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The King's Fund

Interim report

Evaluating the Care Quality Commission's acute hospital regulatory model: emerging findings

Introduction

In September 2013, the Care Quality Commission asked a team from Manchester Business School and the King's Fund to undertake a formative evaluation of CQC's new acute hospital regulatory model.

The design of the new acute hospital regulatory model is described in the inspection framework [1] and guidance, and in other CQC documents such as the logic model [2]. It is an almost complete departure from the approach used by CQC in recent years. The key differences – as described in those documents and to us in interviews – are:

- **Inspection teams** – the use of much larger teams of inspectors, able therefore to conduct significantly greater amounts of fieldwork across services and locations within an acute hospital, and teams with much more direct and recent clinical and managerial experience of acute care, alongside CQC staff experienced in the inspection process, methods and data analysis, and inspection team leads of more senior standing and credibility. This represents a move away from 'generic' regulation, towards the use of judgements drawing on relevant professional and patient representatives.
- **Inspection processes** – the use of a much wider range of sources of information, and much more detailed and extensive fieldwork in acute hospitals, including the use of a wide range of existing performance data, views and reports sought from many stakeholders, feedback from patients and the public, interviews and focus groups with staff, and less exclusive reliance on direct observation of care and individual patient feedback
- **Core services** – the process of inspection has been organised around eight defined core service areas (A&E, outpatients, surgery, medicine, paediatrics, maternity, end of life care, intensive/critical care), considered to represent the areas of greatest volume of activity and potential risk. Inspection teams have been structured into sub-teams to deal with each of these areas with efforts made to allocate team members to service areas which match their expertise and experience
- **Judgements and ratings** – much less focus on reaching dichotomous regulatory judgements based on the essential standards and their supporting statutory regulations, and instead the use of a framework of five domains (safety, effectiveness, caring, responsive and well-led) and ratings on a four point scale in each domain made at service and/or hospital level (inadequate, requires improvement, good or outstanding), alongside the production of much more narrative description of performance
- **Reporting** – the production of much more detailed and comprehensive inspection reports with a narrative description in each of eight core service areas as well as at hospital level, and the publication of the report and the response of the acute hospital and other stakeholders through a quality summit

The new regulatory model clearly draws most immediately on some recent experiences of and approaches to the Keogh reviews of some acute hospitals in 2013 [3]. It also shares some features with models of acute hospital inspection or accreditation in use in other countries such as the USA, Canada and Australia [4], and with the approach to inspection used in the past in the NHS by the Commission for Health Improvement [5]. It is, of course, a much more resource intensive model of regulation.

This new model has been introduced very rapidly with a limited amount of time for preparation, the development of inspection guidance and processes, the recruitment and training of CQC inspection teams, and the planning and implementation of inspections themselves. In this developmental phase we have observed a concerted effort by CQC to learn from the first wave of inspections between September and December 2013 and to introduce many improvements to the second wave of inspections in early 2014, prior to the model being rolled out more widely later in 2014.

In the first stages of this evaluation, we have had two main areas of inquiry:

- **Diagnostic purpose** – does the new model provide a better diagnostic analysis of the performance of an acute hospital, are the measures used valid and reliable, is the data meaningful, does it add significantly to what is already known, and does it help not just to assess performance but to understand the causes of performance variation?
- **Implementation** – how does the new model actually work in practice, how are inspections planned, prepared, undertaken and reported, what features of the regulatory team, standards, documents, processes and results seem to have positive or negative effects, what does the process cost and could it be done more effectively or efficiently?

This report presents the emerging findings from this research, and we have produced it to help inform the further development of the acute hospital regulatory model. We have discussed these findings already in meetings with David Behan, Mike Richards and Paul Bate; and with the Heads of Hospital Inspection, and are keen to continue to engage in presenting and discussing our findings to inform the ongoing development of the model during the early implementation phase.

This report first briefly explains what the research team has done, and what research is still in progress – there is more information about these issues in our research proposal [6]. We then set out our summary findings in five areas:

- Evidence, key lines of enquiry and the use of information
- Inspection teams
- Inspection processes
- Judgements, ratings and reports
- Trust perspectives and responses

We conclude by summarising what we would see as the key learning from the research to date. The report throughout refers to “acute hospitals” as the focus of inspection – these hospitals are of course part of NHS trusts or NHS foundation trusts, and the inspections have been of those trusts, some of which run a single acute hospital but some of which have two or more major acute hospital sites (or locations) within their organisation.

The research team would like to record their thanks to the many people from CQC, its inspection teams, and from the acute hospitals which have been inspected, for being willing to share their views and experiences with us and to commit time to doing so, especially at times when many have been working under great pressure and to very tight deadlines. We have found a consistent and shared interest among them in understanding how the new acute hospital regulatory model works, and how it can be improved.

Research: progress to date

Between September 2013 and January 2014 we gathered information from a wide range of sources including:

- Documents about the new regulatory model and the acute hospital inspection framework, including guidance, templates and the documents produced for the inspections in wave 1
- Interviews with 18 people in CQC and from some other agencies (NHS England, Department of Health, Monitor, the Trust Development Authority) about the new acute hospital regulatory model, how it had been developed and how they thought it was intended to work
- Observed inspections for 6 acute hospitals in wave 1, chosen to provide a range of size/scale, geography and risk/performance. For each inspection two researchers attended the inspection from start to finish, observed most or all aspects of the inspection process and had many informal discussions with participants from CQC and the hospitals, totalling about 48 person-days of observation
- Telephone interviews with selected CQC inspection team members and hospital staff following wave 1 inspections (both those we observed and those we did not) with about 40 interviews to date
- Attending and observing a number of meetings of the quality assurance group which reviews reports, the quality summits for the acute hospitals where we observed inspections, and various other meetings such as the feedback meetings for representatives from acute hospitals in wave 1

Our fieldwork is continuing, as we seek to complete interviews with some people from acute hospitals in wave 1, undertake interviews with people from CQC inspection teams and acute hospitals in wave 2, and undertake a survey of all CQC inspection team members and a sample of senior managers and clinicians at acute hospitals in wave 2. We are also considering whether it would be useful to undertake some more observed inspections towards the end of wave 2.

We would caution that we have had limited time to fully analyse the data from fieldwork for this interim report, that because of the timing of inspections, report publication and our interviews we have less data from acute hospital interviewees at this stage than we have from people within CQC and its inspection team. These early findings are presented for discussion, and do not represent a summative statement on the new regulatory model.

Evidence, key lines of enquiry and the use of information

The new regulatory model is premised on the use of three main sources of information in inspections: performance data from a range of sources (like the national patient and staff surveys, HES-based indicators, incident reporting data from NRLS etc); documents, reports and the views and assessments of others (such as professional regulators, Royal Colleges, purchasers, etc); and fieldwork conducted by CQC inspection teams themselves.

The data pack prepared for each inspection has been an impressive, high quality and very readable though lengthy summary of the available performance data. It has not been available more than a few days before inspections, and much of the data it contains is at NHS trust/foundation trust or hospital (rather than core service) level. As such, making sense of the data and using it to frame questions or lines of enquiry for the inspection has been a challenging task which requires a sophisticated understanding of the data and its interpretation, and we do not think CQC teams necessarily have those skills at present. For these reasons, we have observed teams using the data pack at the outset of inspections to frame their general understanding of the organisation, but not making much applied use of the data pack during inspections. We are aware that there are already plans to develop more focused data packs for future inspections

The other sources of data – reports, documents, policies and procedures, submissions from organisations and the like – are highly heterogeneous and there is a substantial volume of them – for some inspections there have been 500+ documents to analyse. There has been no established structure or method for doing this, and it requires a lot of resources and skill to sift, sort and synthesise these documents. We have observed data analysts and others in inspection teams trying to use these sources of information, and asking for substantial amounts of further information during the inspection itself, but having insufficient capacity to deal with the volume of unstructured and heterogeneous data that results.

Inspection teams have had key lines of enquiry (KLOEs) which have been essentially high-level structured lists of brief prompts or issues to consider in core service areas and at hospital level, and they have been encouraged to put together their own service-specific KLOEs as part of their preparation for inspection fieldwork. In practice, we have observed the KLOE framework being used quite variably, with some teams making more use than others of the pre-defined lists and teams finding it hard to develop their own KLOEs in the time available at the start of the inspection.

During the inspections, CQC inspection teams have invested most of their time and effort in their own fieldwork – conducting 1:1 interviews with a range of staff, holding focus groups, visiting wards and departments and observing services and care delivered, talking with patients and relatives, holding public listening events, and so on. We think that in practice, it has been this fieldwork that has predominated both in the process of the inspection and its outcomes (forming judgements and, where relevant, ratings, reporting and so on, which are discussed below) because of the challenges that team members face in using the other data sources in the time available.

We would also observe that though acute hospitals have been asked to provide substantial amounts of information for the inspections, both beforehand and during the inspection itself, and that has in

a way been a test of their abilities to retrieve data and report on issues, the inspection process has not provided much insight into the way that these organisations manage and use information about performance for themselves, how accurate and detailed an understanding they have of their own performance, or how they have responded to or acted on performance data to produce improvements.

Inspection teams

The new regulatory model uses inspection teams that are much larger than in the past, with a combination of CQC staff (inspection leads, inspectors acting as sub-team leads, analysts, and planners/logistics support including staff from Pricewaterhouse Cooper); patient/public representatives and/or experts by experience; and NHS staff from other acute hospitals and other agencies with a range of clinical and managerial experience. The non-CQC staff on inspections have included board level medical directors and chief nurses, senior managers, allied health professionals, clinical directors, consultant, senior nurses, junior doctors and student nurses. Inspection teams have typically been made up of about 30 to 40 people but in larger hospitals have involved up to 80 people.

These large inspection teams have undoubtedly contributed to producing a much more rigorous and detailed inspection process, with far more depth and reach into the organisations being inspected than in the past. The greater content expertise and credibility of inspection teams has been widely welcomed. However, the size of the teams makes them more difficult to manage effectively, with communication, coherence of approach, and allocation of roles/responsibilities all proving complex.

Inspection teams had been recruited and assembled rapidly – there had been minimal selection, training and matching of team members to roles, and logistics, timetabling and diary availability have of course been important considerations. The potential for conflicts of interest, where team members had prior relationships with the acute hospitals they were inspecting, has largely not been surfaced.

Most inspection team members have been allocated into subteams with particular core service areas assigned to them to inspect, led by a CQC inspector as the sub-team lead. We found that the best subteams were compact and had members with clearly defined complementary roles and expertise including a subteam lead who both understood the content area and brought regulatory expertise to the subteam. But in some subteams, roles and expertise have been less clearly allocated, and despite their different backgrounds team members have seemed to have a generic role which did not particularly capitalise on their content expertise.

Our observation would be that the combination of strong content knowledge of the clinical service areas being inspected, strong interpersonal and relational skills (rapport, sensitivity to context, questioning skills etc) and strong understanding of the regulatory process (inspection methods, processes, tools etc) is crucial to securing both inspection teams' credibility in the eyes of the acute hospitals they inspect and to the confidence with which inspection team findings can be regarded.

Content expertise is a challenging area to get right. Even with very large inspection teams it is practically difficult or impossible to get clinicians (doctors, nurses, other healthcare professionals) with specialty level content knowledge in every area that a subteam will inspect. So while current content knowledge is important, these team members need to be able to apply their content knowledge of acute hospitals across more than just their own specialty or professional group.

CQC staff on inspection teams act as subteam leads, and CQC data analysts support team functioning in using data and gathering evidence during the inspection. For the CQC inspectors who lead subteams, this new regulatory model has required a complete change of approach, and those who seem to have embraced it and progressed are those with recent acute hospital experience and some existing specialisation in this area within CQC regions. It is a very different task/role from that which they fulfilled in the past. For the CQC data analysts, this has been generally their first direct involvement in undertaking inspections, and a very substantial change in their role. The principle of bringing data analytic capacity more directly into the inspection team seems crucial to the new regulatory model, but we would observe that data analysts will need to develop a more detailed contextual understanding of the performance data in order to be able to advise and support inspection teams effectively, rather than just acting as information providers and collators.

Inspections have been led by a CQC inspection lead (generally a senior inspector/compliance manager, and now a role taken on by the recently appointed Heads of Hospital Inspection) and an inspection chair (generally a board level doctor with experience as a trust medical director and in other senior roles outside their own organisation). These dyads often seemed to work well, but there was some overlap in roles and some ambiguity about responsibilities and leadership in different parts of the inspection process. It seemed that board level inspection team members (not just board level doctors) were very important to the credibility of the CQC inspection and particularly to the interactions with the board of the organisation being inspected.

Inspection processes

Inspections have generally taken place over three to five days, depending on the scale and complexity of the acute hospital being inspected. The format of the inspection has changed somewhat over time, but in general terms there has been an initial day when the inspection team has met face to face for the first time, and been briefed by the CQC inspection lead, chair and CQC staff on the inspection process and on the acute hospital they are inspecting. They have usually had a presentation from the hospital chief executive, and time to work in their subteams to plan their fieldwork in core service areas, using the available data to decide what services/departments to visit, who they want to see, what KLOEs to follow and why, what further information they want or need, and which subteam member will take on each fieldwork task.

There has then been usually two or three days of actual fieldwork – with the inspection team working largely in their subteams on the fieldwork they have planned, but meeting at least three times a day as a subteam to share findings and review progress, and meeting twice a day with other subteams in corroboration sessions to share and test emerging findings. The final day of the inspection has been given over to completing any remaining fieldwork, and working in subteams and in the whole inspection team to agree and refine judgements, to test the methodology for ratings

and to discuss the supporting narrative content to be used in the report. At the end of the final day, the CQC inspection lead and chair have given initial feedback on the inspection to senior executives from the acute hospital. Some members of the inspection team (largely but not solely CQC staff) have then undertaken a further unscheduled or "unannounced" inspection after the main inspection has finished.

The initial day of the inspection has been termed a training day, but we observed that inspection team members received little actual training and the time was necessarily mostly devoted to team familiarisation/team building, to briefing/learning about the acute hospital being inspected, and to inspection planning. There was quite a lot of information in the inspection framework and guidance for inspection team members to absorb, and most had not done much preparation in advance of the inspection, in part because information was often sent out close to the inspection date.

Inspection fieldwork has been an intensive and very demanding process both for CQC inspection team members and for the acute hospitals being inspected. In the absence of either much prior training or much explicit guidance and methodological direction, fieldwork has been highly inductive, experiential and intuitively led by inspection team members, whose prior knowledge, experience and views/attitudes have tended to shape the direction and content of their enquiries. Fieldwork has not been particularly structured or directed by, for example, the performance data and other information gathered in advance, but has been largely led by what inspection teams have found themselves through their own data collection.

Corroboration sessions, where team members meet both in their subteams and then in plenary with the whole inspection team, have been important opportunities to discuss and share emerging findings. Subteams have often struggled with the time pressures of fieldwork and corroboration and have been still agreeing their own findings while plenary corroboration discussions progressed, and in large teams the plenary sessions have been difficult to make really interactive and productive. The process of rating hospitals and core service areas has tended to take up much or even most of the time in corroboration sessions.

The intensity of the inspection process – with inspection teams working very long days, and undertaking difficult and complex tasks – may be seen as either a strength or a concern. It may contribute to the overall sense of purpose of the inspection and make the maximum use of inspectors' time in the acute hospital. But it may also make unreasonable demands on inspection teams' stamina, lead to less than optimal performance at times, and discourage some inspection team members from taking on the role again in the future. More importantly, we would question whether the relentless pace of fieldwork allows sufficient time for reflection and analysis, or represents the effective use of inspection teams' time.

The structuring of the inspection team and the process into eight core service areas seems to be an effective and generally well received way to break down the complex multi-service nature of the acute hospital into manageable subunits, and this structure has been adjusted to some degree for individual inspections to take account of the different configurations of secondary and tertiary acute hospitals. However, there are some significant clinical services which don't naturally fit into this structure, and some services (like radiology, pathology, therapy services etc) which cut across all

core service areas but may not be the focus of attention in any of them. A further issue to note is that many non-clinical organisational or corporate functions (like education and professional development; research and innovation; information management; audit or clinical governance; and so on) are even less well covered by the core clinical service areas, but may be equally important both to measuring and understanding the performance of those service and the acute hospital as a whole.

Judgements, ratings and reports

In each acute hospital inspection in wave 1, inspection teams have been asked to make judgements about the performance of the hospital in five domains (safety, effectiveness, caring, responsiveness, well-led) and have tested how they might rate each of eight core service area and the acute hospital as a whole in each of these areas on a four point scale (inadequate, requires improvement, good or outstanding). In practice, this would mean that each hospital would get about 45 individual ratings or scores, and an NHS or foundation trust with more than one major acute site gets ratings for each site individually. Ratings have not been included in reports. With the exception of 3 trusts that had been part of a shadow ratings pilot (Heart of England NHS Foundation Trust, Dartford and Gravesham NHS Trust, and Royal Surrey County Hospital NHS Foundation Trust), the trusts were not formally rated as this had been an internal exercise in testing out the rating process.

There has been relatively little guidance in the inspection framework on how to arrive at these judgements and ratings – the five domains are defined quite briefly, and the meaning of each of the four grade descriptors is not spelt out in much detail either. None of the guidance has been currently specific to core service areas, so there is little so far to say what service specific issues or characteristics belong in which domain, or what represents performance at each grade descriptor level. As a result, we observed that the process of reaching judgements and assigning ratings was largely implicit, and was shaped by inspection teams' prior experience and views/attitudes and by subteam discussions where one or two team members' opinions could be very influential. Much of the discussion in corroboration meetings related to the issue of how to reach these decisions. We think that domains and grade descriptors were interpreted differently within and across inspection teams.

We found that inspection teams have engaged readily with testing the process of assigning ratings, and the framework has provided a mechanism for ensuring all areas are considered and promoting some consistency of approach. They have found the process difficult, but because of the pressures of time and deadlines tended, with encouragement from subteam leads and inspection leads/chairs, to just get on with doing it. They often had a lot of data about a given core service area, from many different sources, and there was no defined method or approach for combining or synthesising this into a single rating. We heard many debates about how to weight or value different sorts of evidence, and how to combine evidence of performance at different grade descriptor levels (for example, instances of both outstanding and poor practice) into a single rating.

Perhaps because of the intensive pressures of fieldwork during the inspection and the focus on testing the rating process, rather less attention was given during inspections to creating the narrative accounts of performance in each core service area and domain for the report. As a result,

the drafting of those reports has fallen largely to CQC inspectors acting as subteam leads, who have had to work from the evidence sheets completed by inspection team members during the inspection – which, in themselves represent a very immediate impression from observations, rather than a balanced reflection.

The purpose of the unscheduled or "unannounced" inspection was principally to address the concern that because the hospital knew when the inspection would take place and had some weeks or months of advance warning, they would be able to prepare for the inspection and present a perhaps unduly positive picture of performance during the inspection. It was also to be focused on out of hours provision, given the main inspection took place largely during the working week. In practice we found the unscheduled inspection was used partly for these purposes, but also became a way for the inspection team to follow up on areas where at the end of the main inspection they either had concerns or felt they had insufficient information to report.

Trust perspectives and responses

Overall, the new regulatory model seems to have been received very positively, and seen as both more credible and more rigorous than the inspection process it replaced. Some trusts have made a positive effort to get their staff involved in the inspection teams, both to contribute to the process and to learn about it for the benefit of their own organisation.

For the NHS trusts whose acute hospitals have been the subject of these inspections, the process has been a substantial undertaking, with most organisations setting up some form of project team and assigning staff to lead on preparation and to manage the process. There were many concerns about the cost, scale and pace of the process – the amount of work needed in advance to prepare and to supply information, the size and scale of the inspection team and its impact on services during the inspection, and the deadlines for providing information and responding to CQC before, during and after the inspection.

We saw some efforts on the part of NHS trusts to "manage" the inspection process – for example through briefing their staff on what to say to inspection teams and on what to do during the inspection, selecting staff to take part in staff focus groups, ensuring that ward and departments were fully staffed during the inspection, asking staff to report during the inspection on their contact with the CQC inspection team, and so on. We are not sure whether these efforts made much difference to the assessment of the acute hospital made by CQC or to the contents of the report.

Each inspection has been followed by a process for drafting the report, agreeing it with the NHS trust/foundation trust, and then publishing it at the same time as a quality summit at which CQC has reported on its findings and the NHS trust/foundation trust has responded and outlined its action plans. Other stakeholders, such as Monitor, the Trust Development Authority, NHS England, and local clinical commissioning groups (CCGs) have also been represented at the quality summit. From our observations, we think the quality summit provides a useful public platform for report publication, but we are not sure that in itself it leads to the development of an effective action plan from the NHS trust/foundation trust. The report is published around the day of the summit and so has not been widely shared or distributed within the acute hospital beforehand, which probably

hampers effective action planning. Further, it was sometimes unclear to us and those represented at the summit who is subsequently responsible for holding the trust to account – particularly foundation trusts.

Conclusions and key learning

We conclude that CQC has made remarkably rapid progress in developing and establishing a largely new acute hospital regulatory model over the last six to nine months. This is a complex and challenging undertaking, which has been tackled at great pace. In retrospect, a less ambitious programme of inspections in wave 1 and wave 2 might have allowed those centrally involved in developing the new regulatory model more time and space for development, testing and refinement.

We think at this stage there are four main areas where further development of regulatory model could bring real benefits:

- The quality of inspection team members seems to be a key determinant of the diagnostic value and effectiveness of the inspection process – they are, to the acute hospitals, the face of CQC and their competence, credibility and confidence in what is a difficult role is crucial. The selection, training, deployment and performance appraisal of inspection team members needs detailed attention. We think higher quality inspection teams could function with fewer members. Work is also needed to build the skills, capacity and contribution of CQC team members such as inspectors and data analysts.
- There needs to be somewhat more structure across many of the systems for inspection and the inspection process, in order to maximise the validity and reliability of inspection judgements and the efficiency and utility of inspection teams. For example, there could be more structured forms of enquiry to gather performance information for the core service areas in advance of inspection, more detailed and specific core service KLOEs and associated guidance, and more templates and frameworks to guide the content of fieldwork. There is a difficult balance to strike here – enough structure and guidance to make fieldwork robust and reproducible, while still allowing scope for professional judgement and discretion on the part of the inspection team. Again, we think more structured forms of fieldwork could help to make better use of inspection team resources.
- The processes for arriving at ratings of acute hospitals and core service areas need to be more transparent and defensible. This is perhaps the most challenging of the four areas for improvement, as building robust and reproducible rating systems for such complex organisations is difficult. One approach might be to reduce and simplify the number and form of individual ratings required for each hospital; another could be to specify in much more detail the domain and grade descriptors, probably at the level of each core service area; a third could be to train inspection teams using sample ratings, and regularly review ratings from inspections to assure the consistency of inspection ratings.
- It is too early for us to be able to draw any meaningful conclusions about the impact of the new acute hospital regulatory model, and particularly the extent to which it leads to changes and improvements following inspection. However, we think that this is perhaps the hardest part of

the regulatory model to get right, and one which may often get less attention because of the more urgent or immediate needs of the inspection process itself. So far, the quality summits do not seem likely to be, in themselves, the primary level for post-inspection action and improvement.

References

1. Care Quality Commission. Acute NHS trust and foundation trust hospitals: framework for inspecting wave 1 and wave 2. London: CQC, 2014.
2. Care Quality Commission. Acute hospital regulatory approach – logic model. London: CQC, 2013.
3. Keogh B. Review into the quality of care and treatment provided by 14 hospital trusts in England: overview report**.** London: DH, 2013.
4. Greenfield D, Braithwaite J. health sector accreditation research: a systematic review. Int J Qual Health Care (2008) 20(3): 172-183.doi: 10.1093/intqhc/mzn00
5. Benson LA, Boyd A, Walshe K. Learning from regulatory interventions in healthcare: The Commission for Health Improvement and its clinical governance review process. Clinical Governance: An International Journal, 2006; 11(3):213-224.
6. Walshe K. Evaluation of the Care Quality Commission's acute hospital regulatory model: research proposal. Manchester: MBS, 2013.