Report on the CQC Consultation on How to Regulate Independent Acute Healthcare Providers

March 2015

Contents

1. Introduction

About the consultation

CQC ran a consultation between 28 November 2014 to 23 January 2015, where they asked members of the public, stakeholders and providers, about their plans to change the way we regulate the following services:

- Ambulance services
- Primary care dental services
- Independent acute healthcare services.

About Quality Health

Quality Health is an independent healthcare consultancy, commissioned by the Care Quality Commission to support this consultation process. The consultation documents and the various processes for collecting feedback were designed and organised by the Care Quality Commission.

Quality Health has collected all the response data from all aspects of the process and captured it in this document.

Any conclusions reached in this report are therefore the conclusions of Quality Health based solely on the responses provided to the consultation; they do not necessarily represent our own views or the views of the Care Quality Commission.

You can read the full consultation response on the CQC's website here – www.cqc.org.uk.

2. Key numbers

39 respondents replied to the 8 consultation questions

31 of these replied via the webform:

- 13 Healthcare Professionals
- 6 Providers of Services
- 4 Stakeholders
- 4 Members of the Public
- 2 were a Voluntary and Community Sector Representative
- 1 CQC Staff Member
- 1 Recipient of Health or Social Care

8 submitted written responses to the consultation questions:

- 7 Professional Bodies
- 1 Borough Council

In addition, general written comments were received from

- 1 Borough Council
- 1 Professional Body

3. Responses to consultation questions

1. Do you agree that our approach to separating independent healthcare providers into three groups – as we describe in the handbook – is meaningful and appropriate?

33 respondents replied to this question:

27 agreed with this approach:

- 10 Healthcare Professionals
- 5 Providers of Services
- 4 Professional Bodies
- 2 Members of the Public
- 2 Stakeholders
- 2 Voluntary and Community Sector Representative
- 1 Recipient of Health or Social Care
- 1 Borough Council

6 disagreed with this approach:

- 3 Healthcare Professionals
- 1 Provider of Services
- 1 Member of the Public
- 1 CQC Staff Member) did not.

If you are an independent healthcare provider, can you readily recognise which of the three groups you fit into?

20 respondents replied to this question:

10 said they could readily recognise which of the three groups they fit into:

- 5 Healthcare Professionals
- 4 Providers of Services
- 1 Stakeholder

10 said they could not readily recognise which of the three groups they fit into:

- 6 Healthcare Professionals
- 2 Providers of Services
- 1 Stakeholder
- 1 Member of the Public

If not, do you have any suggestions for how the three groups could be otherwise structured or better defined?

10 Respondents replied to this question:

<u>Healthcare Professionals</u>

- I think the single specialty services band needs to be broader. I work on behalf a group of 200+ ophthalmologists who are divided into 37 Limited Liability Partnerships (LLPs). These groups provide private ophthalmic services from contracted NHS and private hospitals (in a minority of cases they have their own facilities). It's hard to differentiate whether they would be classed within the "Hospital" or "Non hospital acute" service bands. Although to class them as "single specialty service" would probably make most sense. The few LLPs who do own their own facilities are currently registered as "other independent healthcare" registered at 1 location and so pay a fee of £1540 (soon to go up!). Under these bandings, if they were to be considered as "hospitals" they would have to pay a significantly higher CQC fee and would probably have to close.
- I am a cosmetic doctor Non-surgical.
- I own a 4D baby bonding centre which is an entertainment field. We do not fit in any of the categories. We only do bonding, non-diagnostic scans. My income is around 1500/month. I only work 2-3 days per week. Registration fee is killing me. I am not taking any salary and depending on my wife’s salary. There should be earning dependant fee.
- I think the single speciality makes no sense because hair transplant clinics may also offer injectable cosmetic treatments and refractive surgery clinics may also provide cataract and squint day case surgery. it seems arbitrary to those services that someone happened to think of! better to differentiate between outpatient/day case treatment centres with no sedation/anaesthesia, (low risk), day case with with sedation/anaesthesia (moderate risk) and in patient hospitals. all the existing would fall into these, so the single specialities would be classed depending on whether they gave anaesthesia or sedation and kept overnight facilities, which are the things that increase risk in procedures and care.

- Not all facilities within HCA fit easily. Where would IHS clinical trials units sit for example? The term ˜hospital" limits the alignment of Leaders in Oncology Care (LOC) within this group as it is a stand-alone Chemotherapy Day Unit. Could the definition of a hospital environment be expanded?

Providers of Services

- We are a treatment clinic for chronic conditions and as a private clinic in integrated health, we could fit in a single speciality service or we could fit in a non-hospital service but not an acute service. Ideally there should be a separate category which deals with chronic condition treatment centres.
- I think you need link it to the old system, so the services you provide indicate which group you fall in. You need to be more specific. i think the proposed groups are unclear and as a provider i am not not sure which group i fall into.
- For some organisations, the groups defined by the CQC are practical. Ramsay Health Care UK recognises where it fits into the groupings and is content with that approach. However, it would appear that it remains a real difficulty for those organisations that provide genuinely integrated services across primary and independent care.

Stakeholder

- We do not really fit into the Hospital acute providers, but more into the small providers of more specialist services.

CQC Staff Member

- I think you need to put the non-acute independent health care such as Clinics, Vein Surgery, breast enlargement etc. into a specialist' team. The reason I say this is last years I had a 99% portfolio of such services. There is a real danger they do not get properly focused on. They require specific skills and knowledge that I acquired. This has now been lost. Plus the people who use these services are in very subtle ways very vulnerable and I think we need to put a proper emphasise on how we regulate them. I would jump at the chances to do this work as it is very specialised and deceptively complicated.

Professional Bodies

- It is important that the differences between each provider in each group are recognised and that inspections are tailored accordingly.
- For some organisations, the groups defined in the consultation are broadly practical. However, there remains a real difficulty for organisations that provide genuinely integrated services across primary and independent care. To address this we would go back to guiding principles and ask what the purpose of regulation is for. If providers are offering services that are

integrated around the needs of patients, then the regulatory approach needs to start from the same point, i.e. by looking at the approach from the same perspective as that experienced by patients. In more straightforward cases, the models proposed by the CQC work; but there necessarily needs to be appropriate adaptation for more innovative and nuanced models of care.

2. Do you agree with the approach we are proposing for regulating independent acute hospitals?

31 respondents replied to this question:

29 agree with the approach CQC is proposing for regulating independent acute hospitals:

- 12 Healthcare Professionals
- 5 Provider of Services
- 4 Professional Bodies
- 2 Members of the Public
- 2 Stakeholders
- 2 Voluntary and Community Sector Representative
- 1 Recipient of Health or Social Care
- 1 CQC Staff Member

2 Disagree with the approach CQC is proposing for regulating independent acute hospitals:

- 1 Stakeholder
- 1 Healthcare Professional

Do you have any suggestions for other things we could take into account?

14 recipients replied to this question:

<u>Healthcare Professionals</u>

- Can't provide written material requested. Either doesn't exist or is confidential (could breach UK listing rules. Some general financial information about the company is available in the public domain. To provide additional info to CQC. We would expect assurance that: it would not be published or made available to third parties or anyone outside the CQC. CQC would use only it to perform

its regulatory functions and would restrict access internally and would ensure those with access were subject to confidentiality agreements. CQC would store it securely and only hold it for as long as necessary to perform regulatory functions before returning or confidentially destroying. CQC would acknowledge that the information could constitute inside information and those with access to it should act accordingly. CQC acknowledges that it is aware of its obligations under all applicable law and regulations and ensure that all relevant staff, advisers etc. are likewise aware and will provide a list of these. Requests for such information should be submitted centrally to our Company Secretary and not to the individual Spire hospitals.

- Would the ratings be banded the same as NHS trusts?
- All providers of injectable cosmetic and surgical cosmetic treatments should be CQC registered. This should be mandatory and inspection should be enforced.
- I hope that the CCG is represented in the multi-disciplinary feedback session if the independent acute hospital provides NHS care / treatment.
- Would a Clinical Trials Unit be treated in the same way as Fertility Services in that they are also highly and specially regulated by an independent regulator?

<u>Provider of Services</u>

- In essence yes, but I think it's unclear. I also think independent healthcare is so vast and so different from NHS that i think you should publish a separate handbook. I don't think it's appropriate that we should just have to accept the NHS one. You say that inspectors will be expert that is we expect them to be experts in the services we provide and in independent healthcare. we have been told that we will have inspectors from the NHS, which is not always appropriate. I have also heard that you already have agreed figures for which organisations can get an outstanding and good rating.
- In some independent provider hospitals in order to make a complete assessment of all of the 5 areas of concentration of the core services relevant to that organisation. It may be necessary to engage in an appropriate level of discussion in advance of the assessment for dates and services provided on those dates. This would ensure a comprehensive inspection visit.
- The new approach represents a significant improvement on the old essential standards model. It is useful to note the CQC has been responsive during the consultation process, for example in adopting a distinctly more positive articulation of good care. However, we do have a number of concerns that have arisen from the consultation document and also from the pilot inspections themselves: The size and composition of inspection teams in several of the wave one inspections: the size of teams has been

disproportionately large for relatively small providers and has on occasions lacked relevant expertise and experience of independent sector care. This has been stressful for both patients and staff. The number of inspectors for the length of time has caused significant disruption to the hospital. The use of Intelligent Monitoring we welcome the principle of intelligent monitoring and we share the CQC's view that the metrics used to assess NHS organisations do not always translate to independent providers. The independent providers do, in most cases, measure similar statistics but often using different metrics and these should not be ignored. We would welcome more intensive engagement as each individual metric often requires significant work to understand issues related to its comparability with NHS indicators. The schedule for rating services. We welcome the principle that all services should be rated according to the same principles and characteristics and we also welcome a risk-based approach informed by Intelligent Monitoring. However, this means that those organisations identified as posing the least risk through the Intelligent Monitoring process may not receive full ratings until well into 2016. These delays will not support informed decisions by patients and referrers. It is therefore important that once we have a clear view of how the Intelligent Monitoring process applies to independent providers, patients and other healthcare professionals should be able to view this information in an easy-to-understand way in lieu of formal ratings. The CQC is proposing to regulate all facilities within Year 1 (2015) and issue a rating. This will be particularly onerous for large providers if this is done before the corporate provider is assessed centrally, as it will require the same information being uploaded from each hospital site. As this takes a great deal of man hours it will be both onerous and costly. Consideration should be given to uploading information centrally as well as locally. We have a concern about the element of subjectivity of the inspectors and how they are trained for the role. We believe it is possible that personal views and less than clear detail in the KLOEs may lead to subjectivity particularly from those who do not understand the independent sector. Our experience to date shows that the minority of inspectors have experience working in the independent sector. In addition, if an organisation has valid concerns about an individual inspector, would it have the right to decline that individual as an inspector? There may be issues regarding business sensitivity or commercial conflict. We recognise the impartiality of inspectors, however there may be potential conflicts not previously recognised.

Stakeholder

- Just classifying the types of overall service provided, does not take into account the key differences in the patient demographics which impact most on service outcomes. It is important to recognise that independent sector hospitals can choose lower risk, less complex cases (ASA level 1 and 2) and therefore they may appear to have better results if comparison to NHS Centres is made.

Recipient of Health or Social Care

- I think that checks should be at least as thorough as for the NHS.

Professional Bodies

- While we are aware of the Memorandum of Understanding between the independent healthcare sector and the NHS about the transfer of patients in the event of emergency situations, checks should be made that provision is in place safely to deal with emergencies which arise and for the safe transfer of patients to an NHS hospital if necessary.
- Whilst aiming for comparability with the NHS the differences should be recognised and not viewed as a negative. In most cases it is a positive for example the waiting times and/or choice of time to suit patients. More work needs to be done to broaden the understanding of the Independent Healthcare Sector model and how the service differs from the NHS. Perhaps actively recruiting inspectors from the Independent Sector would help in this? The corporate data which will apply to all the organisations/hospitals should be collected/assessed and then applied to the individual hospital rather that at each inspection. The size and composition of inspection teams as experienced in the wave one inspections: the size of teams has been disproportionately large for relatively small providers and has on occasions lacked relevant expertise and experience of independent sector care – while we welcome the consultation's comments that the teams 'will be significantly smaller than most comprehensive inspection teams for NHS trusts' members are still uncertain about how this will be implemented. The use of Intelligent Monitoring – we welcome the principle of intelligent monitoring and we share the CQC's view that the metrics used to assess NHS organisations do not always translate to independent providers. We recognise that the CQC's EAG is looking at this area and would stress the need for continued and more intensive engagement as each individual metric often requires significant work to understand issues related to its comparability with NHS indicators. The schedule for rating services – we welcome the principle that all services should be rated according to the same principles and characteristics and we also welcome a risk-based approach informed by Intelligent Monitoring.

However, this means that those organisations identified as posing the least risk through the Intelligent Monitoring process may not receive full ratings until well into 2016. These delays will not support informed decisions by patients and referrers. It is therefore important that once we have a clear view of how the Intelligent Monitoring process applies to independent providers, patients and other healthcare professionals should be able to view this information in an easy-to-understand way in lieu of formal ratings.

- We believe that service accreditation schemes could also provide valuable information for informing CQC inspections. We are currently working with the Clinical Service Accreditation Alliance (CSAA), which is a cross-Royal College group, developing a common methodology to meet the needs of a variety of stakeholders in relation to hospital service accreditation. Their work will focus on producing a generic framework that will form the basis of individual clinical service accreditation schemes. In order to develop this work, we are collaborating with the CSAA to facilitate the process of developing and publishing a generic, national standard. This will involve stakeholders from a variety of clinical services, experts from primary and community care, regulators and statutory bodies, healthcare commissioners and trust boards, and patient advocacy groups from across the UK, and CQC has been supportive of this initiative during the preliminary discussions that have been held. There is a potential for new, professionally-led accreditation schemes to be developed that will cover different services and procedures. By following a common methodology, these schemes could provide useful information to CQC in helping to inform when, what and where to inspect.
- There are two major problems which need to be overcome to ensure that inspections and grading of these units are meaningful. The first is to ensure that accurate data is collected. Secondly, the CQC will require feedback from the local population about local services. However, a private hospital's population may be more diverse and in some cases spread over a region. Achieving meaningful patient/user feedback may become more difficult.

3. Do you agree with the approach we are proposing for regulating single specialty services?

28 respondents replied to this question.

25 respondents agree with what CQC is proposing for single speciality services:

- 12 Healthcare Professionals
- 4 Providers of Services
- 2 Members of the Public
- 2 Stakeholders
- 2 Voluntary and Community Sector Representatives
- 1 Recipients of Health or Social Care
- 2 Professional Bodies

3 respondents disagree with what CQC is proposing for single speciality services:

- 1 CQC Staff Member
- 1 Stakeholder
- 1 Healthcare Professional

Do you have any suggestions for other things we could take into account?

12 respondents replied to this question:

<u>Healthcare Professionals</u>

- I think the concept of inspecting similar services at the same time is good. This would however limit the element of "surprise" inspections.
- The single speciality service list is too specific
- If HCA Laboratories fall into this category there is concern that they are already regulated by UKAS through the CPA Clinical Pathology Accreditation programme. Will there be a combined approach to avoid duplication?

<u>Providers of Services</u>

- Inspections: Size and configuration of inspection teams - please be mindful that there can be huge variation within the independent sector in single speciality services (SSS) in relation to the size and staffing complement of units/clinics/treatment centres and that those will require the CQC to consider carefully how large an inspection team to send, and how much time the inspection will take. For services with few staff, taking out a single staff member to host the CQC inspection, particularly if unannounced, can have a significant and detrimental impact on immediate service delivery. Specialist inspectors - in an SSS like abortion care, there are two main independent providers which provide around 50% of abortion procedures between them, and then numerous NHS providers which provide relatively tiny numbers of abortion procedures each, to make up the other 50%. The expertise in

abortion care therefore largely comes from the independent sector, with a few notable NHS provider exceptions. The questions then are (i) who will be the specialist inspectors for termination of pregnancy who will have sufficient expertise to usefully and effectively inspect and make recommendations, as the resource pool is tiny and largely concentrated within the independent sector? (ii) how will the CQC 'manage' potential conflicts of interest should specialist inspectors from one independent provider be part of a team inspecting a competitor - in such a specialist area as abortion, this may very well be the case (iii) given the politically and ethically sensitive issue of abortion, how will the CQC assure itself, and those being regulated, that personal views of inspectors are congruent with a responsibility to inspect abortion providers? PIR - please give as much notice for completion as possible and please gather as much data corporately as possible, rather than duplicating the request for the same data from each individual site. BPAS has 35+ separate units but much of the data the CQC will request can be provided on a corporate level and this will relieve the pressure on the individual sites.

- We agree but feel they should be tested as well before rolling out.

<u>Stakeholders</u>

- Single private clinics represent some difficulty in that they are comparable to similar privately organised clinics. It is essential that these are judged by validated PREMs and PROMs. As stated above, for hospital services, the types of cases and patients being treated in the service should be taken into account.
- The present changes of the CCG management obviously have a certain amount of effect on this small provider service and may make it necessary for us to reduce or upscale what we are doing in any one year.

<u>Professional Bodies</u>

- We note that the single specialty services are certain services which are the independent provider's 'main' or 'sole' activity. If there is a degree of judgement as to whether a provider is 'mainly' or 'solely' single specialty, it may be helpful for providers be asked to review their categorisation. On the proposals on scheduling and inspecting for larger providers with multiple locations, it might be more efficient, and help to provide relevant evidence, to assess much of the governance process at a centralised level and then check the application of those procedures at a sample of locations. Then, over time, the sample could be rotated to assess all sites. Single specialty services prompts – When looking at the prompts and service-specific guidance we have a concern over taking a single approach to diagnostic imaging and

endoscopy and diagnostic laboratories as, for example, laboratories will do little if any direct patient facing activity.

- The CQC should take into consideration the work that Health Education England has done with regards standards for Hair Transplantation services.
- The proposals to schedule the inspection of single specialty services in separate blocks makes sense and members appear to be broadly content with the proposals. We would caution the CQC that inspections of each specialty area should be tested before the block inspections are rolled out so that learning can be incorporated into the inspection processes.
- In addition to working in a national capacity that we have outlined in Q2, we also represent the UK in the European and international standards organizations. We have established national stakeholder committees that provide input into the developing European (CEN) standards for aesthetic surgery services, aesthetic non-surgical medical services and beauty care services. With the imminent publication of these standards, we are currently speaking to several professional and statutory stakeholders with regard to the next steps of implementation, and the potential for accreditation scheme development. An example of this is with Health Education England (HEE), who are considering establishing a joint industry standards body to consider cosmetic procedure qualification requirements. The benefits for this group in working with us are based on us being an independent organization with no allegiance to any particular group of stakeholders, on our robust and inclusive processes for developing, publishing and maintaining standards and on our experience with managing diverse stakeholder groups to develop principles that allow everyone to achieve a common goal. Whilst the focus of HEE is on qualifications, rather than service provision, we believe that we have an established stakeholder group who would be interested in developing accreditation schemes to support a range of cosmetic services. We would welcome the opportunity to discuss this with you further, in order to ensure that any future schemes can help inform CQC inspections.
- In regulating single specialty services listed in the paper, some specialty services may be easier to regulate than others - haemodialysis services will be linked to renal units based in NHS Trusts, thereby allowing accurate data on outcomes, complications and feedback being achieved. In contrast, we have seen a growth in private diagnostic imaging services being set up. This growth has come about from increasing use of private diagnostic imaging being conducted within NHS Trusts. To ensure that these private radiology services are providing a safe, effective and well led service will entail input from their NHS users and potential follow up unannounced visits.

4. Do you agree with the approach we are proposing for regulating non-hospital acute services?

29 respondents replied to this question.

26 respondents agreed with this approach :

- 11 Healthcare Professionals
- 5 Providers of Services
- 2 Members of the Public
- 2 Stakeholders
- 2 Voluntary and Community Services Representative
- 1 Recipient of Health or Social Care
- 1 CQC Staff Member
- 2 Professional Bodies

3 respondents did not agree with this approach:

- 2 Healthcare Professionals
- 1 Provider of Services

Do you have any suggestions for other things we could take into account?

9 respondents replied to this question:

<u>Healthcare professionals</u>

- We need clear guidance for our core standards which will allow a rolling audit programme of these. It is important that we show how good a service we are delivering but also are able to continue to deliver it rather than place increasing burdens of evidence gathering on our front line clinicians. Audit, training and record keeping 'rules' would standardise assessments and ultimately make comparisons easier.
- Would "Expert hospital inspectors" be experts in the specific services being provided? Greater clarification is needed on who would be included within this band.
- I think the importance the CQC places on engaging with service users and people with experience of using care should be built into the inspection.

- Aligning patient feedback scoring with the approach used in GP appraisals/validation, so one data set can be used for both activities.

Provider of services

- This category is not clear.
- BPAS (as one of the largest independent abortion providers) would very much welcome the opportunity to be included as a pilot provider for the new regime.
- We recognise that any system of ratings should have a robust basis and we therefore understand the CQC's reluctance to commit to a ratings approach at this stage. We would encourage close engagement with non-hospital acute providers before deciding on ratings.

Professional Body

- Section 2 proposes that indicative 'shadow' ratings are published for those independent acute hospitals in the second wave of testing. As it is possible shadow ratings may be given the same weight in the public forum as formal ratings it should be clear that these ratings are not draft or indicative designations.
- However, some form of rating system is required to help the consumer assess the suitability of that service before paying for that service. The rating system needs to be fair, consistent and replicable. To achieve that, the desired rating system may require a longer lead time than that proposed in the paper.

Do you agree that we should continue to engage with non-hospital acute providers before deciding on ratings?

29 respondents replied to this question.

27 agree that CQC should continue to engage with non-hospital acute providers on ratings.

The 10 of these respondents who explained their answers said:

Healthcare professionals

- This is crucial to them and it is always easier to justify a decision after discussion.
- The agreed rating needs to be meaningful and to inform the patients who use the service of the quality of the service and any shortfalls so that the decision to use the service is an informed decision.
- Yes for the public perception.

- To ensure transparency and openness the CQC should continue to engage with non-hospital acute providers to identify a meaningful and practical way of rating these services.

Providers of services

- Patients using these services are far more likely to be influenced by their friend's or family's experience of the service than any rating that they can look up on a web site. These services are personal and relate to personalities as well as absolute standards and quality of service. If we do not provide quality of service then word gets round and we go out of business.
- Although this is a potential high risk but one which requires some further explanation of consistent regulation prior to ratings.
- We believe that the principle of developing comparable ratings across all services is one that should be encouraged as it is helpful to patients and other essential groups as well as driving improvement. However, the lack of ratings for this group poses potential problems: specifically patients and referrers will find it harder to make decisions about the relative performance of services; and there is potential for confusion when assessing organisations that provide both hospital-based and non-hospital-based acute services

Stakeholders

- We welcome you to try to rate us, but we are tending to specialise in an unusual specialty which no one else seems to want to belong to. I only know of one other clinic in the UK.
- Yes this is essential.
- Engagement should produce a jointly agreed approach that has most impact.

2 respondents did not agree that CQC should continue to engage with non-hospital acute providers on ratings:

1 Member of the Public

- Engagement and consultation is usually good idea, but can be used to frustrate much needed reform. Sometimes you need to show some leadership and direction.

1 Voluntary and Community Sector Representative

- Similar rating processes as for other organisations would seem appropriate.

What sort of guidance would be useful for this sector in the meantime?

7 respondents answered this question:

Healthcare Professionals

- A short set of standards to which they would be expected to work.
- Greater clarification on the bands. Further clarification on how the fundamental standards would be mapped against the give key questions and, if the provider handbooks aren't applicable, what high level prompts would be used to each key question.
- Ratings are always open to criticism as to a certain extent they are regarded as value judgements and often resented - unless top grade. Actual findings factually reported and highlighted if necessary are more effective and retain better relationships even if the conclusion is "could do better".
- Publishing the supporting guidance outlining the assessment process, criteria used and scoring system in plain English Hosting Workshops to engage and inform the sector lead by CQC assessors, rather than third party training firms. The ICO uses that approach and it is hugely helpful

Stakeholders

- PREMs and PROMs would be a useful measure of quality.
- Learning from similar inspections, things to consider and put to place with examples.

Professional Body

- We recognise that any system of ratings should have a robust basis and we therefore understand the CQC's reluctance to commit to a ratings approach at this stage. To this end, we would certainly encourage close engagement with non-hospital acute providers before deciding on ratings. We believe that the principle of developing comparable ratings across all services is one that should be encouraged as it is helpful to patients and other essential groups as well as driving improvement. Consistent with this approach, it is important to avoid circumstances that have arisen in the past when blunt statements along the lines of 'information not available' have been used. Such wording fosters uncertainty and gives no explanation for what can often be reasonable situations. It is therefore important that should circumstances arise were ratings cannot be published, the underlying reasons are explained clearly to patients and other audiences, and should be easily available.

5. Do you feel confident that the changes we propose to the acute provider handbook will help our inspectors to assure the public on how safe, effective, caring, responsive and well-led independent acute hospital and single specialty providers are?

26 respondents answered this question.

21 respondents agreed that the changes proposed will help inspectors to assure the public on how safe, effective, caring, responsive and well-led independent acute hospital and single speciality providers are:

- 8 Healthcare Professionals
- 3 Professional Bodies
- 2 Providers of Services
- 2 Members of the Public
- 2 Stakeholders
- 2 Voluntary and Community Services Representative
- 1 Recipient of Health or Social Care
- 1 CQC Staff Member

5 Respondents did not agree that the changes proposed will help inspectors to assure the public on how safe, effective, caring, responsive and well-led independent acute hospital and single speciality providers are:

- 3 Healthcare Professionals
- 1 Provider of Services
- 1 Stakeholder

If not, what is missing?

11 Respondents replied to this question:

<u>Healthcare Professionals</u>

- It will depend on how the changes are explained and how the inspections are reported. General public knowledge about private services is scanty and the actual reports of the inspections will be studied very carefully.

- Inspections are seen more as box ticking exercises that actual assessments of safety and caring. it would make more sense if inspectors went in more like 'secret shoppers' where they experienced the service first hand rather than had providers tell them what they want to hear.
- Training for all non IS inspectors on the difference between the two sectors and the knowledge base in the sector. It is different and we cannot compare the two like for like. We have guidance documents with which to work that have to be acknowledged and ratified. Our hospitals are extremely varied in their specialities and should be inspected as such not expected to 'conform' to the NHS way of undertaking things.

Providers of Services

- Difficult to comment because the categorisation is unclear for our circumstances.
- It is not specific enough. I feel the information you have is too rigid and one size fits all, rather than flexible enough to properly inspect and make it meaningful for the public.
- We support the proposals outlined in the section on the acute provider handbook: Adjusting the model to tailor the size and composition of inspection teams, and the time needed on site during the visit, currently we do not believe that the right balance has been achieved in the wave one inspections. Not holding listening events - we agree with the reasons outlined in the consultation paper. We agree with the proposal to replace Quality Summits with feedback sessions.

Stakeholders

- A more open discussion on the way forward for the future.
- The proposed assessment of independent and NHS providers within this manual will differ, partly due to lack of comparable data on service provision and quality of care. Without parity of assessment and enforcement, parity in rating will be ineffective.

Professional Bodies

- It is critical that there is clarity about how an independent provider will facilitate and provide onward management of patients' access to further services if things go wrong whilst receiving care.
- As part of the handbook it is important to specifically identify under each of the five key questions what "good" looks like and then make sure that the right information is collected and assessed. When it has been identified what is needed then assurance can be provided to the public

- The independent domain may be more challenging to assess as consultants working in the independent acute sector will normally be independent practitioners and not involved in day to day management, or providing a leadership role. It would be useful to convene a Quality and Leadership summit addressing these issues in the independent sector.

6. Do you have any suggestions for how we could develop our approach to special measures in the independent acute sector?

16 respondents replied to this question:

Healthcare Professionals

- It is important to be collaborative in approach so that the organisation does not become overwhelmed by being in special measures. Any public criticism of an independent organisation has a negative effect on the business and could then render it an unviable business. The emphasis has to be on making sure that patients are safely cared for whilst measures are in place.
- This is a very complicated and delicate area within our business and will have to differ to the NHS Trusts.
- They need to be meaningful also quicker response would be better and better communication to the parties in question you need to look further into what is meant by safe be more holistic so the homes have to be more proactive in approach.
- Obviously it will depend on whether the services have any NHS contracts, if not and regulations are being met I assume that special measures would have to be voluntary but the recommendation should be in the report. No doubt publicity would help persuade agreement.
- Inspectors should be able to go in as a user of the service and go through the process, rather than ask questions, where providers are quite able to hide the reality for the one day the inspectors are there.
- Could the term “levers for improvement” be changed to “continuous quality improvement in raising standards” as this will resonate more within Independent Healthcare Publication by CQC of providers with “time-limited last chance to improve” will be just as detrimental to a provider as an enforcement notice given that the public’s awareness of quality within healthcare is increasing. Consistency across the NHS and HIS is important and we support the CQC as the main prosecuting authority but only where

strict guidelines around the ability to issue enforcement notices are provided in respect of specialist services and the skill set of the inspectorate.

Providers of Services

- I feel that the current method is too rigid to properly judge a service. I am interested how you would 'support' an organisation through special measures, as the focus has not been on supporting in the past. You say " where there is less dependency on using a particular service provider, should we go straight to enforcement rather than offering last chance?" my view is no. This is the wrong way around. where people heavily depend on a service which is under performing you need to be tougher on them as patients are at risk!
- How will the CQC balance its approach to special measures in the independent sector compared with the NHS, given the very different market and competitive contexts? Clearly placing a major NHS Acute Trust in special measures is a very different prospect (financially, politically, public confidence-wise etc.) to placing a small independent provider in special measures. The CQC should be able to evidence a comparative and consistent approach in each case. The other issue for the CQC to consider is how independent providers stand when they are placed in special measures and they provide Commissioner Requested Services. The nature of being designated CRS is in recognition that those services are key and cannot easily be replaced if independent provision failed for any reason. How would the CQC balance this with a finding of special measures?
- One of the key differences between larger independent providers and NHS organisations is the relationship between provider sites and their corporate headquarters. The corporate function provided by the leadership of corporate groups should be the first port of call for an independent provider site that the CQC would consider appropriate to go into some form of special measures. We believe that the new enforcement powers held by the CQC as the main prosecuting authority should act as the absolute safeguard against slipping below fundamental standards of care and that the reputational impact on a group's commercial viability by having one or more sites facing some former special measures designation would be a powerful driver for that group's central leadership to affect improvement. However, we do recognise that this approach only works for groups of a certain size and that smaller organisation with one or just a handful of provider sites may require more direct intervention. We believe the approach by the CQC needs be responsive to the scale of the

organisation that is under consideration. We also recognise that it is possible that a multi-site organisation may experience systemic failings at the group level. In the absence of any mechanism to bail out independent organisations, the impact of such failings is likely to have a direct impact on the reputation and commercial viability of the group far sooner than it might for other types of organisation.

Stakeholders

- If a private clinic does not conform with the agreed standards of care, then it should cease to trade.
- Perhaps the inspectors should have a more clear understanding of the particular specialty that he or she is regulating

Voluntary and Community Sector Representative

- In consultation with providers agree similar measures.

Professional Bodies

- There has to be equity of regulation for all providers. If the CQC are looking to introduce a form of special measures to independent acute hospitals and single speciality providers these should be given a 'last chance to improve' unless the situation is so serious that immediate cessation of activity is necessary.
- This is a very complicated issue and some general principles will need to be drawn up. There is a long list of questions which will need to answered, including Should the local population depend on a service which has special measures (NHS)? Why should it only be services where it appears that patients are depending on that should be allowed to continue? The assistance provided to NHS organisations in special measures to improve. Should similar assistance be provided to IS organisations?
- We believe that the new enforcement powers held by the CQC as the main prosecuting authority should act as the absolute safeguard against slipping below fundamental standards of care and that the reputational imperative on a group's commercial viability of having one or more sites facing some former special measures designation would be a powerful driver for that group's central leadership to affect improvement. As noted above, we have already seen a significant impact on Circle Holdings following the publication of the Hinchingbrooke report.
- It is important that there is equivalence across NHS and independent providers in the approach taken to special measures. We would appreciate clarification on the enforcement policy mentioned in the paper and it is

important that any definition of NHS dependency on private services, which would lead to different thresholds for closure, is made explicitly clear. The effects of special measures on adjacent providers should also be considered.

7. Do you have any suggestions for how we should or should not develop our approach to corporate provider assessment in the independent acute sector?

15 respondents replied to this question:

Healthcare Professionals

- It is important to look at what support is provided to each facility from the Head Office perspective. Are their overarching policies up to date? Do they have the right expertise to support individual facilities who may be experiencing difficulties? If Head Office is supportive of all facilities and has the right governance processes in place then the individual facilities will flourish. If there is an obvious disconnect in communication then there are more likely to be issues to address. A visit to Head office would be undertaken before going to the individual facilities so that a picture of the expected standards is gained. You can then rate facilities on their compliance with the corporate standards set out.
- A self-assessment would be an appropriate place to begin with requests for any additional information such as the vision, mission, values, overall percentage of mandatory training, governance and central risk arrangements, (a reduced version of the PIR document overall to be completed at HO level.) A corporate visit could then be triggered if a specific number of the hospitals within the group receive require improvement or inadequate during the inspection process.
- They need to look at resources and how they are being utilised properly, not just tick box exercises.
- For larger providers of Acute services (i.e. Hospitals) this could be beneficial. But would not benefit smaller services.
- Why should there be any difference? All providers should be required to disclose their part in any corporate structure including information about the nationality of any over-arching company structure. It would also be helpful to know their tax position if they are receiving NHS funds for services.
- In relation to this I think that the corporate provider should be included in the inspection process. This could be undertaken once every three years if they

are rated as good. A corporate inspection should be completed to mirror that within the NHS sector. In order to fairly assess the well-led domain corporate services have to be inspected as this is where leadership and the culture of the organisation stem. Recent findings have shown that many problems stem from either leadership or the culture of the organisation. One inspection of corporate services could be completed and then any subsequent inspection reports should make reference back to this.

- Definite advantage for the Well-led domain but would be beneficial for the other domains too. Would reduce duplication of information provided and give CQC a better understanding of the relationship between corporate and individual facilities.

Provider of Services

- We believe there is value in developing an aggregate corporate-level assessment of independent providers. We believe: The corporate ˜centre" makes a valuable contribution and in some cases sets the agenda and manages core issues such as quality and governance. It sets core policies and standards and monitors audit, incidents, trends and the governance of the introduction of new procedures and research. We strongly support the principle of comparability between all providers of care but this cannot mean simply applying exactly the same measure without consideration of whether it is appropriate or not. While the independent corporate function/provider sites relationship is broadly analogous to the NHS Trust/hospital relationship, there are circumstances in which this analogy does not hold. For example, the size of a group plays a significant role in affecting the relationship the centre has with its individual provider sites. Coordination between the CQC and independent providers' corporate centres should be an essential mechanism to ensure the CQC is fully informed and to reduce duplication of assessment. We believe the threshold of 20 locations adopted in the past by the CQC to engage at the corporate level is too high: coordination and the avoidance of duplication could be achieved by engaging with organisations with 10 or more locations.
- When assessing leadership and if a service is well led you need to engage more with the leaders of the business and not just the registered manager or staff who you see what inspection.
- More detailed consultation with providers in the independent acute sector, single speciality services please. The stakeholder consultation meetings are extremely useful and it would be very welcome if the CQC would run stakeholder consultation groups for the single speciality services in the same way too.

Stakeholder

- An accurate assessment of the extent of the practice, through the whole patient pathway, should be included in the overall assessment of the private organisation.

Professional Bodies

- There should be a general assumption in favour of parity across provider sectors. It seems to be logical that corporate systems for quality governance at central level would have an impact on quality governance at individual locations. Therefore, whilst we can appreciate that determining ratings for this can be more complex for some independent providers, it would seem to appropriate for the CQC to pursue a practical way to pursue this goal. In the past, we have suggested that CQC phase the introduction of ratings, in order to make sure there is confidence in the methodology and that they are credible for a given service level, for example. This approach would seem to make sense in this case.
- Some areas should be assessed corporately for example governance and leadership and then applied/checked out at individual sites.
- We suggest approaching this by considering the purpose of regulation and its effect on patients: any corporate assessment should add value in terms of improving patient care and be cost-effective both in its own right and through its impact on the regulatory approach to individual sites, given that the corporate centre neither provides care nor is a registered provider of services. It follows that, regardless of whether there is a corporate rating, the corporate function should be assessed efficiently and effectively. The wave one approach has been to review policies at unit level including all frameworks and strategies many of which are set at the corporate level. It would be more sensible and efficient for all concerned, including the CQC, to assess the corporate framework once in any given period with the priority focus on how its registered locations implement any corporate policy(s) on the ground. Individual units' compliance with corporate frameworks would remain an important element of unit-level inspection, but the current practice of uploading and then scrutinising the same policies for each individual unit makes little sense.
- The College feels that a corporate provider should be assessed on two levels. The first is assessment of what is being provided at a local site and local managers being held responsible for what is happening within that unit. The second is the need for a provider to have corporate responsibility for what is

taking place at a local level and analysis of how corporate policies may positively or negatively impact on patient care or safety.

8. As part of this consultation we have published a regulatory impact assessment. We would also like your comments on this.

7 respondents replied to this question:

Healthcare Professionals

- The way that the CQC inspections are carried out has a key effect on the individual businesses and it is important to understand the impact of this.
- Communication through 1 person at the business. Organisation of data and the logistics of the inspection - data collection challenging because lack of understanding of how the sector works. Multiple data request. Pre inspection telephone call stated what should be expected in terms of behaviours of CQC inspectorate which should be implicit - Patient questionnaires not expected and needed to be carefully supported as quite complicated questioning at interviews - Requires opportunity to clarify context of aspects of verbal feedback at end of inspection - draft report is very hefty document at 79 pages and appears quite repetitive. size and composition of team should be relevant to hospital size to ensure no overlap.
- I do not believe that the accepted method of impact assessments have much relevance to health services.

Provider of Services

- What costs have you experienced in terms of time and one-off expenditures relating to individual CQC inspections in the past? Costs relating to the old style of CQC visits have been minimal and of no significant effect. How do you envisage the costs of inspection to change for your provider as a result of our new inspection model? To date the new style of inspections have been significantly more costly. The provision of data has taken significant time and effort, the equivalent of at least one whole time equivalent member of staff for the 2 weeks of data collection and uploading. The number of inspectors has meant an additional member of staff is required to project manage the process during the visit. Space is required for a large number of inspectors and in many of our hospitals that space is not readily available. In some instances it may be necessary to cancel outpatient clinics to free up rooms, or

to remove staff from their offices in which case they cannot carry out their duties. In one case we have cancelled building works to ensure there is enough space on site, this will extend building times. What benefits to your organisation do you feel will be experienced as a result of these proposed changes? The benefits will be significant and the new style of inspection more thorough, accurate and open to scrutiny and challenge. The staff feels more valued and as though they have contributed. Staff and patients are assured by the process. Have we missed out any other costs and benefits that you feel should be included in the analysis? No.

Stakeholder

- As a small social enterprise without any provider input from the NHS at present it is important to us that costs bear some relation to what we are able to achieve in the financial market.

Professional Bodies

- Main features of the approach: The size and composition of the team and duration of the inspection visit, being relevant and appropriate to the size and nature of the service being inspected (this means teams will be significantly smaller than most comprehensive inspection teams for NHS trusts, although with experts continuing to form the majority). We note proportionality and questions who is paying? However, the signposting document noted the lack of consistent, comparable, nationally available data in most of the independent sector, and described the challenges in improving our access to accurate, complete and meaningful data and information about services (page 16).
- We would highlight the concerns raised earlier about the size and scale of inspection teams, and the subsequent impact that this has had on service delivery on providers in the wave one process. We are aware that the CQC has acknowledged this as a potential problem and we look forward to future more focused inspections. We believe it is fundamentally important that clinical regulation should focus on clinical standards. The learning from the Hinchingbrooke experience should be that CQC inspections have an immediate and very significant impact on independent providers which goes beyond that typically experienced by NHS Trusts. It is therefore vital that we work together to ensure that the inspection process is balanced, accurate and fair.
- The impact of the new regulations will encourage the private sector to raise standards, as they will be very conscious that a poor rating will negatively affect their business. There will be a need for the CQC to enforce these regulations and stand up to potential legal action by private providers, who

may fear the loss of revenue that a negative assessment could potentially have on their business.

4. Additional Comments from Written Submissions

Borough Council

Key Questions

- Good approach
- Puts safety at the heart of inspection
- Focusing on outcomes for service users, rather than compliance.
- It is still a little unclear as to how they will be measured in practice
- Consideration will need to be given to the issue of 'inter-rater reliability'.
- We would also like to see greater detail as to the framework that inspectors use to judge the outcomes at and how the CQC will be regulated to ensure the quality outcomes from the work they are doing.

Rating System

- 'Good' and 'outstanding' ratings are helpful as the public are familiar with the concepts from the education sector.
- However, the 'inadequate' rating requires improvement in terms of public understanding. E.g., are people's lives in danger in an inadequate health setting or can people still receive a service that meets their needs?

Use of prosecutions

- We would like to see greater clarity on this and on the power the CQC has.
- We would hope that such powers (fines etc.,) could be used if evidence of bad practice is picked up before something goes wrong.

Other

- We welcome that the inspection frameworks have a degree of specialty, so that a one-size fits all policy is not being applied to different health settings.
- The CQC is not the only organisation when it comes to professional oversight and we would like greater detail on how they will work with partner organisations.
- The simplification from 16 standards to 5 questions is ultimately a good idea, as stated, but there remains a problem of subjectivity in the measurement and the danger that some poor practice could be overlooked if the framework is not robust enough.
- Finally, we welcome proposals and hope that it leads to a more open and transparent system and that for a prolonged period there is no substantial further change.

Professional Body

- We welcome the clarity provided by the approach and your commitment to align the new model for the independent healthcare sector with other sectors, including NHS acute services and primary care services, as far as possible.
- We already supported the proposed approach outlined in the handbook for NHS acute hospitals.
- We therefore welcome the alignment between this and the approach proposed for the independent healthcare sector, noting those circumstances in which key differences in service delivery require an alternative approach.
- We agree that the key lines of enquiry, as set out within the Provider handbook for NHS acute hospitals, should also apply to independent acute hospitals.
- It is important that an assessment of a provider, irrespective of whether it is independently run or part of the NHS, should take account of adherence to professional responsibilities.
- We continue to suggest that inspections take into account arrangements for appraisal, as a key element of revalidation.
- With regard to the independent sector, it is particularly important that a doctor's appraisal addresses the whole scope of their practice, and that there is effective communication between NHS and independent providers to facilitate this.