The PDA's response to the Care Quality Commission's draft new strategy document:

"The world of health and social care is changing. So are we."

March 2021

| representing **your** interests | | defending **your** reputation |

About the PDA

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.

Delivering more than 5,000 episodes of support provided to members who have found themselves in a critical incident situation in the last year alone, provides the PDA with a rich vein of up to date experiences which have informed policies and future strategy.

This experience has recently been informed by the very considerable number of Covid-19 related issues being faced by members. The practical experience gained in supporting member issues from the coal face is further enhanced by regular member surveys and focus group interactions. The information in this document is largely built upon the experience of our 32,000 members .

The primary aims of the PDA are to:

- Support pharmacists in their legal, practise and employment needs
- Represent the individual or collective concerns of pharmacists in the most appropriate manner
- Proactively seek to influence the professional, practise and employment agenda to support members
- Lead and support initiatives designed to improve the knowledge and skills of pharmacists in managing risk and safe practises, so improving patient care
- Work with like-minded organisations to further improve the membership benefits to individual pharmacists
- Arrange insurance cover for individual pharmacists to safeguard and defend their reputation.

Summary:

The Care Quality Commission (CQC) is consulting about its new draft strategy in light of the impending Government reorganisation of Health and Care provisions and taking into account its experience of the Covid-19 pandemic. The CQC currently regulates in a "single service provider" setting theme but the new emerging systems incorporate multiple providers in multiple settings. It is now seeking to provide leadership and regulate these systems in addition to changes in how it discharges its existing inspection and regulatory duties.

Proposals include removing set frequencies of in-situ inspections which would be replaced by information and artificial intelligence driven data assessments leading to more "targeted inspections".

The draft strategy is built around 4 themes:

- People and communities
- Smarter regulation
- Safety through learning
- Accelerating improvement

The consultation closes on the 4th of March 2021.

Introduction:

We all appreciate that the pandemic has taught us many lessons on how regulatory activity can best support healthcare professionals to deliver safe patient care.

We also appreciate that the wider Government agenda is to reduce regulatory burden and to ensure that what remains is fit for purpose.

Mixed in with this is the need to integrate health and social care into one seamless patient health and care system. Embedding a safe systemwide working culture will be essential especially as there will be many multidisciplinary teams working over many places of health or care delivery.

We thus agree that there will need to be greater oversight and changes to regulation which takes into account all these factors.

Countless public inquiries following health and care scandals have shown that systemic issues are brushed aside and the focus is always on blaming individuals. The Bawa-Garba case is a seminal example of how a clinically competent junior doctor was subjected not only to the full weight of professional disciplinary action and but also to criminal prosecution. Yet, it was clearly demonstrated that the system and inherent systemic failings had created the high risk situation that Mrs Bawa-Garba was left to solely deal with.

We can contrast this with the air safety sector. The focus there is that following an incident the priority is preventing reoccurrence whereas in the health sector the prioritisation seems to be around apportioning blame.

In air safety, investigations and action following an incident commence with an understanding that the cause may be systemic. The focus is on correcting any potential systemic causes and learning and as such practitioners (pilots) see their contribution to safety reporting as part of the solution and engage habitually. In contrast many healthcare practitioners fear being referred to their regulator if they honestly and openly record errors.

In healthcare too often the default suspicion is that it will be an individual practitioner that is at fault and systemic or organisational factors seem too often overlooked. Discussion feels too often about apportioning blame and infrequently about preventing reoccurrence, save from removing a particular practitioner from a register.

For greater patient safety any change to the ethos of the regime should be a movement towards a culture of supportive learning and system change rather than blame apportionment.

This may become increasingly difficult as the Government has expressed a clear desire to exert greater control of the NHS and to set its direction. The need for ensuring that individuals are not scapegoated for failures arising from politically controlled system prioritisation which may result in under resourcing (in both monetary and staffing terms) will become even more critical.

The role of the CQC in this brave new world to ensure that safe systemwide working is in place will prove especially challenging unless it can physically inspect places and systems in-situ.

In the following pages we answer the questions asked in the consultation document.

People and communities

We want to be an advocate for change, with our regulation driven by people's needs and their experiences of health and care services, rather than how providers want to deliver them. This means focusing on what matters to the public, and to local communities, when they access, use and move between services. Working in partnership, we have an opportunity to help build care around the person: we want to regulate to make that happen.

What do you think?

The Government has given a clear steer about how it sees integrated care systems (ICSs) working together in delivering joined up health and care within a defined local footprint.

These new pathways will involve multiple entities who may be regulated by different organisations. For example, the CQC inspects GP premises whilst the GPhC inspects community pharmacy premises but the GMC, the NMC, the HCPC and the GPhC may be overseeing regulation of individuals working within these premises.

Integrated care will increasingly involve multi-disciplinary teams (MDTs) and accountability and responsibility may span multiple professions and multiple premises.

The Government recognise that their proposals will necessitate reforms and has stated in the White Paper that it is exploring how to "enhance the role of the CQC in reviewing system working."

We are particularly disappointed that the CQC has chosen to base this consultation on the basis of a revised assessment process (including a revised need for site inspections) which is subject to a separate consultation. People need to understand the ratings given by CQC for them to be meaningful, and these need to be thorough and fully documented.

We believe that the proposal for change to the current CQC rating system is overly simplistic. We note that the consultees included groups that represent people who use health and care services and groups representing service providers. It would have been helpful to publish the full consultee list and details about the engagement process.

1a. To what extent do you support the ambitions set out in this theme?

We welcome the acknowledgement by the CQC that its original remit in 2009 was to oversee a single service provider model and that its processes need to change to take into account the major structural changes that are imminent, as outlined in the Government's recent White Paper.

We believe that that the CQC should also recognise that there are many determinants of inequality and that factors such as education and income are indivisibly linked and also areas which over which health and care systems working in isolation have no control.

The PDA welcome the proposed widening of patient involvement, but it is often the communities that are most educated, best connected and prepared to shout the loudest that get their voices heard. Hearing and engaging with those most in need has always been challenging, and engagement will necessarily involve local authorities and social care entities rather than traditional healthcare entities. We would like to see tangible proposals around how the CQC will

engage with hard to reach groups and some mechanism to assess to determine whether it has been successful in doing so.

There is little that a GP can do to counter a damp house provided by a local authority to a family suffering from asthma. The 'place' based approach outlined in the White Paper therefore is encouraging on this topic.

The consultation states that services would be expected to engage with their communities and "it will be unacceptable if providers are not doing this". We seek clarification on how the CQC would address this area where persistent failings were found, given that local authorities within systems are elected by the local population and the CQC is not.

We also have concerns about how the 'any system provider' approach would deal with a care pathway which included, for example a community pharmacy, but the community pharmacy refused to take part as the renumeration was not sufficient or not covered by the essential requirements of the national contract. This could equally apply to all primary care providers (GPs, Dentists, Opticians and Pharmacies).

1b. Please give more details to explain why you chose this answer.

We note that the CQC already monitors and inspects a diverse range of providers (from hospitals to GP surgeries to care homes). However, this is relatively straightforward and compartmentalised. To oversee a whole care system is an altogether different proposition.

The Government is also proposing to widen the remit of the CQC to include "a new duty for the Care Quality Commission to assess local authorities' delivery of their adult social care duties."

We would support any organisation that aspires to effectively oversee and regulate the new structures that are about to evolve providing it can demonstrate a clear :

- vision of how its oversight and regulation will deliver better care
- methodology of how it will deliver the oversight and quality control
- understanding of its legal remit and how it would work within this
- understanding of how it would work with other regulators to avoid duplication

Whilst we acknowledge that the CQC is seeking to reduce health inequalities many of these inequalities have a root cause linked to education or income inequality. Research in the UK recently showed a life expectancy gap of 8.4 years between a boy born in 2015 in the top 20% of neighbourhoods when compared to one born in the bottom 20%.

The drivers of inequalities in health are deeper seated than the standards of healthcare or social care provided by a system; it is a societal issue. The CQC needs to therefore be clear about how it measures the effectiveness of the health and care system in not increasing health inequalities further and improving outcomes. It cannot however address the wider determinants of health without working in partnership across a much broader public sector footprint.

Smarter regulation

We will be smarter in how we regulate. We'll keep pace with changes in health and care, providing up-to-date, high quality information and ratings for the public, providers and all our partners. We'll regulate in a more dynamic and flexible way so that we can adapt to the future changes that we can anticipate – as well as those we can't. Smarter use of data means we'll target our resources where we can have the greatest impact, focusing on risk and where care is poor, to ensure we're an effective, proportionate and efficient regulator.

What do you think?

We agree with the ethos of smarter regulation rather than tick-box regulation, however we have concerns about an over-dependence on data analysis and feedback loops which would rely on retrospective information.

The CQC needs to be specific about what it means by "We now have a baseline understanding of quality across health and social care". This is important as it seems that this "baseline" will form the foundation for future reviews/inspections/monitoring.

Some of the proposals made in this document are wholly reliant on untested IT systems based around Artificial Intelligence (AI) and an untested analytical model to profile risk. The whole business of regulation and especially when radical change is proposed, should be based on risk mitigation and therefore we would seek reassurance that models and systems proposed were robust and tested.

Across all sectors, there is significant concern that wherever AI has been used, it has inbuilt biases that discriminate due to poorly designed algorithms. That discrimination manifests itself in a variety of ways.

Thus a targeted approach may in reality result in a biased approach.

Within healthcare, there is a disproportionate number of BAME workers. Many work within small GP practices or are owners of smaller care homes or care providers. The CQC has not shown any cognisance of the risk of bias in algorithms and how it would mitigate against this significant risk of in-built bias.

2a. To what extent do you support the ambitions set out in this theme?

As artificial intelligence (AI) becomes part of more aspects of life, so the risks of reliance on such a system become more clear. A poorly designed artificial intelligence can just be discriminatory quicker and more consistently that a similarly flawed human system.

To mitigate against such an outcome there must be absolute transparency as to who decides, and about the content of, the "algorithms" that shape the AI and institutional discrimination and unconscious bias must not be allowed to corrupt a solution which is intended to make matters fairer.

As we have said previously, we support the ethos of smarter regulation however, we are concerned that the CQC may be being over-ambitious in not fully recognising the limitations and risks that the proposals introduce. The value of regular on-site inspection visits should not be

brushed aside. Furthermore, we would want to see an independent assessment of the CQC data analysis system to determine that it is fit for purpose.

2b. Please give more details to explain why you chose this answer.

The smarter regulation process seems to be based on visiting services “when we respond to risk”. This seems like an altogether retrospective after the event process rather than an anticipatory event.

We agree that ratings systems need to evolve but they must evolve following due process and stakeholder engagement. We would like to see details around the engagement process (including details of diversity of the groups engaged) for the changes being proposed in tandem with this consultation.

We also agree that continual scrutiny of information rather than periodic reviews may give a better measure of the quality of service but alerting mechanisms together with safeguards need to be robust and fit for purpose. Tailoring regulation sounds good in theory but in reality, it may just be embedding poor process or underlying bias. Regulation must be seen to be consistent, applicable universally and free from any perception of unwarranted targeting.

Throughout the NHS there is an acknowledged systemic bias against BAME professionals. One known bias is patients making vexatious complaints against BAME professionals, another is employers following discriminatory processes and there exist a whole host of other documented biases that manifest themselves in a variety of ways. The reliance on patient or other feedback needs to factor in this systemic bias which is prevalent across all NHS systems.

Patient groups and feedback loops may not fully understand what “good looks like”. They may just accept the service provided as this is the only experience they have. The CQC would need to ensure that it provides a whole range of supporting tools including online videos and infographics that explain “what good looks like”. Reaching certain groups and demographics will be especially challenging and we would like to see tangible evidence of how the CQC intends to able to engage these groups.

Reliance on feedback is predicated on that feedback being relevant and robust and fit for purpose and being received from any recipient of care that chooses to do so.

We agree that data collection should avoid duplication, that it should be shared and used smartly. We recommend that an overarching commitment the CQC should make is that it will publish on its website ALL the data it holds (meaningfully collated/formatted/accessible) unless there is a compelling public interest case in not doing so.

Safety through learning

We want all services to have stronger safety and learning cultures. Health and care staff work hard every day to make sure people's care is safe. Despite this, safety is still a key concern for us as it's consistently the poorest area of performance in our assessments. It's time to prioritise safety: creating stronger safety cultures, focusing on learning, improving expertise, listening and acting on people's experiences, and taking clear and proactive action when safety doesn't improve.

What do you think?

This section needs to be considered in light of the February 2021 Government White Paper which proposed "the creation of Health Services Safety Investigations Body (HSSIB) to investigate incidents which have or may have implications for the safety of patients in the NHS."

The White Paper has introduced two proposals:

1/ a wider remit for the CQC encompassing oversight of whole system healthcare

2/ the creation of a new Safety Body

The remit or scope of the 2 bodies need to function in defined complementary ways so that problems and issues do not fall in between the cracks.

Considering this, several proposals will need to be agreed with other regulators. For example, the CQC definition of "safe care" if that care is provided across a system that includes a hospital, GP practice, community pharmacy, district nurses, local social services and homecare, may not be straightforward.

We note the reliance on self-assurance as a possible mechanism of monitoring. Of equal and probably more concerning note is the absolute absence of any mention of whistle-blowing and how the CQC would encourage and deal with feedback provided by a whistle blower. Inquiry after public inquiry has shown that staff have often been reluctant to report issues that may cause patient harm because they see little value in doing so, the subsequent action taken is not perceived to warrant the risk of speaking up.

3a. To what extent do you support the ambitions set out in this theme?

We wholeheartedly support the ambition of "creating strong safety cultures" and note that the CQC acknowledges that it too has to improve and increase its safety expertise. The ambitions have to be deliverable and cognisant of wider system issues.

3b. Please give more details to explain why you chose this answer.

The CQC proposals do not acknowledge the link between a "just culture" and a strong safety culture and the interlink of these with leadership.

We are concerned at this lack of emphasis on leadership and a lack of acknowledgement of systemic risk and its role in safety.

The Bawa-Garba case showed the importance of a "just culture" and how systemic risk was introduced into the healthcare setting by poor staffing levels. Nothing in the CQC proposals reduce or mitigate for an example of poor leadership that allows inadequate staffing which leads to systemic risk resulting in patient harm.

There is little in this CQC proposal that would prevent a repetition of the Bawa-Garba case and the focus may still be blaming a clinically competent junior doctor caught up in a system that was not fit for purpose.

Given that the Government is seeking powers to "direct" the NHS we have real concern that political imperatives my introduce systemic risk and health leaders will be impotent as has been the case in the past, to resist political pressures and instead focus on "targets".

The Health Service, in toto, has been under severe financial pressure over the last decade and will be increasingly so in the post-COVID-19 world. This could also be exacerbated by Brexit and the potential loss of many valuable and trained EU professionals. The systemic risks and the role of leadership will be far more critical to patient welfare than the errors or mistakes of any one individual.

Accelerating improvement

We will do more with what we know to drive improvements across individual services and systems of care. We'll use our unique position to spotlight the priority areas that need to improve and enable access to support where it's needed most. We want to empower services to help themselves, while retaining our strong regulatory role. The key to this is by collaborating and strengthening our relationships with services, the people who use them, and our partners across health and care.

What do you think?

We have already noted that the Government is seeking powers to direct the priorities within the NHS. We have also noted it is exploring widening the role of the CQC. The CQC priorities would need to align with these and, if they were to not then how would this potential conflict be managed? How would public protection be preserved?

We cannot agree with the CQC desire to take on an active leadership role. This is best left to professionals (not managers) working within the settings and systems that the CQC is regulating.

Following the seminal Shipman Inquiry where Dame Janet Smith recommended the separation of professional leadership bodies from regulatory oversight activity due to conflicts of interest, the whole approach of Government has been just this.

We are therefore surprised that the CQC is now seeking to take on a "leadership" role for activities and systems that it will subsequently regulate.

A virtuous cycle of learning and improvement is an aspirational aim globally and not unique to England. The emerging role of the CQC and how it uses data to facilitate a virtuous cycle of reflection and improvement needs to be clearly defined. Indeed, the CQC should be evaluated for its own effectiveness by a robust process.

4a. To what extent do you support the ambitions set out in this theme?

The role of the CQC in improving care should be seen in context that it is a regulator. We cannot support the underlying thinking around the extended role that the CQC is proposing for itself.

It seems that the CQC envisages its role is to get involved in or direct how professionals working within the settings and systems it regulates. This would be a fundamental mistake.

We believe that the role of the regulator is to create a supportive environment which allows improvement and innovation to occur and to take action when there is a systemic issue preventing it.

4b. Please give more details to explain why you chose this answer.

Context will become increasingly important if Government seizes control for setting priorities within the NHS. The role of the CQC in providing a robust first line of defence to stop political imperatives driving or favouring one improvement over another will be critical.

For example, the political imperative may be driven by statistics that look at post-operation hospital stay duration. Whilst we all agree that discharge should occur as soon as is safe, there may be a political driver for faster discharge to free up capacity, so that operating theatres are used as production lines and elective waiting lists reduce. This may lead to embedding poor practice and increase patient risk.

Similarly, the pandemic has shown that the routine usage of GP video consultations has maintained or increased GP capacity during the Covid-19 pandemic. This may become embedded in all care systems but whilst wealthy regions with affluent demographics may gain from this, areas with an elderly or materially deprived demographic may not. One size will not fit all.

We think it is well outside the scope, ability and remit of the CQC to seek to "encourage innovation". Clinicians are the best placed individuals to drive and embed innovative practices within their working environments with the local knowledge of their patients.

The role of the CQC should be to highlight systems and examples of where innovative practice has led to a better care. Its role should be more of highlighting and facilitating the sharing of best practice and ensuring that this embeds into care settings nationally where it is appropriate. The CQC will be most effective when its regulatory activities do not stifle or hinder innovative practice.

Our core ambitions In each of the four themes in this strategy, we have an ambition to improve people's care by:

- **assessing how well health and care services work as a local system**
- **looking at how services and local systems are acting to reduce inequalities.**

5a. To what extent do you support our ambition to assess health and care systems?

We agree that as the planned reforms for healthcare emerge and become a reality there should be some regulatory oversight of this. The effectiveness of systemwide working and especially how it is being structured to reduce inequalities should be assessed. However, as we discussed earlier, inequalities have several inter-related components.

The wider more pertinent question is how would the CQC maintain the existing quality of oversight and inspection whilst now placing this into the context of the overarching care provided as part of the wider ICS health and care system. This is a critical role that must not be diluted.

5b. Please give more details to explain why you chose this answer.

The CQC proposals suggest a major change (or reduction) in individual setting oversight and inspection, whilst adding in whole system regulation. We think it would be a grave error to do so especially as there will be tensions in the emerging systems into who does what and who pays.

Within an ICS for example, there may be a prevalence of persons over 75. This demographic may need more primary care support and social care support to reduce the need for secondary care and especially emergency secondary care. Whilst we all agree that this is desirable there will be capacity constraints.

Following a fall, should the burden of at-home recuperation fall on local social services and the GP or should the hospital provide physiotherapy and rehab from its own resource. The burden should not only be thought of in monetary terms. Physiotherapy and rehab staff capacity in primary care is severely limited.

In a different ICS region, there may be more call for maternity support as birth rates are high.

How would the ICS share the care responsibility, and would it be the role of the CQC to monitor the whole system? How would the CQC be equipped to do so?

And finally, within an ICS which has a statutory footing, whilst different parts within it may argue over who provides that care, it will be the "system" that will be legally obliged to provide it.

6a. To what extent do you think the ambitions in the strategy will help to tackle inequalities?

We do not think that the strategy will address the underlying issues around inequality.

6b. Please give more details to explain why you chose this answer.

We do not believe that the CQC remit in isolation could oversee the wider determinants of health, such as educational inequality or income inequality – which both ultimately contribute to health inequality.

Repeated data analysis has shown the inextricable link between poverty and health outcomes. Health outcomes need to be seen in context of ALL inequalities and NOT in isolation.

If the reduction of inequalities is a significant objective of the CQC, we believe that it would need to work across multiple agencies to really be able to influence this agenda, and the ambition would need to be factored into all public policy areas. Government, regulators, and arm's length bodies would need to work in partnership to address this systemic issue, which also manifests in areas outside of healthcare.

Measuring the impact on equality We need to consider equality and human rights in all our work, so we've produced a draft equality and human rights impact assessment. It identifies the opportunities and risks for doing this through our new strategy. Importantly, it identifies the actions we'll take to minimise the risks and make positive change happen.

7. 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 ambitions in the strategy 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.**

We note that the CQC engaged with groups that use health and care services. However, there is no detail as to whether these groups included those that are hard to reach at local levels (for example the Traveller population).

A number of CQC reports based on the current Inspection models have noted the lack of diversity within organisations at a Senior level. Some reports note the lack of career progression for staff, which may be an indicator for systemic poor practice across a whole range of diversity issues. Despite noting these in the Inspection reports there has been no improvement notice served around these key areas.

Similarly, many CQC reports make no 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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