Inspections and their role in ensuring safe care. However, that support is predicated on the CQC ensuring that the Inspections are free from bias and it enters into discussions with GP leaders to ensure that their concerns are adequately addressed.

The Covid-19 pandemic has highlighted the disproportional impact on many with protected characteristics, both patients and providers of care. There are no proposals made by the CQC regarding how the new ratings process would embed equality of treatment for all patients and providers and this is a systemic failing that needs to be addressed.

A number of CQC reports note the lack of opportunity for BAME staff to progress and also of a lack of BAME persons at Senior Trust Level. This systemic problem is noted but not actioned with notices to improve. A culture within a Trust that fails to embrace equality within its staff and senior management will be subtly sending a message regarding equality in patient care.

Similarly, many CQC reports make a cursory mention of how services within NHS Hospital trusts are delivered in terms of equality and diversity nor any assessment of the Diversity or Equality Plans of the Trust. Given this baseline of not addressing Equality or Diversity in the currently published Inspection Reports we struggle to see how the CQC will monitor any diversity and equality issues as a baseline seems not to exist despite the Equality Act having been in place since 2010.

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