Changes to the way the CQC inspects, regulates and monitors care

Key Points

- A *New Start* implies a determination from the CQC to return to the more targeted scrutiny of its earlier incarnations, as well as to refine and improve its surveillance and inspection methods. It is a strategy that we support, particularly the emphasis on specialist inspection
- The creation of linked 'pseudonymous' datasets means that it is now possible to capture events for large populations in order to promote more comprehensive analysis and greater understanding of care services provided at the person level. We would encourage the CQC to make the most of these new resources as it determines which thematic reviews to undertake.
- The surveillance and inspection system needs to identify where failures are occurring promptly enough to trigger actions that minimise harm to service users *before* the situation becomes catastrophic. We are concerned that many of the indicators proposed are generally ones that would reveal problems only after they have reached an advanced stage, dampening the system's ability to be responsive.
- On the move to produce ratings for acute trusts the stakes for those organisations deemed to be inadequate will be high. Further assurances are required over whether providers and stakeholders will have sufficient time to engage with the standards. It is also important that equal attention is paid (and is seen to be paid) to developing a sector appropriate assessments for social care and primary care.
- There needs to be ways in which ratings can be suspended or qualified in some way and consideration should be given to introducing a minimal random element of inspection so that no provider – however good its information – can feel assured that they will not be inspected by the CQC tomorrow.

Consultation response

Date 12th August 2013

> A fully patient-centred healthy system needs…..to be able to detect and respond to individual failures that might be occurring within one ward or department of an otherwise high-performing hospital, as well as identify and respond to the larger scale, more systematic failures of individual institutions. This is the dual challenge facing health systems, particularly regulators and commissioners: creating a system that can detect (and prevent) individual failures at the same time as setting a threshold For when cumulative failures trigger a more resource-intensive, regulatory response.[1]

Introduction

The Nuffield Trust is an authoritative and independent source of evidence based health service research and policy analysis. In late 2012 we were asked by the Secretary of State to consider whether aggregate ratings of provider performance should be used in health and social care, and if so how best this might be done. The final report: *Rating providers for quality: a policy worth pursuing?* was published in March 2013. Members of staff also provided expert support and testimony to Robert Francis QC during his Public Inquiry, as well as subsequent analyses of the report.

Later this year, with the Health Foundation, we will launch a programme of research designed to track a range of indicators across the NHS and provide deeper analysis in key areas. Our aim is to provide an independent view across all care sectors, reflecting the way that key aspects of quality of care in England are developing over time. We welcome the opportunity to respond to the CQC's consultation on the inspection and regulation of services. Below we offer some answers to some of the specific questions raised in this consultation.

What do you think about the overall changes we are making to how we regulate? What do you like about them? Do you have any concerns?

A new start implies a determination from the CQC to return to the more targeted scrutiny of its earlier incarnations, as well as to refine and improve its surveillance and inspection methods. It is a strategy that we support, particularly the emphasis on specialist inspection.

Sticking to this approach will not necessarily be easy however. Defining standards of care and tightly assessing providers for whether they deliver could well increase the number of NHS organisations perceived to be at risk of failing. The recent furore surrounding Sir Bruce Keogh's review in the media and parliament demonstrated that the findings from inspections can be used by politicians seeking electoral advantage. This will only intensify as the general election draws closer. If it is to command trust in such a fraught climate the CQC will need to be prepared to stand by its assessments, as well as be open in cases where the process of inspection fails to unearth failures of care.

We welcome the CQC's decision to continue its thematic work and the related proposals to investigate whole systems and care pathways. Very often the most important areas to address for good quality care are at the interface between care providers. Though scrutiny of care pathways by the CQC has long been an ambition it has proved difficult to track patents/service users as they progress through the system.

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[1] March 2013. *The Francis Public Inquiry Report: a response.* Nuffield Trust: London.

However this is changing; the range and volume of information collected about health services continues to grow every year, whilst the creation of linked 'pseudonymous' datasets means that it is now possible to capture events for large populations in order to promote more comprehensive analysis and greater understanding of care services provided at the person level.[2] We would encourage the CQC to make the most of these new resources as it determines which reviews to undertake.

We do have some concerns about the proposed speed of implementation. Our understanding is that the draft regulations underpinning the standards, and draft guidance will be issued by the Department of Health and CQC in tandem at some point in the autumn. Given that the first wave of new inspections will take place between August and December, further assurances are required over whether providers and stakeholders will have sufficient time to engage with the standards. In the context of a new single failure regime the stakes for Trusts deemed to be inadequate will be high. The application of immature standards to set ratings could give rise to challenges (possibly even legal ones) over the methodology used to set standards.

The Ratings Review recommended starting with social care where the services are simpler to measure and there is arguably a more pressing need. If the intention is to proceed with acute trusts first it will be important that equal attention is paid (*and is seen to be paid*) to developing a sector appropriate assessments for social care and primary care. Any hint that a system built for the acute sector was being bolted onto the diverse range of providers covered by the new inspection regime would quickly undermine it among practitioners in those sectors.

Do you agree with our definitions of the five questions we will ask about quality and safety?

Yes (largely). It is sensible to include a question on whether the services are well led. Our recent review into quality ratings for the Secretary of State recommended that along with the three 'Darzi' domains of quality some measure of the quality of governance, particularly of large and complex providers should be included.[3] However we note that despite the enthusiasm for assessing the quality of organisational leadership, there are no commonly accepted and validated models. The CQC will need to do some work to establish a consensus on what are the robust models. This is particularly so when the term 'well led' both covers governance (which lends itself more easily to measurement) and 'leadership', a more amorphous concept. Such assessments can consume large amounts of provider resources and that needs to be justified. Thought also needs to be given to how to avoid tarnishing and/or demoralising junior staff in care providers where high quality leadership is found lacking[4].

On the question of effectiveness, it makes sense to link assessments to the uptake of guidance from NICE and other quality setting organisations. However assessments of this type very often require large amounts of information about specific processes of care. Moreover, implementation of NICE guidance has been variable, and there are a

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[2] See for example Bardsley and others' 'Overlap of hospital use and social care in older people in England' *in J Health Serv Res Policy*, 2012. July; 17(3):133-9, a retrospective analysis of linked, pseudonymous, routine service use data of people aged 75 and over (n = 133,055) drawn from the operational systems of four primary care trusts and their corresponding local authorities in England. The study demonstrated that residents of care homes tend to use hospitals less frequently than people receiving home care and suggested the need for detailed work to explain the phenomenon.

[3] March 2013. *Rating providers for quality: a policy worth pursuing?* Nuffield Trust: London p8.

[4] Lilford R, Mohammed MA, Spiegelhalter D, and Thomson R. 'Use and misuse of process and outcome data in managing performance of acute medical care: avoiding institutional stigma'. *Lancet* 2004; 363:1147-54.

number of national and local contextual factors that influence success.[5] NICE itself recognises that organisations may need to work towards implementing NICE guidelines, particularly if it requires investment or significant changes in working practices. That is why NICE guidelines are not subject to the funding direction that applies to Technology Appraisals. Making application of NICE guidelines a regulatory matter might suggest a level of rapid implementation and compulsion that is not currently applied and may raise significant challenges of application and interpretation. The same may be true of quality standards which ate not intended to be an exhaustive list but, amongst other things, to address areas of doubt and where progress needs to be made. Greater clarity is needed on how such regulation would be drafted and applied.

In defining essential standards and their supporting regulatory framework, greater clarity will also be needed over what is rightly the responsibility of regulation and what should be the responsibility of commissioners and contract holders. The example given of a GP practice's opening hours in respect of responsiveness would seem to be more appropriate for action by the contract holder, with whom opening hours should be agreed, rather than the regulator.

Do you think any of the areas in the draft fundamentals of care above should not be included?

N/A

Do you think there are additional areas that should be fundamentals of care?

No.

Are the fundamentals of care expressed in a way that makes it clear whether a standard has been broken?

The challenge is less about agreeing the wording of basic standards of care and red lines, and more about developing assessments which are valid, fair and responsive to failures in the system. Given the volume of care delivered in England we can expect many isolated breaches. Prosecution in every case is not practical, proportionate or desirable. It will be necessary to manage expectations accordingly.

It would also be a mistake for the CQC to be expected to provide a level of assurance to the public and to the provider that is properly the responsibility of the provider's management/board. Inspectors cannot be everywhere. On the other hand, a focus on assurance mechanisms could mean that the regulator is easily misdirected (either intentionally or unintentionally). This is the major challenge for CQC.

In moving forward we suggest that the regulator needs to think about how the practice of assessment is used continually to improve its regulatory mechanisms – ensuring that they balance the needs of the system for reassurances, the accuracy and reliability of the work they are doing and the opportunity costs to the health system. We were therefore disappointed to note the absence of concepts such as:

- Validity of an assessment
- Reproducibility and robustness of judgements
- Sensitivity and specificity of measures

[5] See Sheldon and others' 'What's the evidence that NICE guidance has been implemented? Results from a national evaluation using time series analysis, audit of patients' notes, and interviews' in *BMJ* 2004;329:999

For example, there may be a clinically justifiable reason for withholding pain medication from a patient. Some trusts, such as University Hospitals Birmingham have introduced advanced clinical decision support systems which allow the institution both to record care interventions, as well as an explanation for why a decision might have diverged from the expected rule. However these are far from the norm. In the more usual context of imperfect clinical notes and changing rota patterns which have had implications for the continuity of care, disagreements between the trust and an inspection team are plausible.

We also think that while it is right that the CQC focus on surveillance and inspection, there needs to be an onus on the providers to be continuously assuring themselves that they provide good quality care. Assurance should be a vital part of board activity, not something that is done for the purposes of placating the regulator. CQC should be non-prescriptive on the form that assurance takes, but focus on questions of whether the frontline care meets the standard and whether the board would be able to tell if it did not (this links to the answer to question 2 about whether a service/organisation is well led).

Do the draft fundamentals of care feel relevant to all groups of people and settings?

Yes. However, we recommend that particular priority be paid to ensure the rigour of assessments of standards in relation to vulnerable groups e.g. frail older people. We need to ensure that the groups who may have less opportunity to challenge poor quality care are supported by the regulatory processes. One element of this is to consider how the experiences of the most vulnerable patients/service users and their families can be best captured. We note how in successive investigations the quality of care for vulnerable groups is a recurrent theme e.g. Rowan Ward, Cornwall and Mid Staffs.

Do you agree with the proposals for how we will organise the indicators to inform and direct our regulatory activity?

No. To put it bluntly the process needs to identify where failures are occurring promptly enough to trigger actions that minimise harm to service users *before* the situation becomes catastrophic. In doing so there needs to be a clear hierarchy of measures which seek to maximise the efficiency of the regulatory process – and minimise the adverse impacts on the systems (such as red herrings being flagged). There is no one standard answer for what this should look like – the optimal system would likely need to gradually emerge through trial and error, with the results of inspection ideally being used to influence the indicator set (what works, what doesn't etc.).

But in terms of the weakness in the current starting point we make the following observations:

1. The indicators proposed are generally ones that would reveal problems only after they have reached an advanced stage, dampening the system's ability to be responsive. So for example deaths from low risk conditions are infrequent, meaning that one would have to wait a long time to see enough of them before an organisation were flagged by the system as having a problem.

2. There is too much reliance on mortality measures which are ambiguous. For all these indicators the CQC needs to be explicit about their accuracy and reliability and have systems for measuring their performance as a smoke alarm over time.

3. The grouping into tiers is probably unnecessary and possibly unhelpful. Very often CQC staff will encounter and want to react to an accumulation of

seemingly low grade intelligence that nevertheless point to underlying problems – for example sets of process measures (staff vacancies; turnover; survey results) that precede a failure in outcomes. It is worth bearing in mind the work of John Yates and others on how major disasters may be preceded by failings in a range of process measures.[6] Such work implies the need to remain adaptable in the way information is used and grouped, rather than relying on rigid hierarchies. Holding additional sets of information that are not looked at unless there is a flag in tier 1 runs the risk that CQC might have 'known' about a problem flagged in tier 2 or 3 data for some time, but not acted because of the lack of a tier 1 trigger. The role of hierarchies' should be in relation to how urgently the CQC responds to a signal.

4. We have reservations about the lack of process measures– these provide much more responsive measures and many are now available with clinical validity such as those included in the programme clinical audits. We suggest that the CQC outlines a programme to develop these indicators rather than setting some in stone now.

5. The best information to trigger actions will be soft intelligence – potentially supported by some further confirmatory data analysis. This requires a mixture of qualitative and quantitative methods. The qualitative analysis also needs to be undertaken with a degree of rigour but this is not mentioned.

6. The volume of indicators is irrelevant – computers can handle large amounts of data – the issue is clarity about what information sources trigger what actions.

7. The proposal to use only nationally comparable indicators at Tier 2 may be self-defeating. National comparability is not necessary; just a defensible way to judge whether one measure is very much worse than it should be. A local survey of patient care showing that 80% carers felt the people they looked after weren't treated with dignity and respect should not be ignored just because there is no national comparator.

8. We suggest that when scoring quantitative information the CQC compare observed and expected values – where the latter can be derived by different means – national averages; past performances; international comparisons; normative values; regional benchmarks; local values etc. The CQC already has experience in using these methods.

9. The use of inpatient surveys is fine but they tend not to be very discriminatory at trust level and are only collected once a year.

10. There is no mention of how data from other regulators will be used

The quality of the staff undertaking both quantitative and qualitative analyses is going to be critical to this function operating effectively. They will need to be able to use appropriate statistical methods to ensure that indicators are genuinely different from expected[7] and draw on experience of previous work on the application of statistical

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[6] See for example Harley and others 'Was Rodney Ledward a statistical outlier? Retrospective analysis using routine hospital data to identify gynaecologists' performance' in *BMJ* 2005;330:929

[7] See Bird and others 'Performance Indicators: Good, Bad, and Ugly: the report of a working party on performance monitoring in the public services' in *Journal of the Royal Statistical Society*. Series A (Statistics in Society) Vol. 168, No. 1 (2005), pp. 1-27

methods in regulation , especially the use of statistical process control and time series analyses.[8]

Do you agree with the sources we have identified in the first set of indicators? Please also refer to the annex to this consultation.

In undertaking that process we urge the CQC to consider how it works with the relevant stakeholders to improve measures of quality for the high risk areas. These areas are: care of the elderly (there seem to be no non-mortality indicators for the elderly care pathway), maternity care (only one indicator) and none for people with learning disabilities or on end of life pathways. In relation to the caring domain, we refer to the CQC to the points made in question 6 about needing to find a method to capture the experiences of people unable or less likely to report poor care.

However we also believe that the regulator should have the flexibility to adapt and improve on its sources of information. In part it will be judged on its ability to quickly refine and improve these sources and acquire new and better ones. Lengthy consultation may impinge on that freedom. The emphasis should be on informed, agile consultation; such as through expert panels, agreed key contact points, or hoc groups.

Which approach should we adopt for publishing information and analysis about how we monitor each NHS trust?

The CQC will gather information for two purposes:

a. To detect potential lapses in the systems and trigger change. This information may be partial and inconclusive and there may be adverse consequences if this is shared with trusts too early. It could be argued that at some point these data should be made available to the trust or the public – as the HealthCare Commission did with its selection methods for inspections- but after the inspection took place.

b. Information and intelligence used in a public rating and assessment. In such cases we believe it is important that the criteria for assessment, the evidence used and the judgements made should be open and accessible to all. CQC will have an important role in ensuring that this information is comprehensible to a range of users, perhaps working with HealthWatch and other stakeholders to find the best means of making sure patients in particular find it useful.

Do you agree with our proposals for inspecting NHS and independent acute hospitals?

Direct inspection and investigation, by teams trained in the task and with expertise in clinical care, management practice and patient voice, are critical to any regulatory regime surveillance. The process of developing the inspection regime is likely to be an on-going one however. The main test for the inspection process will be:

a. Can it be applied fairly and rigorously across the sectors?
b. Can it provide robust judgements swiftly and painlessly in ways which minimise the adverse impacts/cost on the providers

[8] See Spiegelhalter and others 'Statistical methods for healthcare regulation: rating, screening and surveillance' in *Journal of the Royal Statistical Society*. Series A (Statistics in Society) Vol.175, No.1 (2007, pages 1–47

c. Can it identify suitable improvement goals for the provider and commissioners that are sufficiently precise and achievable?
d. Can the inspection process itself stimulate positive system wide changes in the quality of care through the sharing of important lessons, or in exploiting the threat of future inspection?

We welcome the idea of developing a wider range of inspection expertise, but also note that inspectors (especially the lead inspectors required to get the most of out of what may be ad hoc teams) themselves need training and support – something that CHI devoted considerable attention too.

Should the rating seek to be the 'single, authoritative assessment of quality and safety'? Although the sources of information to decide a rating will include indicators and the findings of others, should the inspection judgement be the most important factor?

Yes, provided there is an adequate assurance process in relation to the reliability, comparability and comprehensiveness of inspection. Health care systems are complex and require complex assessments. An investigation or inspection based process is able to capture both the findings from analysis of the indicators and supplement this with other intelligence. Ultimately this should produce better assessments. Moreover good inspection programmes should put an inspected organisation in a better position in terms of deciding what it needs to do.

We would also note that an element of humility is necessary when presenting these ratings to the public. Firstly, past performance is not a guarantee for future performance; secondly, no assessment regime is truly comprehensive and timely; and thirdly, that the assessment itself is derived from sets of values that weight the constituent evidence – inevitably there will disagreements with the weightings that CQC applies. In recognition of this fallibility the CQC will have to be prepared to react quickly when it gets them wrong – as it will do. The CQC will also have to be prepared to defend them when it thinks they are right.

Should a core of services always have to be inspected to enable a rating to be awarded at either hospital or trust level?

A rating is based on an aggregation of evidence –the regulator will need rules to say at what point it has sufficient evidence to make a rating – this does not have to be defined in terms of a set of core services. However, we also note that beyond this consultation, it is not clear what engagement activity CQC is planning with stakeholders on determining the final set of expected standards. The assertion that 'good' trusts should retain their organisational rating despite having a small number of services which 'require improvement' would need to be discussed more fully once there is a clearer list of what is required under the Fundamentals of Care and Expected Standards. Without a clearer understanding of what the Expected Standards include, it is difficult to say whether it is right that a good provider could breach them in some areas.

Would rating the five key questions at the level of an individual service, a hospital and a whole trust provide the right level of information and be clear to the public, providers and commissioners?

Yes. The more information the CQC can provide to underpin the overall rating the better, in terms of being clear about how the overall judgement was derived, and to help identify actions for improvement. However, how best to present the information to the

public and the extent to which concerns about quality could be appropriately signalled requires significant market research (see below).

Do you agree with the ratings labels and scale and are they clear and fair?

A more finely varied scale – for example 1-10 might reduce the frequency and vigour of battles that the CQC finds itself in over boundaries and thresholds. But arguably whatever categorisation system is used is bound to provoke ire among those providers found to be sub-optimal.

Do you agree with the risk adjusted inspection frequency set out which is based on ratings, i.e. outstanding every 3-5 years, good every 2-3 years, requires improvement at least once per year and inadequate as and when needed?

No – rooting out poor quality care means that inspection must always be aware of the risk that an organisation – or one element of it - not inspected in years slides into mediocrity or worse.

The proposal to launch ad hoc investigations if the wider monitoring system triggers concern will therefore be very important – more so than a rating system. There needs to be ways in which ratings can be suspended or qualified in some way and consideration should be given to introducing a minimal random element of inspection so that no provider – however good its information – can feel assured that they will not be inspected by the CQC tomorrow.

The model set out in this chapter applies to all NHS acute trusts. Which elements of the approach might apply to other types of NHS provider?

We suggest that any rating should include measures of safety, effectiveness, and user experience – a crucial element. They also have the advantage that they are common currency in the NHS, can apply equally well to social care and health sectors.

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