Consultation

How CQC regulates:

Ambulance services

Provider handbook

November 2014

The Care Quality Commission is the independent regulator of health and adult social care in England.

Our purpose

We make sure health and social care services provide people with safe, effective, compassionate, high-quality care and we encourage care services to improve.

Our role

We monitor, inspect and regulate services to make sure they meet fundamental standards of quality and safety and we publish what we find, including performance ratings to help people choose care.

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Foreword

In April 2014, I set out our proposed approach towards inspecting and regulating providers of ambulance services. Our signposting document, *A fresh start for the regulation of ambulance services*, set out the main characteristics of ambulance services and our priorities for improving how CQC monitors, inspects and regulates them.

Ambulance services are unique in that, compared to some other parts of the health and social care system, their staff regularly work across a range of other providers and professionals. The ability of ambulance staff to work effectively with them to meet the needs of patients is very important.

This consultation on our handbook for providers sets out our detailed proposals for how we intend to regulate and inspect ambulance services. The handbook explains the end to end inspection process of how we rate services and what 'good' looks like. It includes:

- What we look at on inspection.
- How we judge what 'good' looks like.
- How we rate care services to help people who use services choose care.
- How we use information to help us decide when and where we inspect.

We have developed these proposals by working closely with our ambulance partners, providers, key stakeholders and with the public and people who use services to make sure we get this right.

Do please take the time to respond to this consultation. We ask a number of specific consultation questions throughout this handbook and we would like to receive your views by 23 January 2015. Your views are important and matter to us. They are important in helping us to develop our model for regulating and inspecting ambulance services. Thank you.

Professor Sir Mike Richards

Chief Inspector of Hospitals

Introduction

In this handbook, we are consulting on our proposed new approach to regulating, inspecting and rating both NHS and independent ambulance services. This consultation will run from 28 November 2014 to 23 January 2015 – details on how to respond are at the end of this document. The detail of the consultation is set out in this draft handbook for providers.

Our regulation powers enable us to rate NHS ambulances currently. We are working with the Department of Health to ensure the regulations are in place to extend our powers to rate independent ambulances as well from October 2015. To prepare for this, we will carry out a small number of pilot inspections of independent ambulance services that will include shadow ratings.

Our approach is based on our initial consultation, *A new start*, which proposed radical changes to the way we inspect and regulate all health and social care services. However, we have developed our approach further through more recent consultations on handbooks for acute hospitals, specialist mental health, community health, primary care and adult social care services.

Our approach will include using a national team of expert inspectors and clinical and other experts, including people with experience of receiving care (Experts by Experience). We will use Intelligent Monitoring to decide when, where and what to inspect, including listening better to people's experiences of care and using the best information across the system. Our inspections will be in-depth and longer, and we will also inspect in the evening and at weekends when we know people can experience poorer care. Our inspectors will use professional judgement, supported by objective measures and evidence, to assess services against our five key questions:

- Are they safe?
- Are they effective?
- Are they caring?
- Are they responsive to people's needs
- Are they well-led?

We will rate NHS ambulance services. These ratings will help people to compare services and will highlight where care is outstanding, good, requires improvement or inadequate.

There has been strong support for the changes to our approach, with a desire to give providers enough time to understand them and adapt their services. We have listened to what people said and we will continue to develop and evaluate the changes as we carry out our new style inspections. This is so that we can finalise an approach that has the best impact on the quality of care.

In *A fresh start for the regulation of ambulance services* (April 2014), we set out four main strands to developing our new regulatory approach. These included:

1. What matters to patients
2. Developing how we inspect ambulance services
3. Developing our information to monitor providers
4. Focusing on local partnership and integrated arrangements

We also acknowledged that ambulance services are unique in that, compared to some other parts of the health and social care system, their staff regularly work across a range of other providers and professionals. The ability of ambulance staff to work effectively with them to meet the needs of patients is very important.

Services that fall within the NHS ambulance sector include the following:

- Emergency and operation callers handling 999 calls and urgent and emergency services responding to these calls
- Specialist service transfers (high dependency, intensive care transfer, paediatric patients)
- Patient transport services (PTS)
- Resilience planning (to respond to major incidents and events)
- 111 services (which is included in our approach to inspecting and regulating GPs).

Independent ambulances may provide all the same services as the NHS, except for receiving 999 calls. However, they provide a higher proportion of PTS services, events cover and transfers between hospitals than responding to 999 calls, compared to the NHS.

Independent ambulances are also very diverse in terms of size of provider, services provided and geographical area covered. All are likely to be commissioned to provide services with some having NHS contracts as well.

Not all independent ambulances have to register with CQC; the detail of those that are exempted are in our scope guidance that can be found here.

Next stages of development for NHS ambulances

We began testing our new approach in two NHS ambulance trusts (we called these Wave 1 inspections) in August and September 2014. Our approach for the Wave 2 inspections (January 2014) will incorporate our learning and experience from those first inspections.

This guidance for ambulance services reflects our current thinking and will be refined as we test it further during January 2014. We will use the feedback

from this consultation and further work with the public, people who use services, providers and organisations with an interest in our work to develop our thinking further.

We will publish an update of this guidance with our final approach for NHS ambulances in March 2015. We will then roll out our new approach from April 2015, with the intention of rating all NHS ambulances by the end of March 2016.

Next stages of development for independent ambulances

We will continue working with independent ambulance services to develop our approach for regulating and inspecting these services, as well as using the feedback from this consultation.

We will begin piloting our approach for inspecting and regulating independent ambulances from April 2015. Using the learning and experience from these pilots we will refine the approach further with input from independent ambulance services and people who use services before rolling out our final approach by October 2015.

1. Our framework

Although we inspect and regulate different services in different ways, there are some key principles that guide our operating model across all our work.

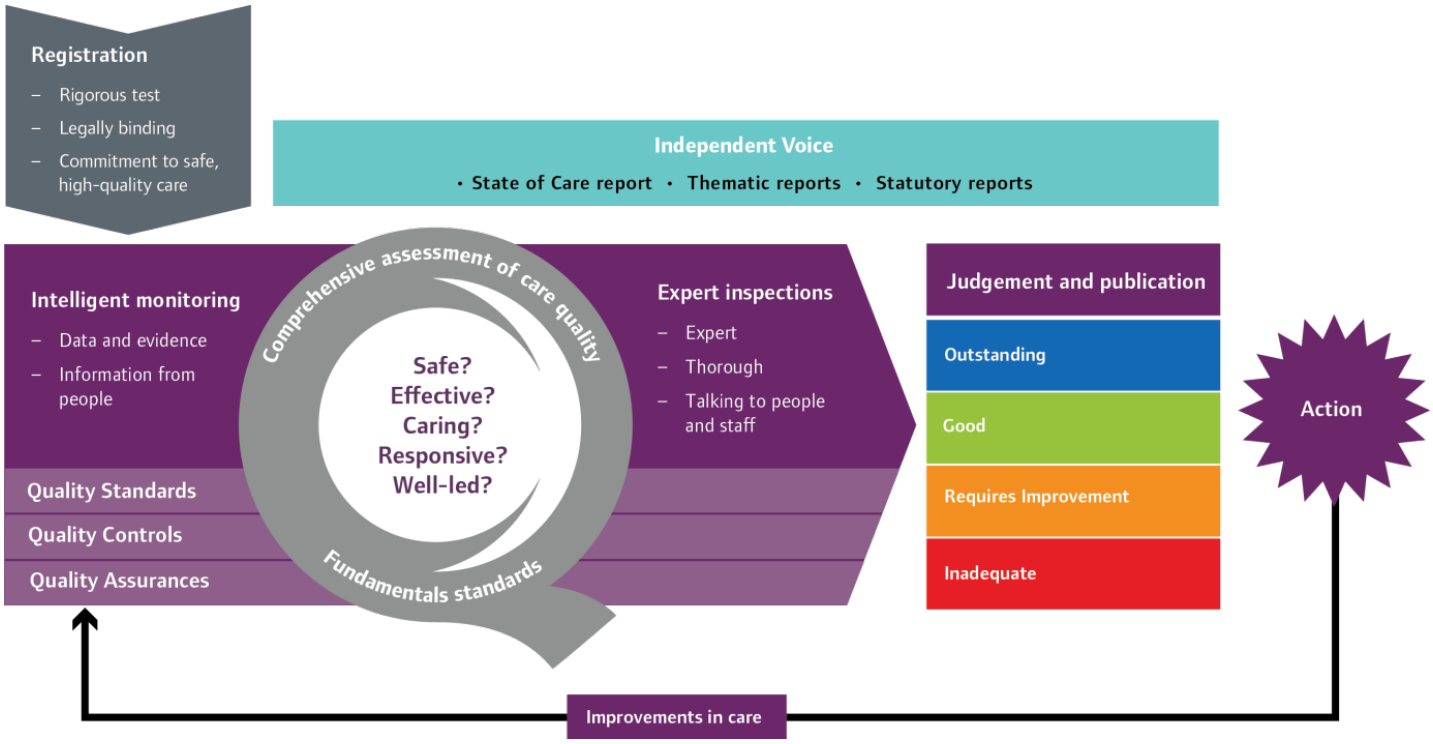
Our operating model

The following diagram shows an overview of our overall operating model. It covers all the steps in the process, including:

- Registering those that apply to CQC to provide services – see section 2 on our registration process.
- Intelligent use of data, evidence and information to monitor services.
- Using feedback from people who use services and the public to inform our judgements about services.
- Inspections carried out by experts.
- Information for the public on our judgements about care quality, including a rating to help people choose services.
- The action we take to require improvements and, where necessary, the action we take to make sure those responsible for poor care are held accountable for it. Our enforcement policy sets out how we will do this.

Our model is underpinned by the new fundamental standards, to be introduced in April 2015. We will issue guidance to help providers understand how they can meet the new regulations (see section 11).

Figure 1: CQC's overall operating model



The five key questions we ask

To get to the heart of people's experiences of care, the focus of our inspections is on the quality and safety of services, based on the things that matter to people. We always ask the following five questions of services.

- Are they safe?
- Are they effective?
- Are they caring?
- Are they responsive to people's needs?
- Are they well-led?

For all health and social care services, we have defined these five questions as follows:

Safe	By safe, we mean that people are protected from abuse and avoidable harm.
Effective	By effective, we mean that people's care, treatment and support achieves good outcomes, promotes a good quality of life and is based on the best available evidence.
Caring	By caring, we mean that staff involve and treat people with compassion, kindness, dignity and respect.
Responsive	By responsive, we mean that services are organised so that they meet people's needs.
Well-led	By well-led, we mean that the leadership, management and governance of the organisation assures the delivery of high-quality person-centred care, supports learning and innovation, and promotes an open and fair culture.

Core services

The size and complexity of some providers means that, for some, we will not be able to inspect every aspect of their service. However, we have identified a set of core services that we will always inspect if provided:

- Emergency operations centre
- Emergency and urgent care services
- Patient transport services
- Resilience planning

We have set out our definitions of these core services in appendix A.

Our inspections will normally be limited to these core services. However, if we identify particular services, or the use of pathways of care that provide cause for concern, or where we believe the quality of care could be outstanding, and they are not covered by these core services, we will look at

them in detail and report on them. We may also focus on additional areas where these represent a large proportion of a provider's activity or expenditure, for example specialist independent ambulances, such as air ambulances and ambulances that convey detained patients.

Due to the geographical spread of ambulance services, we will not always be able to visit every location a core service operates from. Therefore, we will visit a sample of sites for each core service. Where we sample services for inspection, we will select some on a random basis and for others we will consider various factors about risk, quality and the context of the services to help us select and prioritise the areas we visit. These may include, for example, services:

- Where previous inspections, our intelligence or information gathered by either Monitor, the NHS Trust Development Authority, NHS England or a local clinical commissioning group, has flagged a concern or risk.
- About which we have concerns or safeguarding alerts from people who use services or staff.
- We have not inspected for a long period or have not previously inspected at all.
- Where the quality of care may be outstanding.

Consultation questions

1. We have identified the core services that we will check during our inspections of ambulance services (see appendix A). These questions are for both NHS and independent ambulance services:

   - Do you agree that these are the right core services to look at?
   - Do you understand what we mean by these core services? If not, what is unclear?

   Issues to consider:

   We believe weighting core services equally is in line with our commitment to promote equality in the services we regulate and to uphold Equality Act legislation. Everyone who receives care and treatment should expect to receive the same good quality care, irrespective of the type of service that they are using.

   An exception might be where an ambulance service provides a core service to a smaller population than another core service; for example where an ambulance service provides patient transport services to 10% of the population they provide emergency and urgent services to. In this situation the inspection team would use their professional judgement to determine what weight to give the core service when aggregating ratings.

   - Do you agree that, in general, core services should be weighted equally with the above exception?

Care pathways

We are committed to including a focus on care pathways and particular patient groups as part of our inspection of ambulance services. This could include, for example, people with dementia or with a learning disability.

We will take this into account in relation to the core services inspected through the questions that we ask and the methods that we use, including the tracking of people through care. This means that we will form a judgement about the points in a care pathway and use this to inform our ratings of our identified core services.

Key lines of enquiry

To direct the focus of their inspection, our inspection teams will use a standard set of key lines of enquiry (KLOEs) that directly relate to the five key questions we ask of all services – are they safe, effective, caring, responsive and well-led?

The KLOEs are set out in appendix B.

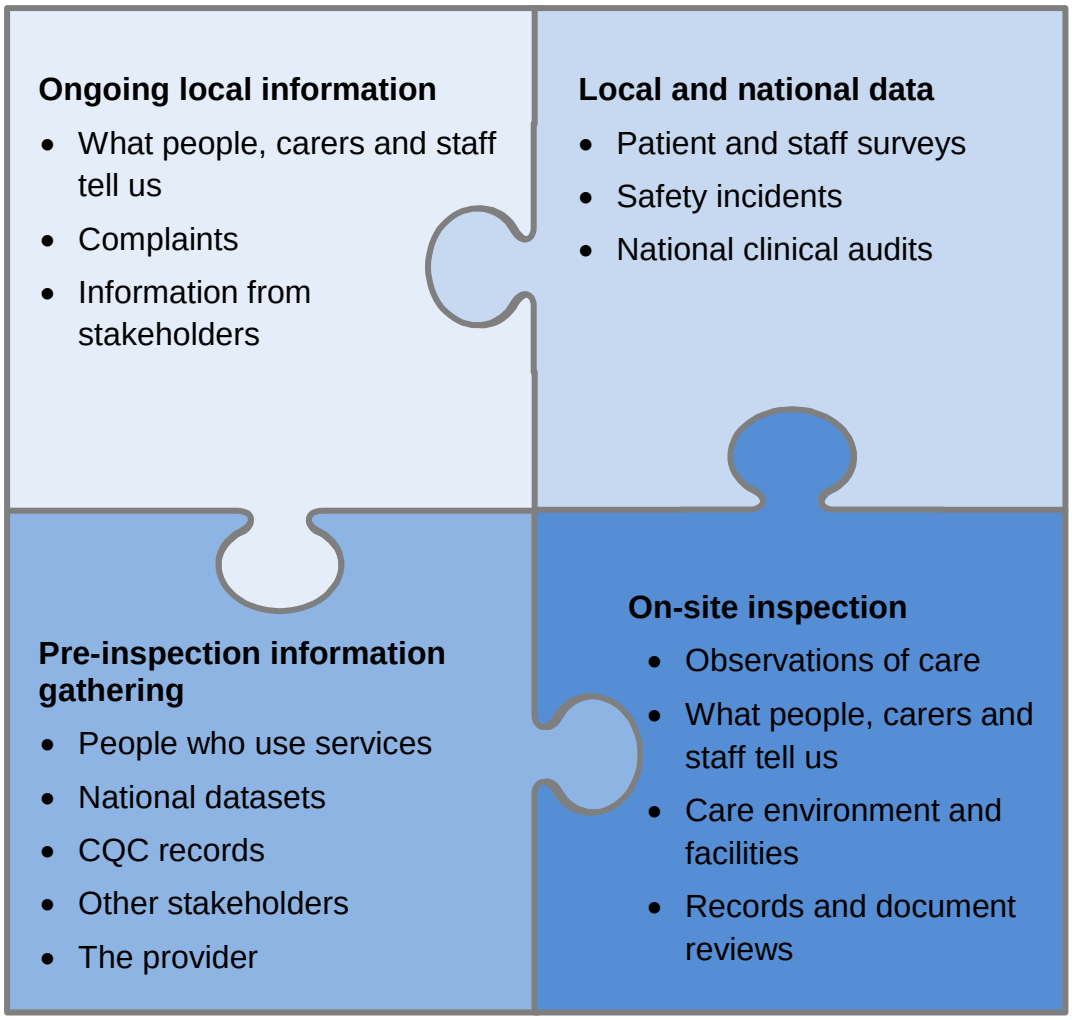
Having a standard set of KLOEs ensures consistency of what we look at under each of the five key questions and that we focus on those areas that matter most. This is vital for reaching a credible, comparable rating. To enable inspection teams to reach a rating, they gather and record evidence in order to answer each KLOE.

Each KLOE is accompanied by a number of questions that inspection teams will consider as part of the assessment. We call these prompts. The prompts are included in appendix B.

Inspection teams use evidence from four main sources in order to answer the KLOEs:

1. Information from the ongoing relationship management with the provider and other stakeholders, including information that the provider provides on how it thinks it is performing, the processes it has in place, and the action it is taking to improve under-performance (as described in section 3).
2. Other nationally available and local information that can inform the inspection judgement. This will typically be included in the data packs described in section 6.
3. Information from activity carried out during the pre-inspection phase (for example, the provider's approach to concerns and complaints raised by people who use services and staff) as set out in section 6.
4. Information from the inspection visit itself.

Figure 2: The four main sources of evidence



Currently we have described one set of KLOEs, prompts and descriptions of what 'good' looks like for all ambulance services (NHS and independent) rather than each core service. We will work with stakeholders to identify where more tailored guidance may be needed, or where we might look for specific evidence for each core service.

Consultation questions

2. These questions are for both NHS and independent ambulance services:
    - Do you feel confident that the key lines of enquiry and the list of prompts will help our inspectors judge how safe, effective, caring, responsive and well-led NHS and independent ambulance services are?
    - Is there anything missing?

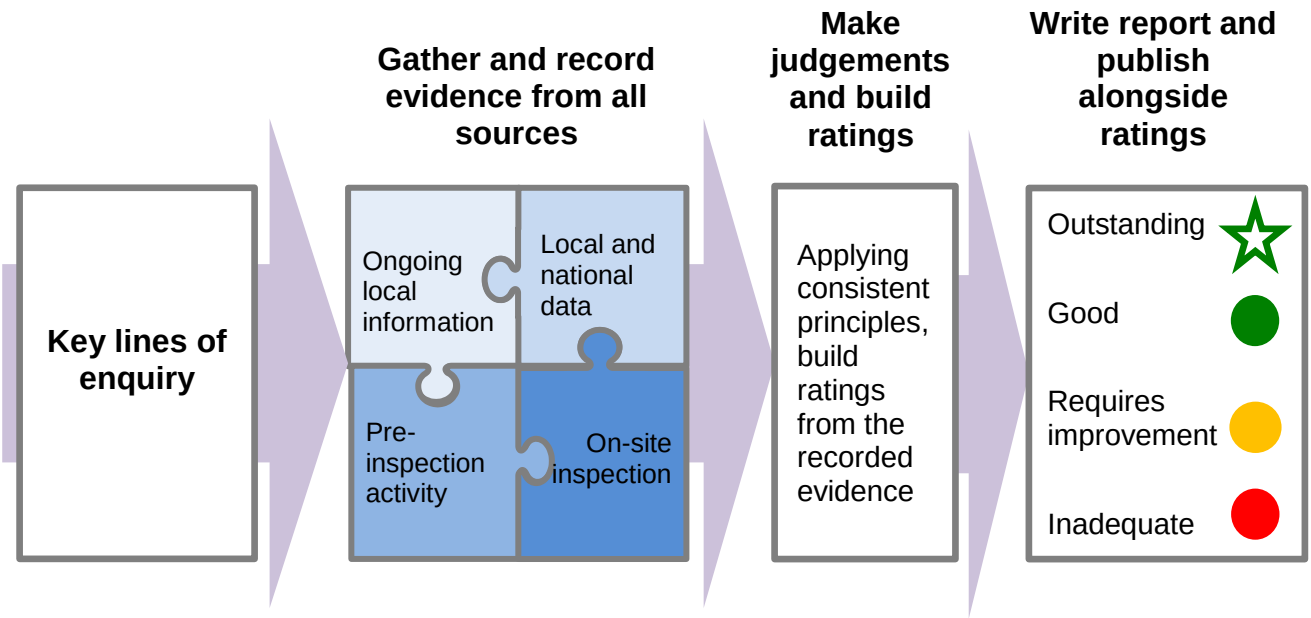
Ratings

We are introducing ratings as an important element of our new approach to inspection and regulation of NHS ambulances.

As set out in figure 3 below, our ratings will always be based on a combination of what we find at inspection, what people tell us, our Intelligent Monitoring data and local information from the provider and other organisations.

We will award them on a four-point scale: outstanding; good; requires improvement; or inadequate.

Figure 3: How KLOEs and evidence build towards ratings



We have developed characteristics to describe what outstanding, good, requires improvement and inadequate care looks like in relation to each of the five key questions. These are set out in appendix C.

These characteristics provide a framework which, when applied using professional judgement, will guide our inspection teams when they award a rating. They are not to be used as a checklist or an exhaustive list. The inspection team will use their professional judgment, taking into account best practice and recognised guidelines, with consistency assured through the quality control process.

Not every characteristic has to be present for the corresponding rating to be given. This is particularly true at the extremes. For example, if the impact on the quality of care or on people's experience is significant, then displaying just one of the characteristics of inadequate could lead to a rating of inadequate. Even those rated as outstanding are likely to have areas where they could improve. In the same way, a service or provider does not need to display every one of the characteristics of 'good' in order to be rated as good.

We have considered whether the benefits of rating all registered ambulance services, including small enterprises and charities, justify the potential costs. We have also considered whether it will achieve the five purposes described in the Nuffield trust report on ratings:

- Accountability
- Public / commissioner choice
- Performance
- Identifying / preventing failure
- Offering reassurance.

Our view is that all of these apply to this sector and we propose that all ambulances should be rated.

Ratings are discussed in more detail in section 9.

Consultation questions

3. These questions are for both NHS and independent ambulance services:
    - Do you agree that the characteristics of 'outstanding' (in appendix C) are what you would expect to see in an outstanding NHS and independent ambulance service?
    - Do you agree that the characteristics of 'good' (in appendices B and C) are what you would expect to see in a good NHS and independent ambulance service?
    - Do you agree that the characteristics of 'requires improvement' (in appendix C) are what you would expect to see in an NHS and independent ambulance service that requires improvement?
    - Do you agree that the characteristics of 'inadequate' (in appendix C) are what you would expect to see in an NHS and independent ambulance service that was inadequate?
    - Do you agree that rating all ambulances will achieve the purposes described in the Nuffield report?

Equality and human rights

One of CQC's principles is to promote equality, diversity and human rights. This is a means to an end and not an end in itself. The end is good quality care for all. Respecting diversity, promoting equality and ensuring human rights will help to ensure that everyone using health and social care services receives good quality care.

To put this into practice, we have a human rights approach to regulation. This looks at a set of human rights principles – fairness, respect, equality, dignity,

autonomy, right to life and rights for staff – in relation to the five key questions we ask. All of these principles are enshrined in the NHS Constitution.

Using a human rights approach that is based on the rights that people hold, rather than what services should deliver, will also help us to look at care from the perspectives of patients.

Human rights are important in all our key questions – for example, safe, effective pre-hospital treatment is necessary to protect people's right to life, and both the leadership of ambulance services and the frontline service delivery need to promote equality, dignity and respect for people. Where ambulance services are being provided, there may be challenges in ensuring human rights that rely on responding to the needs of individuals. Because of the type of services being provided, and the nature of some of the incidents involved, many patients spend only a short period using a particular service and some individuals might not be able to make their wishes known.

There are a number of sources of information about equality and human rights available for ambulance services – such as patient data, surveys and, importantly for NHS services, the NHS Equality Delivery System (EDS2). We intend to draw on existing data sources where we can. However, for many human rights topics, the only way we can assess how well ambulances are performing is by gathering and understanding the experiences and views of people. Our approach will enable us to gather more evidence from people who use services, including ways of finding out the experiences and outcomes of pre-hospital care for particular groups of people who may be at a higher risk of receiving poor care, such as people with a learning disability and people with dementia.

This focus on human rights is integrated into our approach to inspection and regulation. We believe this is the best way to ensure equality and human rights are promoted in our work

Monitoring the use of the Mental Capacity Act 2005 including the Deprivation of Liberty Safeguards

The Mental Capacity Act (2005) is a crucial safeguard for the human rights of adults who might (or may be assumed to) lack mental capacity to make decisions, including whether or not to consent to proposed care or treatment interventions. The Mental Capacity Act (MCA) provides the essential framework for balancing autonomy and protection when staff are assessing whether people aged 16 and over have the mental capacity to make specific decisions at the time they need to be made.

Any decision taken on behalf of a person lacking capacity must be made in their best interests and be the least restrictive option that can be identified to meet a specific need.

The importance of working within the empowering ethos of the wider MCA will be reflected in our inspections. A specific KLOE about consent takes account of the requirements of the Mental Capacity Act and other relevant legislation.

During our inspections, we will assess how well providers are using the MCA to promote and protect the rights of people using their services. In particular, we will look at how well people lacking mental capacity, who are being transferred while being detained, are being cared for and whether their dignity and respect is being considered. We will also look at staff understanding of advance decisions to refuse treatment and lasting powers of attorney for health and welfare decisions.

We will also look for evidence that restraint, if used to deliver necessary care or treatment to someone lacking mental capacity, is:

- in the best interests of the person
- proportionate
- necessary to prevent harm to the person
- in accordance with the MCA.

Concerns, complaints and whistleblowing

Concerns raised by people using services, those close to them, and staff working in services provide vital information that helps us to understand the quality of care. We will gather this information in three main ways:

- Encouraging people and staff to contact us directly through our website and phone line, and providing opportunities to share concerns with inspectors when they visit a service.
- Asking national and local partners (for example, the Ombudsmen, the local authority, Health Education England and Healthwatch) to share with us concerns, complaints and whistleblowing information that they hold.
- Requesting information about concerns, complaints and whistleblowing from providers themselves.

We will also look at how providers handle concerns, complaints and whistleblowing in every inspection. A service that is safe, responsive and well-led will treat every concern as an opportunity to improve, will encourage its staff to raise concerns without fear of reprisal, and will respond to complaints openly and honestly. The Parliamentary and Health Service Ombudsman, the Local Government Ombudsman and Healthwatch England will set out standard expectations for handling complaints, which are consistent with our assessment framework, and describe the good practice we will look for.

We will draw on different sources of evidence to understand how well providers encourage, listen to, respond to and learn from concerns. Sources of evidence may include complaints and whistleblowing policies, indicators such as a backlog of complaints and staff survey results, speaking with people who use services and those close to them and staff, and reviewing files from investigations of complaints.

2. Registration

Before a provider can begin to provide a regulated activity, they must apply to CQC for registration and satisfy us that they are meeting a number of registration requirements.

Registration will assess whether all new providers, whether they are organisations, individuals or partnerships, have the capability, capacity, resources and leadership skills to meet relevant legal requirements, and are therefore likely to demonstrate that they will provide people with safe, effective, caring, responsive and high-quality care.

The assessment framework will allow registration inspectors to gather and consider comprehensive information about proposed applicants and the services they intend to provide, including where providers are varying their existing registration, to make judgements about whether applicants are likely to meet the legal requirements of the regulations.

We will make judgements about, for example, the fitness and suitability of applicants; the skills, qualifications, experience and numbers of key individuals and other staff; the size, layout and design of premises; the quality and likely effectiveness of key policies, systems and procedures; governance and decision-making arrangements; and the extent to which providers and managers understand them and use them in practice.

We intend to focus on the robustness and effectiveness of the registration system in a way that does not stifle innovation or discourage good providers of care services, but does ensure that those most likely to provide poor quality services are discouraged and prevented from doing so.

3. How we work with others

Good ongoing relationships with stakeholders will be vital to our inspection approach. These relationships will allow CQC better access to qualitative as well as quantitative information about services, particularly local evidence about people's experience of care. Local relationships will also provide opportunities to identify good practice and to work with others to push up standards.

Working with providers

A good ongoing relationship with services is a key element of our inspection model. A CQC Head of Inspection or local inspection manager will be responsible for developing and maintaining relationships at a local level. They will have primary responsibility for the day-to-day communication, information exchange and management of our relationship with providers and partners.

Our approach will include continuous monitoring of local data and intelligence and risk assessment. Where risks are identified, the local Head of Inspection or inspection manager will check what the provider is doing to address the risk.

Service providers also routinely gather and use information from people who use services, the public, carers and other representatives. We will make use of this information, including:

- Local patient surveys or other patient experience information and feedback.
- Information about the number and types of complaints people make about their care and how these are handled.
- Ambulances provide a vital link between a wide range of health and care services; we will therefore seek feedback from other providers, such as hospitals, and we will take account of information from inspecting other providers.

Working with people who use services

People's experiences of care are vital to our work; they help to inform when, where and what we inspect. We want people to tell us about their care at any time through our website, helpline and social media, and we are committed to engaging with the public to encourage people who use services and those close to them to share their views and experiences with us.

We will gather and analyse information from people who use services, for example through:

Nationally collated feedback from people who use services and carers

- Patient survey data
- Information from NHS Choices

Feedback from groups representing communities, people who use services and public representatives

- Local Healthwatch.
- Organisations that represent or act on behalf of people who use services, including equality groups.
- The NHS Complaints Advocacy services.
- Community groups and groups that represent carers.

Comments and feedback sent to CQC from individual people who use services and those close to them

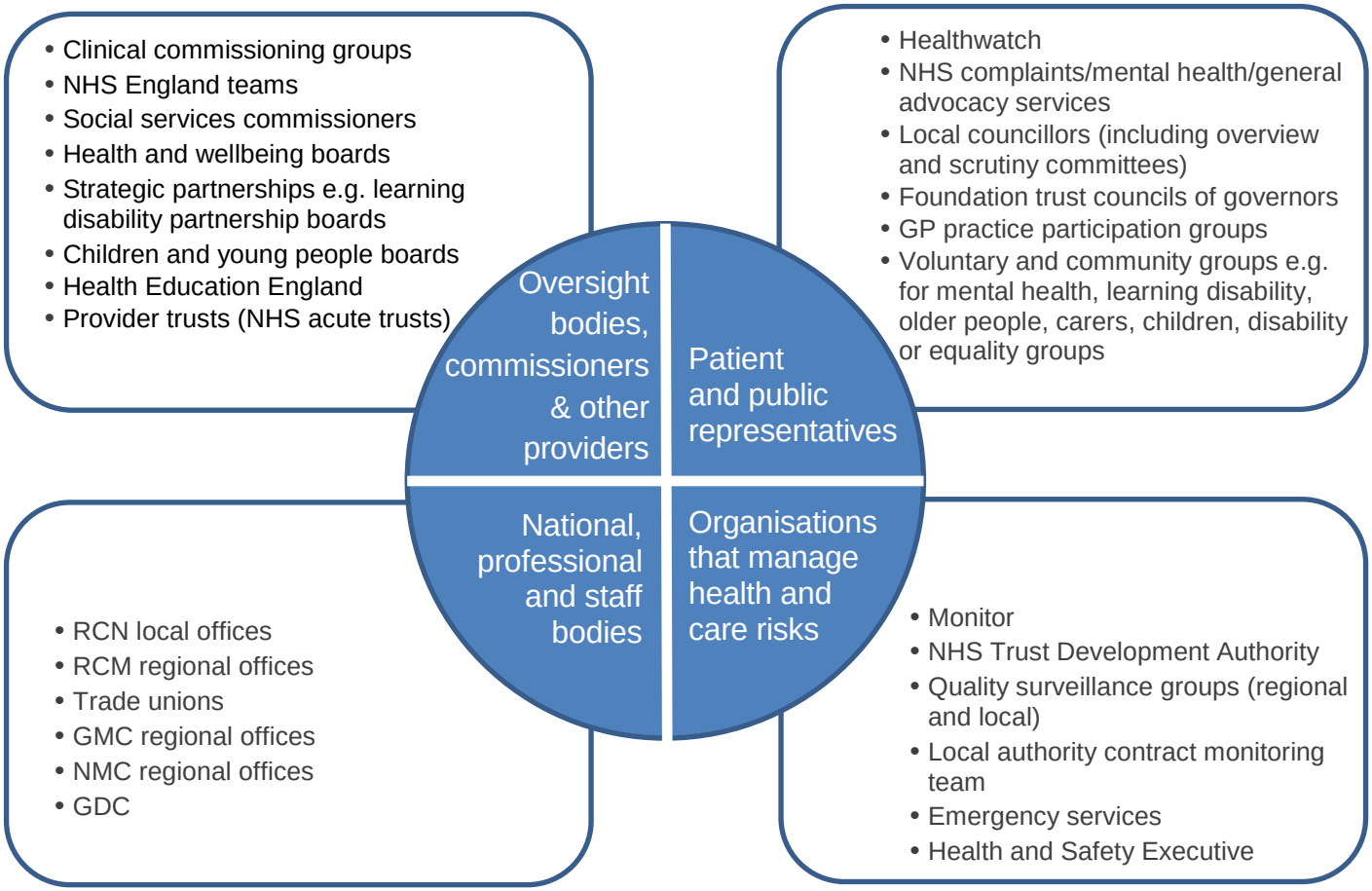
- Feedback on services submitted through CQC's online "share your experience" form or through telephone calls to our national call centre.
- Engagement activity specifically designed to encourage people to share their experiences of care.

Working with local organisations and community groups

It will also be important to maintain good relationships with local organisations and community groups that represent people who use services, and to routinely gather their views. We will ask them to share with us the information that they hold. These include:

- Local health overview and scrutiny committees
- Quality surveillance groups
- Health Education England
- Local Healthwatch
- Clinical commissioning groups
- NHS complaints advocacy organisations.
- Other emergency services, such as police and fire services.

Figure 4: How we work with local and national partner organisations



Working with partner organisations

Many national partner organisations that we work with have information about providers and about people's experiences and we want to make the best use of their evidence. It is also important that our inspectors and inspection managers will also have an ongoing relationship with other stakeholders. This includes, for example:

- Monitor
- The NHS Trust Development Authority
- NHS England
- The Parliamentary and Health Service Ombudsman

We will work with these bodies and gather different types of information on a regular basis and in the lead-up to an inspection.

We worked closely with Monitor and the NHS Trust Development Authority to develop a single overarching framework for judging whether services are well-led. At CQC, our KLOEs for this key question reflect this single framework and our prompts focus on the aspects of the framework that we assess. This ensures that our respective approaches for assessing leadership, culture and governance are aligned.

We will not carry out a detailed review of financial stewardship or financial viability. This element of well-led is the responsibility of Monitor and the NHS Trust Development Authority in NHS bodies. Our assessment will include a focus on how the management of finances impacts on the quality of service. For example, at core service level we will consider the potential impact of cost improvement plans on safety and quality, and how well this is understood. At provider level we will interview the director of finance (where relevant) and others and review key documents such as board meeting minutes.

We will work with Monitor and the NHS Trust Development Authority to share information, coordinate evidence gathering and site visits for NHS bodies. This enables us to use the findings of their work as evidence to inform our judgement and reduce the burden on these providers.

4. Intelligent Monitoring

Our new operating model aims to check whether there is a risk that services are not providing either safe or good quality care. Intelligent Monitoring is how we describe the processes we use to gather and analyse information to make these checks about services.

Intelligent Monitoring combines information from a wide range of data sources, including those shown earlier in figure 2, to give our inspectors a clear picture of the areas of care that may need to be followed up within a provider. Together with local insight and other factors, this information helps us to decide when, where and what to inspect. This means that we can anticipate, identify and respond more quickly to providers that are at risk of failing.

Our approach to Intelligent Monitoring will vary for different types of providers, where the amount and quality of available information may vary. For example, more information is normally available for NHS trusts compared with independent sector providers.

The Intelligent Monitoring tool is built on a set of indicators that relate to the five key questions we ask of all services – are they safe, effective, caring, responsive and well-led? The tool analyses a range of information including patient experience, staff experience and patient outcomes measures

The indicators raise questions about the quality and safety of care, but they are not used on their own to make final judgements. These judgements will always be based on a combination of what we find at inspection, Intelligent Monitoring data and local information from the ambulance service and other organisations.

We will be developing a set of indicators that we will use for NHS and independent ambulances from 2015.

5. Inspection

Our inspections are at the heart of our regulatory model and are focused on the things that matter to people. Within our approach we have two types of inspection:

Type of inspection	Description
Comprehensive (Sections 6 and 7)	• Review the provider in relation to the five key questions leading to a rating on each on a four-point scale. • Assess all of the core services, where they exist, covering all KLOEs. • Large inspection team. • Typically, two to four days announced site visit plus unannounced visits. • At least once every three years.
Focused (Section 8)	• Follow up a previous inspection or respond to a particular issue or concern, covering the relevant KLOEs or regulations. • Team size and composition depends on the focus of the inspection. • Length of site visit and whether it is announced or unannounced is flexed. • As frequent as required.

Inspecting a combination of services

As the health and care sectors become more complex, we need to be flexible to ensure we can assess providers that offer a wide range of services that are not just limited to a single type of service (for example, some NHS ambulance trusts also provide GP out-of-hours and NHS 111 services).

Where a provider has services that sit in more than one of our inspection approaches, and the range of services are either provided from one location or to a local population, we want to assess how well quality is managed across the range of services and give ratings for the provider or the location that reflect this. Therefore, when we inspect we will use our different approaches in combination to reflect the range of services that are provided (we call this a 'combined' inspection).

Our overall aims in these circumstances will be to:

- Deliver a comparable assessment of the five questions for each type of service, whether it is inspected on its own or as part of a combined provider.

- At provider or location level, assess how well quality and risks are managed across the range of services provided.
- Generate ratings and publish reports in a way that is meaningful to the public and people who use services, the provider and to our partners.
- Be proportionate and flexible to reflect the way the services are provided and consider any benefits derived from service integration.
- Use appropriate inspection methods and an inspection team with the relevant expertise to assess the services provided.
- Wherever possible, align steps throughout the inspection process in order to minimise the burden on providers.

We will continue to develop and test how we can make this work effectively and also how we should present our findings so that they are meaningful to all audiences. We will consider different scenarios in terms of the size and range of services being provided so that we can understand how to apply our approach in an appropriate, consistent and proportionate way.

As for any provider, if necessary between comprehensive inspections, we will undertake focused inspections that only look at some of the services or aspects of a service. The relationship holder for a provider will have oversight of this and consider any implications for our understanding of the provider's performance more broadly.

Services provided by third party providers

Sometimes a provider will have an arrangement in place where a third party organisation provides treatment or care as part or all of a core service. Where this is the case, it is essential that the services provided work effectively with those provided by the third party.

The inspection team will not inspect or rate the third party service as part of the services inspection. However, they will consider the care pathways between the services as part of their inspection. Our reports will explain where a third party provider is delivering part or all of a core service and who that third party provider is.

When planning the inspection we will consider whether it would be helpful, for the public and people using services, if we inspected the third party service at (or close to) the same time.

6. Planning the inspection

To make the most of the time that we are on site for an inspection, we must make sure we have the right information to help us focus on what matters most to people. This influences what we look at, who we will talk to and how we will configure our team. The information we gather during this time will also be used as evidence when we make our ratings judgements.

As described in section 3 and section 4, we will analyse data from a range of sources including information from people who use services, information from other stakeholders and information sent to us by providers.

We will collate our analysis into a data pack to be used by the inspection team. Our inspectors will use this information along with their knowledge of the service and their professional judgement to plan the inspection.

The provider will have the opportunity to review the data pack for accuracy and raise queries on the data. We will normally give providers at least 12 weeks' notice before a comprehensive inspection.

Gathering information from people who use services and stakeholders

Before or during the inspection site visit, we will also gather specific information. This includes:

- Engagement activity specifically designed to encourage people to share their experiences of care.
- Contacting and gathering information from stakeholders, as set out in section 3.
- Engaging with and asking for information from commissioners, Monitor or the NHS Trust Development Authority.
- Going into local hospitals – A&E, discharge lounges to talk to patients and staff

Gathering information from the provider

To prepare for an inspection we analyse information from a range of sources, including the provider themselves. The specific information we will request from a provider varies depending on the type of services offered, but will include information about:

- Management and governance structures
- Numbers, types and locations of services and teams
- Safety and quality governance arrangements
- Key performance indicators, issues, risks and concerns

- How the board monitors and takes action on issues relating to safety, clinical effectiveness and patient experience.

We will ask the provider to tell us about their performance against each of the five key questions, summarising this at overall service level as well as providing detail for each of their core services. In doing so, providers are expected to highlight areas of good and outstanding practice, as well as telling us about where the quality of services is less good, and in these cases, what action they are taking. This will allow us to assess how providers view themselves in terms of quality against the five key questions and to understand how their quality improvement plans reflect this, ahead of an inspection. The chief executive (or equivalent) should provide assurance to CQC that the information given is accurate and comprehensive in setting out the provider's view of its own performance.

Following the initial request, we may ask providers to submit additional information, particularly if the initial submission highlights areas that need to be clarified before the inspection site visit.

We expect providers to be open and honest with us, sharing all appropriate information. A lack of openness and transparency will be taken into account when we assess the well-led question.

We will advise providers about the timescales for submitting information, and will give them a point of contact so they can liaise with us if they have any questions. We ask providers to only send the information we have requested and to discuss with their point of contact any difficulties in sending the information, or where they believe they have extra information that they think may be useful to the inspection team.

Other information gathering activity

Throughout the year, and particularly in the weeks leading up to an inspection, we will gather information to give us insight into the provider's quality performance. This may involve looking at:

- **Concerns from people who use services and staff**: Information about complaints and concerns raised by patients and staff will help us understand how well a provider listens, investigates and learns, and to highlight potential areas of concern.
- **Quality governance:** Information on quality governance will enable us to see what systems and processes a provider has in place and understand how effective they are at ensuring organisation-wide learning, so that improvements are embedded where necessary. We will also look at how well information is used to assess and monitor the quality of care being delivered and to identify, assess and manage risks by board and sub-committees.
- **Safety alerts and serious incidents:** This enables us to explore how well a provider reports, investigates and learns from serious incidents

(including never events) and implements the improvements needed to prevent such incidents happening again. It also tests how a provider disseminates and acts on the requirements and supporting information published in selected safety alerts.

The inspection team

The inspection of ambulance services will be carried out by a team composed of the following roles:

- Inspection Chair (a very senior clinician, or manager with knowledge of quality and safety)
- CQC Head of Inspection or team leader
- Clinical and other experts
- Experts by Experience/patient and public representatives
- CQC managers and inspectors (varying levels of seniority)
- CQC data analysts
- CQC inspection planner
- CQC administrative support.

For the larger providers, such as NHS ambulance services, the team composition is likely to include all of these roles described above while a small independent ambulance services will be inspected by a much smaller team with just some of the roles represented.

However the team will always include specialists with specific skills to reflect the services provided and the areas of focus for the inspection – for example this may include paramedics, emergency medical technicians or call handlers.

Planning the focus of the inspection

The planning of the inspection will involve:

- Considering how to best engage with the public, people who use the service and specific communities to get a range of views and experiences about the services.
- Deciding on the areas of focus, which are informed by the data pack and information we have gathered before the site visit.
- Meeting with the chief executive or other senior member of staff to identify any specific aspects of the quality of care that should be reviewed as part of the inspection.
- Identifying members of the inspection team based on the specific skills, knowledge and experience needed, including the need for specialists.

- Ensuring that we follow up any outstanding compliance actions and Warning Notices or conditions of registration, and any improvement plans for providers in special measures.
- Making an outline plan for the site visit.
- Setting a provisional date for the quality summit (see section 10).

Making arrangements for the inspection

The Head of Inspection and the inspection planner will be the main CQC points of contact with the provider. The inspection planner will liaise with the provider on all logistical requirements, for example room bookings, arranging interviews, parking and security passes.

We will contact the provider when we need local information to help us to advertise and arrange listening activities, for example where best to hold them, and for information on local groups and patient representatives who may be able to support us with this activity.

The Head of Inspection and the Inspection Chair will also hold an introductory session with the provider's chief executive and other senior staff. This which will be an opportunity to understand the logistics of the service and to explain:

- The scope and purpose of the inspection
- Who will be involved
- How the inspection will be carried out, including our relevant powers
- How we will communicate our findings.

7. Site visits

Site visits are a key part of our regulatory framework, giving us an opportunity to talk to people using services, staff and other professionals to find out their experiences. They allow us to observe care being delivered and to review people's records to see how their needs are managed both within and between services.

Site visit timetable

The site visit will generally include the following stages:

- Briefing and planning session for the inspection team
- Announced site visits (two to four days for NHS trusts)
- Closing the announced inspection visit
- Unannounced visits
- Additional site visits (if required).

Briefing and planning session

Before the site visit there will be a briefing and planning session for the inspection team led by the Head of Hospital Inspection and the Inspection Chair.

Provider presentation

At the start of the site visit the ambulance service will make a 30-minute presentation to the inspection team. This presentation should set out:

- Background to the organisation
- Its approach to ensuring good quality care
- What is working well or is outstanding
- The areas of concern or risk.

Gathering evidence

The inspection team will use the key lines of enquiry (KLOEs) and any concerns identified through the preparation work to structure their site visit and focus on specific areas of concern or potential areas of outstanding practice. They will collect evidence against the KLOEs using the methods described below.

Gathering the views of people who use services

A key principle of the approach to inspecting ambulance services is to seek out and listen to the experiences of the public, people who use these services and those close to them. This includes the views of people who are in vulnerable circumstances or who are less likely to be heard.

We gather people's views through a range of activity such as:

- Speaking individually and in groups with people who use services.
- Holding focus groups with people who use services and those close to them.
- Using comment cards placed in reception areas and other busy areas to gather feedback.
- Using posters to advertise the inspection to give people an opportunity to speak to the inspection team. These will be put in areas where people will see them, such as in the discharge lounge of a local hospital.
- Using the information gathered from our work looking at complaints and concerns.
- Promoting the 'share your experience' form on our website through a variety of channels.
- Visiting places where patients are conveyed to and from, such as A&E and outpatient departments, and gathering evidence.

We will include 'Experts by Experience' on our inspections. Experts by Experience are people who use care services or care for someone who uses health and/or social care services. Their main role is to talk to people who use services and tell us what they say. Many people find it easier to talk to an Expert by Experience rather than an inspector. Experts by Experience can also talk to carers and staff, and can observe the care being delivered.

Experts by Experience are recruited and supported to take part in our work through a number of support organisations. The support organisations also carry out the relevant Disclosure and Barring Service checks. Experts by Experience are provided with training to carry out their role, and their performance is monitored on an ongoing basis. We match their experience to the services that are being inspected. More details on the Experts by Experience programmed are on our website at:

www.cqc.org.uk/content/involving-people-who-use-services.

Gathering the views of staff

The inspection team will interview senior and frontline staff at all levels. We will usually interview the following people at corporate level:

- Chair
- Chief executive

- Medical director
- Director of operations
- Director of finance
- Non-executive director responsible for quality/safety
- Complaints lead
- The senior lead for human resources.
- Senior information and risk owner (SIRO).

For independent providers with multiple services, we will interview these people once to inform the separate inspections of the different services (rather than interviewing them repeatedly).

The team will hold focus groups with separate groups of staff. These will be peer to peer focus groups involving the clinical experts on our inspection team. We normally hold focus groups with:

- Paramedics
- Emergency care assistants
- Call handlers
- PTS staff.

We may also seek the views of staff through an online survey or email.

Other inspection methods/information gathering

We have introduced a new approach to gather evidence to inform our inspections and judgements of ambulance services by observing care provided to people by paramedics and emergency care assistants. This involves our inspectors and specialist advisers riding in an emergency ambulance during a shift. This will allow them to observe care being delivered and to have the opportunity to speak to staff.

Other ways of gathering evidence will include:

- Inspecting care environments
- Reviewing records
- Reviewing policies and documents.
- Inspecting facilities – for example, for storage of medicines.

Consultation question

4. Do you think observing care in or from an ambulance is an appropriate way to gather evidence to inform the inspection?

Continual evidence evaluation

Throughout the inspection the CQC team leader will continually review the emerging findings with the inspection team to maintain consistency. This keeps the team up to date with all issues and enables the focus of the inspection to be shifted if new areas of concern or outstanding practice are identified. It also enables the team to identify what further evidence might be needed in relation to a line of enquiry and which relevant facts might still be needed to corroborate a judgment or, where appropriate, a rating.

We will establish subteams where the service covers a large geographical area to enable the team to visit depots, garages and other offices to gather the evidence they require. In these circumstances, we will share and validate evidence by teleconference.

Continual evaluation is also an opportunity to make connections across different areas of inspection where there may be common themes, such as findings from audits, and which might raise questions about corporate level systems, such as those for governance.

Feedback on the announced visit

At the end of the announced inspection visit, the Inspection Chair and Head of Inspection/team leader will hold a feedback meeting with the chief executive and other senior members of the provider's staff. This is to give high level initial feedback only, illustrated with some examples. We will not provide indicative ratings at this stage.

The meeting will cover:

- Thanking the ambulance services staff for their support and contribution.
- Explaining, in general terms, our findings to date, but noting that further analysis of the evidence will be needed before final judgements can be reached on all of the issues.
- Any issues that were escalated during the visit.
- Any plans for follow-up or additional visits (unless they are unannounced).
- Reminding the provider that we may carry out unannounced visits.
- Explaining that further analysis is required before we can award ratings.
- Explaining how we will make judgements against the existing regulations.
- Explaining the next steps, including challenging factual accuracy in the report and final report sign-off, quality summits and publication.
- Answering any questions from the ambulance service.

Unannounced inspection visits

Following the announced visit the inspection team will normally carry out further inspection activities.

These unannounced visits may be during the day or out of normal working hours and will involve a subset of the inspection team. They will use the inspection methods described above and we may go back to areas we have already visited. At the start of these visits, the team will meet with the provider's senior operations lead on duty at the time, and at the end will feed back if there are any immediate safety concerns. Because of the logistical issues involved in organising visits for large geographically dispersed services, we will complete the unannounced inspection within 30 days of the announced visit. This is an extension to the normal time period, so may result in a longer period for publication of our inspection report.

Consultation question

5. Do you think that 30 days is an appropriate period of time to complete an unannounced visit of an NHS ambulance service?

8. Focused inspections

There will be circumstances when we will carry out a focused inspection rather than a comprehensive inspection. We will carry out a focused inspection for one of two reasons:

- To focus on an area of concern
- For NHS providers, where changes occur that affect the organisational structure of the provider.

Focused inspections do not look at all five key questions; they focus on the areas indicated by the information that triggers the focused inspection.

Areas of concern

We will carry out a focused inspection when we are following up on areas of concern, including:

- Concerns that were originally identified during a comprehensive inspection and have resulted in enforcement or compliance action. This is normally within three months of the date set in the warning notice / compliance action, or of the provider notifying us that they have taken the action needed if that is before the date set.
- Concerns that have been raised with us outside an inspection through other sources such as information from Intelligent Monitoring, Mental Health Act monitoring visits, members of the public, staff or stakeholders.

Changes in the service provider

When there is a planned merger, acquisition or takeover of an NHS provider, Monitor or the NHS Trust Development Authority will need to seek our advice before authorising the transaction. We will typically undertake a focused inspection in order to inform our advice or a comprehensive inspection if necessary. We will coordinate our evidence gathering and site visits with Monitor or the NHS Trust Development Authority to reduce the burden on ambulance services.

The focused inspection process

Although they are smaller in scale, focused inspections broadly follow the same process as a comprehensive inspection.

The reason for the inspection determines many aspects, such as the scope of the inspection, when to visit, what evidence needs to be gathered, the size of the team and which specialist advisers to involve. Visits may be

announced or unannounced at our discretion depending on the focus of the inspection.

Although smaller in scope, the inspection may result in a change to ratings at the key question or core service level. The same ratings principles apply as for a comprehensive inspection. The revised ratings resulting from a focused inspection will not necessarily lead to a change of the overall provider rating if the focused inspection was carried out more than six months after the comprehensive inspection. As a focused inspection is not an inspection of the whole of a provider or service it will not produce ratings where they do not already exist.

When a focused inspection identifies significant concerns, it may trigger a comprehensive inspection.

9. Judgements and ratings

Making judgements and ratings

Inspection teams will base their judgements on the available evidence, using their professional judgement. For each individual rating (for example, safety in patient transport services), the judgement is made following a review of the evidence under each key line of enquiry (KLOE), with this evidence coming from the four sources of information: our ongoing relationship, Intelligent Monitoring, pre-inspection work and from the inspection visit itself. This hard link between KLOEs, the evidence gathered under them, and the rating judgements lies at the heart of our approach to ensuring consistent, authoritative judgements on the quality of care.

When making our judgements, we will consider the weight of each piece of relevant evidence. In most cases we will need to corroborate our evidence with other sources to support our findings and to enable us to make a robust judgement.

When we have conflicting evidence, we will consider the weight of each piece of evidence, its source, how robust it is, and which is the strongest. We may conclude that we need to seek additional evidence or specialist advice in order to make a judgement.

Ratings

What do we give a rating to?

For each ambulance service we inspect, we will rate performance at four levels:

Level 1: Rate every core service for every key question

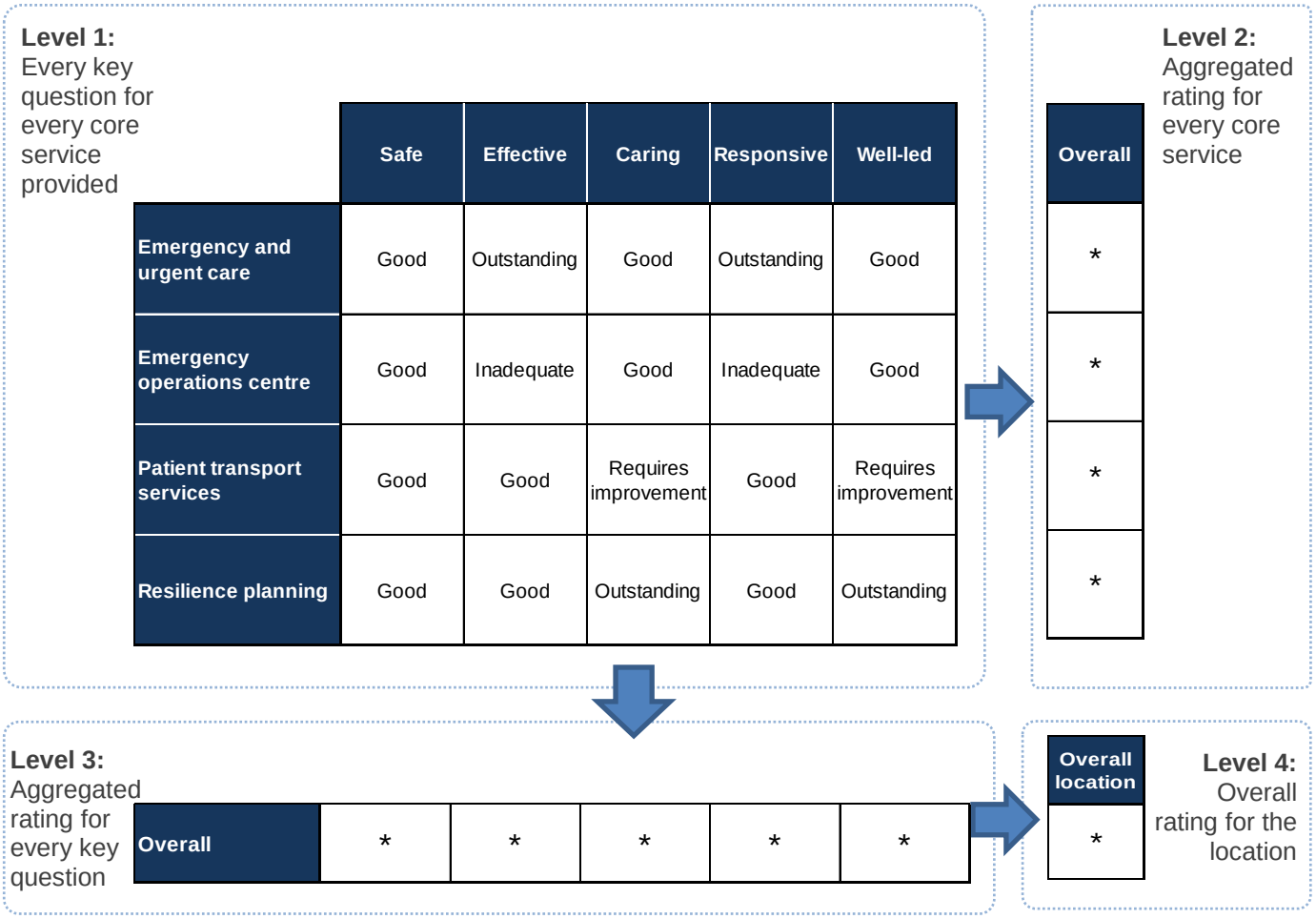
Level 2: An aggregated rating for each core service

Level 3: An aggregated rating for each key question

Level 4: An aggregated overall rating for the trust as a whole.

The following example shows how the four levels work together:

Figure 5: The levels at which ambulance services are rated

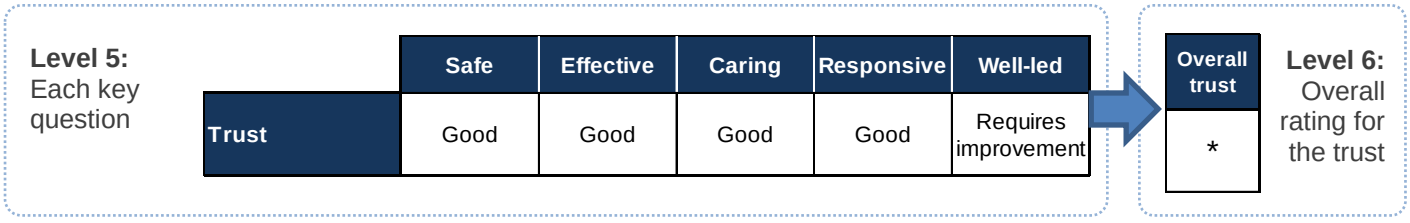


* These will be aggregated ratings (outstanding, good, requires improvement or inadequate), which will be determined using the ratings principles (see below).

For NHS providers, we will rate performance at the following two levels:

Level 5: Each of the key questions trust-wide. This is informed by our findings at level 3 for each location in the trust, and information on the five key questions that is available at trust level only.

Level 6: The trust as a whole.



Sometimes, we will have inspected but will not be able to award a rating. This could be because:

- We do not have enough evidence, or
- The service has recently been reconfigured, such as being taken over by a new trust.

In these cases we will use the phrase ‘inspected but not rated’.

We may also suspend a rating at any level. For example, we may have identified significant concerns that, after reviewing but before a full assessment, lead us to re-consider our previous rating. In this case we would suspend our rating and then investigate the concerns.

How we decide on a rating

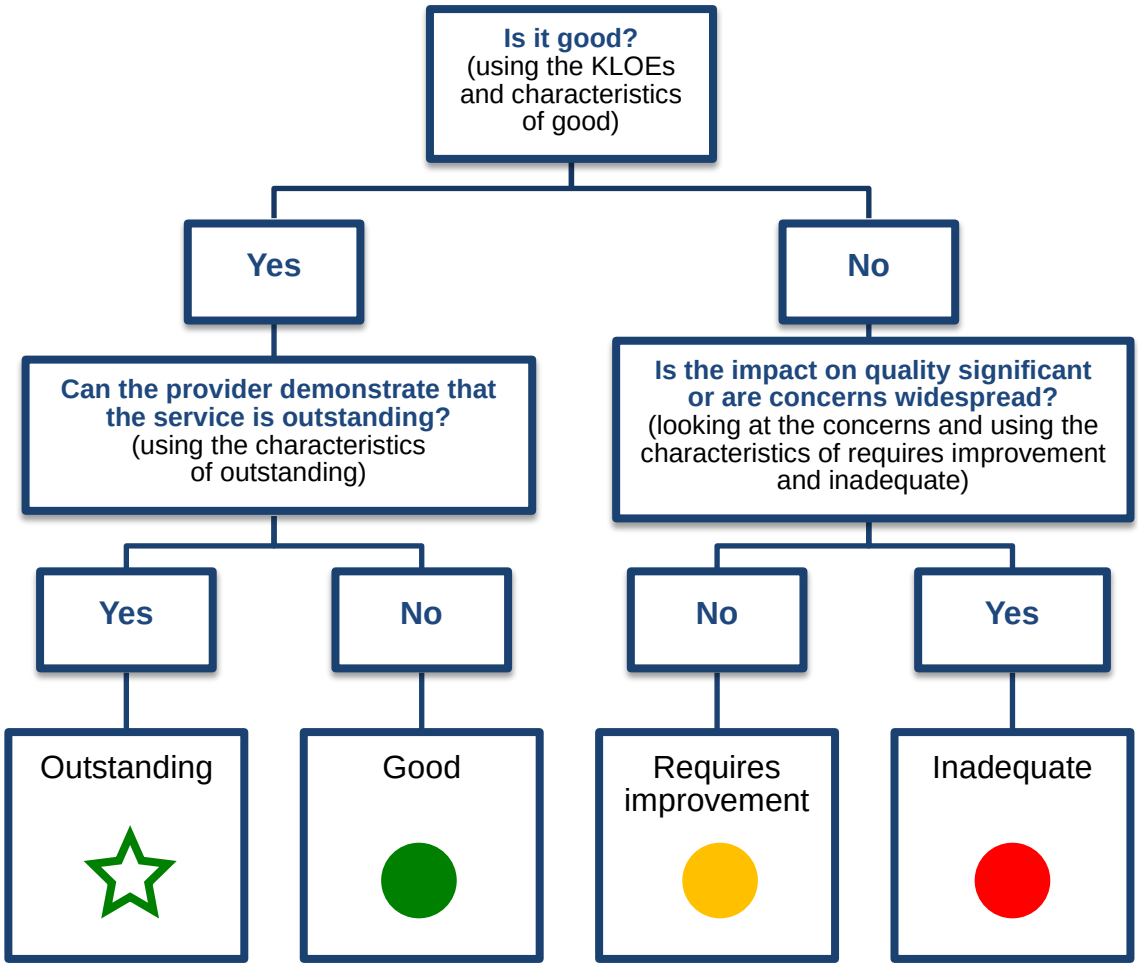
When awarding ratings of the five key questions at service level, our inspection teams will consider the evidence they have gathered for each of the KLOEs and use the guidance supplied to decide on a rating.

In deciding on a rating, the inspection team will look to answer the following questions:

- Does the evidence demonstrate a potential rating of good?
- If yes – does it exceed the standard of good and could it be outstanding?
- If no – does it match the characteristics of requires improvement or inadequate?

The following flowchart (figure 6) shows how this would work.

Figure 6: How we decide on a rating



Aggregating ratings

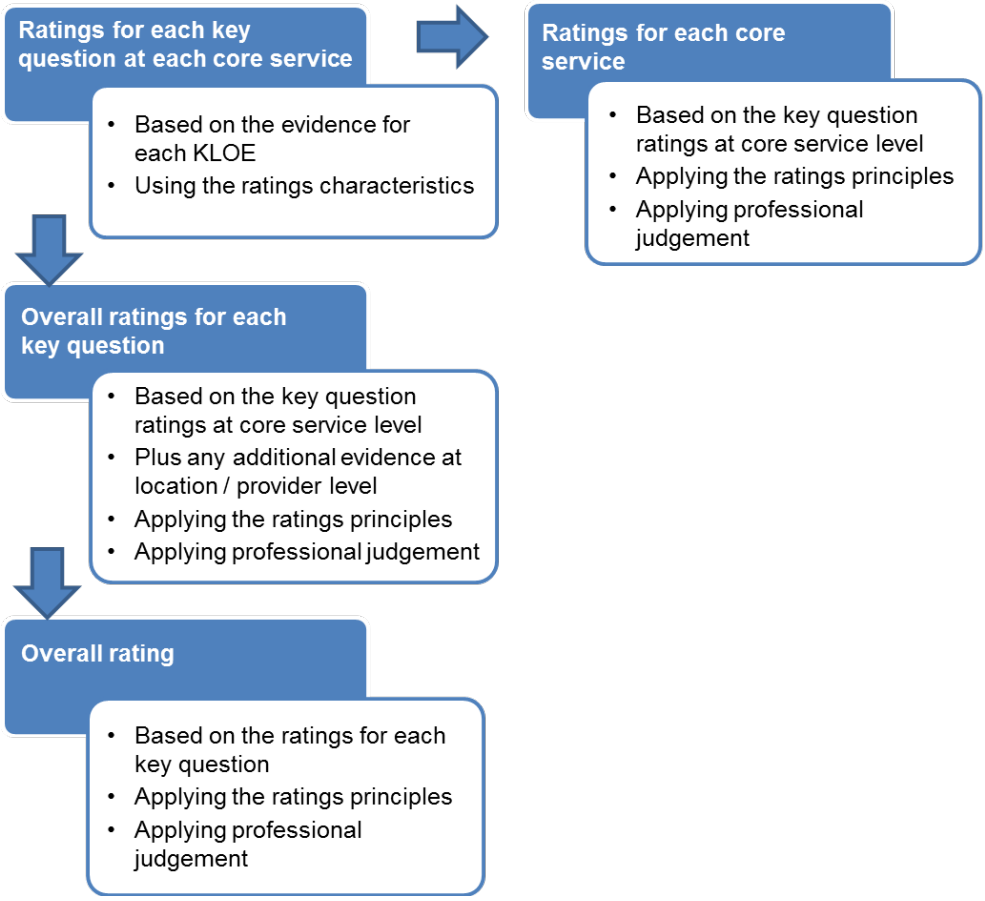
When aggregating ratings, our inspection teams will follow a set of principles to ensure consistent decisions. Our principles are set out in appendix D.

The principles will normally apply but will be balanced by inspection teams using their professional judgement. Our ratings must be proportionate to all of the available evidence and the specific facts and circumstances.

Examples of when we may use professional judgement to depart from the principles include:

- Where the concerns identified have a very low impact on people who use services
- Where we have confidence in the service to address concerns or where action has already been taken
- Where a single concern has been identified in a small part of a very large and wide ranging service
- Where a core service is very small compared to the other core services within a provider.

Figure 7: How we aggregate ratings



Where a rating decision is not consistent with the principles, the rationale will be clearly recorded and the decision reviewed by a national quality control and consistency panel. The role of this group is to ensure the quality of every quality report before it is shared with the organisation being inspected.
The ratings principles described above for an NHS ambulance service are based on the concept that we will report on and rate the core services and the five key questions for the trust, which will be aggregated to give an overall trust rating.

Consultation questions

These questions are specific to NHS ambulance services:

6. Do you agree that we should report on and rate core services at trust level?
7. Due to the large geographical areas covered by NHS ambulance services, do you think we should rate core services at area level within an NHS ambulance service? If so, how would we identify the areas, and what criteria could we use?

This question is specific to independent ambulance services:

8. If we rated independent ambulance services, what would be useful, a rating at location level or at core service level?

Appendix D sets out the principles that we propose to apply when aggregating ratings with some further questions for consultation.**Aggregating ratings for a combined inspection**

As described in section 5, some ambulance providers also provide non-ambulance services. In these cases we will:

1. For each service type, aggregate the underlying ratings of each service type (for example, NHS 111, GP out-of-hours services) to provide ratings for each of the five key questions.
2. Aggregate the service type key questions to derive overall key question ratings at the provider level.

We will use the aggregation principles set out in appendix D. The level of complexity of aggregation means that it may be more likely that professional judgement will need to balance the aggregation principles to produce a fair and proportionate result.

We will keep this approach under review to consider whether specific principles are needed for how we aggregate provider level ratings for combined inspections.

Rating at corporate level

We have not yet decided whether or how to rate independent providers at corporate level. Doing so would promote a fair system in terms of public accountability across NHS and non-NHS services, and could help to engage the entire provider in assuring quality of services. However, we have also heard views that a provider-level rating for independent providers may be of limited interest to the public, and that aggregating multiple services could be difficult in methodological and logistical terms.

Consultation question

9. Do you think we should rate independent providers at corporate level? If so, how should we do this?

10. Reporting, quality control and action planning

Reporting

For each inspection, we will produce a report to cover all the locations or areas (depending on the views of what level we rate and report on) we have visited and a report for the provider overall. The report will include all the ratings. The report will be clear, accessible and written in plain English.

Our reports will focus on what our findings about each of the five key questions mean for the people who use the service. We will describe the good practice we find as well as any concerns we have. In our reports we will clearly set out any evidence about breaches of the regulations.

Quality control

Consistency is one of our core principles that underpins all our work. We have put in place an overall approach for CQC to embed validity and consistency in everything we do. The key elements of this are:

- A strong and agreed core purpose for CQC
- A clear statement of our role in achieving that purpose
- Consistent systems and processes to underpin all our work
- High-quality and consistent training for our staff
- Strong quality assurance processes
- Consistent quality control procedures.

A national quality control and consistency panel, chaired by CQC's Chief Inspector of Hospitals or a Deputy Chief Inspector, will review inspection reports. The panel will include a selection of representatives from key areas of the organisation including CQC's legal, policy, intelligence and enforcement teams. Initially this will apply to all reports, but over time we will move to regional panels and sampling for national panels.

Once approved by the national panel, the reports will be sent to the provider's nominated individual and chief executive, to enable them to comment on the factual accuracy.

We will also share the draft report with Monitor and/or the NHS Trust Development Authority as appropriate.

Action planning

The inspection findings will inform the basis of a discussion at a quality summit. For NHS ambulances, this involves a meeting with the provider and partners in the local health and social care system – organisations that are responsible for commissioning or providing scrutiny of health and social care services in the local area.

The purpose of the quality summit is to agree a plan of action and recommendations based on the inspection team's findings as set out in the inspection report.

Each quality summit will consider:

- The findings of the inspection.
- Whether planned action by the provider to improve quality is adequate or whether additional steps need to be taken.
- Whether support should be made available to the provider from other stakeholders, such as commissioners, to help them improve.

The final reports will be issued to the provider before the quality summit.

The plan of action will be developed by partners in the local health and social care system and the local authority. The quality summit attendees may include:

- Inspection Chair
- The Head of Inspection or team leader for the inspection visit
- Expert(s) from the inspection team
- Expert(s) by Experience or patient and public representatives from the inspection team
- Provider representatives (e.g. chair, chief executive, medical director, director of finance, chief operating officer)
- Monitor/NHS Trust Development Authority
- Local Healthwatch
- NHS England Regional representative
- Quality Surveillance Group regional representative
- Representatives from relevant clinical commissioning groups
- Chairs of local resilience forums
- Others as appropriate (for example, a Health and Safety Executive representative).

For independent ambulances, it may include corporate level partners or other specific partners, such as commissioners if they provide extensive NHS business.

The CQC representative will chair the first part of the quality summit, and present the inspection team's findings. The second part of the summit will not normally led by CQC. It will usually be chaired by a representative from Monitor, the NHS Trust Development Authority or the provider itself, depending on the findings of the inspection. The provider will be given an opportunity to respond to the findings of the report. The focus will then be on the provider and partner organisations to identify and agree any action that needs to be taken in response to the findings of our inspection.

After the quality summit, the recommendations for action will be captured in a high level action plan. Further work will be needed by the provider and its partners to develop detail beneath the high level plan. This should be completed within one month of the quality summit. Action plans will be owned by the provider, and it should use its own action plan template. Once agreed, action plans should be shared with the CQC Head of Hospital Inspection or inspection manager to ensure that all key areas highlighted during the inspection have been appropriately addressed.

Publication

We publish the inspection reports and ratings on our website soon after the quality summit. We will coordinate this with providers and encourage them to publish their action plans on their own website.

11. Enforcement and actions

Types of action and enforcement (under existing regulations)

Where we identify concerns we will decide what action is appropriate to take. The action we take will be proportionate to the impact, or risk of impact, that the concern has on the people who use the service and how serious it is.

Where the concern is linked to a breach in regulations, we have a wide range of enforcement powers given to us by the Health and Social Care Act 2008. We will use 'Warning Notices' to tell providers that they are not complying with a condition of registration, requirement in the Act or a regulation, or any other legal requirement that we think is relevant.

Our published enforcement policy describes our powers in detail and our approach to using them.

We may also make 'recommendations' even though a regulation has not been breached to help a provider move to a higher rating.

We will include in our report any concerns, recommended improvements or enforcement action taken, raise them at the quality summit and expect appropriate action to be taken by the provider and local partners. Regulations are all covered by our key lines of enquiry, so no separate inspection or information collection exercises are needed.

We will follow up any concerns or enforcement action. If the necessary changes and improvements are not made, we will escalate our response, gathering further information through a focused inspection. However, we will always consider each case on its own merit and we will not rigidly apply the enforcement rules when another action may be more appropriate.

Relationship with the new fundamental standards regulations

The Department of Health is introducing new regulations to replace the current registration requirements. The new regulations, called 'fundamental standards' are more focused and clear about the care that people should expect to receive. These regulations are expected to come into full force in April 2015. Until that time we will continue to enforce against the existing regulations.

We have consulted on guidance to help providers to understand how they can meet the new regulations and, when they do not, what actions CQC will take. The final version of this handbook will reflect the new regulations and final guidance.

New requirements: fit and proper person for directors, and duty of candour

Two new requirements, the fit and proper person requirement for directors and the duty of candour, will apply from November 2014 to NHS bodies and from April 2015 for independent providers.

The fit and proper person requirement will play a major part in ensuring the accountability of directors of NHS bodies (and from April 2015, directors or their equivalents in all other registered providers). It places a clear duty on health and social care providers to make sure directors and board members (or their equivalents, including interim post holders) meet the criteria set out.

The new statutory duty of candour will mean that people, and where appropriate their families, must be told openly and honestly when unanticipated things happen that cause them serious or moderate harm. They should be given an apology, an explanation, all necessary practical and emotional support, and assurances about their continuity of care. This statutory duty on organisations supplements the current contractual duty of candour under the NHS standard contract and the existing professional duty of candour on individuals.

These new requirements are incorporated into our assessment framework and registration processes. Where we find that providers are not conforming to these regulations we will report this and take action as appropriate.

Special measures

Sometimes CQC will identify the need for significant improvements in quality, but not have confidence in the leadership of an NHS trust or foundation trust (FT) to make the necessary improvements without additional support. In those circumstances, we have the option to recommend to the NHS Trust Development Authority (NHS TDA) or Monitor that the trust is placed into special measures. Special measures consist of a set of specific interventions designed to support the trust to improve rapidly the quality of care.

During the special measures period we will discuss progress and keep up to date with the trust/FT and with NHS TDA/Monitor. We will inspect at any time during that 12 months if we have any new concerns and take the appropriate enforcement action if necessary.

We will normally re-inspect 12 months from the trust being placed in special measures, but NHS TDA/Monitor may recommend an earlier inspection if there is sufficient evidence of good progress. If, following inspection, we feel sufficient progress has been made we will recommend it is taken out of special measures.

If sufficient progress has not been made when we re-inspect we will consult with NHS TDA/Monitor as to whether the trust remains in special measures or if further action is needed.

Further information can be found in the joint NHS TDA, Monitor and CQC document, A guide to special measures.

Responding to inadequate care in independent ambulances services

In addition to our enforcement powers we will develop an approach to special measures for independent ambulance providers that are rated. This will differ to the approach for NHS ambulances as there are no equivalent bodies to support this sector to improve. However, we intend to offer a time-limited period to the independent sector to take the necessary action to make improvements that we identify through our inspection, which includes an assessment of well-led.

We are developing this approach to make sure that it is aligned across all independent providers registered with CQC.

Consultation questions

10. These questions are specific to independent ambulance services:
    - Do you think we should introduce special measures for independent ambulances?
    - What do you think this should involve?

Challenging the evidence and ratings

We want to ensure that providers can raise legitimate concerns about the evidence we have used and the way we apply our ratings process, and have a fair and open way for resolving them.

The following routes will be open to providers to challenge our judgements.

Factual accuracy check

When providers receive a copy of the draft report (which will include their ratings) they will be invited to provide feedback on its factual accuracy. They will be able to challenge the accuracy and completeness of the evidence on which the ratings are based. Any factual accuracy comments that are upheld may result in a change to one or more rating. As set out in section 7, we propose that providers have 10 working days to review draft reports for factual accuracy and submit their comments to CQC.

Warning Notice representations

If we serve a Warning Notice, we will give providers the opportunity to make representations about the matters in the Notice. The content of the Notice will

be informed by evidence about the breach which is in the inspection report. This evidence will sometimes contribute to decisions about ratings. As with the factual accuracy check, representations that are upheld and that also have an impact on ratings may result in relevant ratings being amended.

Request for a rating review

Providers can ask for a review of ratings.

The only grounds for requesting a review is that CQC did not follow the process for making ratings decisions and aggregating them. Providers will not be able to request reviews on the basis that they disagree with the judgements made by CQC, as such disagreements will be dealt with through the factual accuracy checks and any representations about a Warning Notice if one was served.

Where a provider thinks that we have not followed the published process properly and wants to request a review of one or more of their ratings, they must tell us of their intention to do so once the report is published. We will reply with full instructions on how to request a review.

Providers will have a single opportunity to request a review of their inspection ratings. In the request for review form, providers will be able to say which rating(s) they want to be reviewed and all relevant grounds. Where we do not uphold a request for review, providers will not be able to request a subsequent review of the ratings from the same inspection report.

When we receive a request for review we will explain on our website that the ratings in a published report are being reviewed.

The request for review process will be led by CQC staff who were not involved in the original inspection, with access to an independent reviewer.

We will send the outcome of the review to the provider following the final decision. Where a rating is changed as a result of a review, the report and ratings will be updated on our website as soon as possible. It should be noted that following the conclusion of the review, ratings can go down as well as up.

The review process is the final CQC process for challenging a rating. Providers can challenge our decisions elsewhere – for example, by complaining to the Parliamentary and Health Services Ombudsman or by applying for judicial review.

Complaints about CQC

We aim to deal with all complaints about how we carry out our work, including complaints about members of our staff or people working for us, promptly and efficiently.

Complaints should be made to the person that the provider has been dealing with, because they will usually be the best person to resolve the matter. If the

complainant feels unable to do this, or they have tried and were unsuccessful, they can call, email or write to us. Our contact details are on our website.

We will write back within three working days to say who will handle the complaint.

We will try to resolve the complaint. The complainant will receive a response from us in writing within 15 working days saying what we have done, or plan to do, to put things right.

If the complainant is not happy with how we responded to the complaint, they must contact our Corporate Complaints Team within 20 days and tell us why they were unhappy with our response and what outcome they would like. They can call, email or write to our Corporate Complaints Team. The contact details are on our website.

The team will review the information about the complaint and the way we have dealt with it. In some cases we may ask another member of CQC staff or someone who is independent of CQC to investigate it further. If there is a more appropriate way to resolve the complaint, we will discuss and agree it with the complainant.

We will send the outcome of the review within 20 working days. If we need more time, we will write to explain the reason for the delay.

If the complainant is still unhappy with the outcome of the complaint, they can contact the Parliamentary and Health Service Ombudsman. Details of how to do this are on the Parliamentary and Health Service Ombudsman’s website.

How to respond to this consultation

You can respond to our consultation in the following ways:

Online:

Use our **online form**

You can also find the form and more information at:
www.cqc.org.uk/consultation-dental-independenthealthcare-ambulance

By email:

Email your response to: **CQCchanges.tellus@cqc.org.uk**

By post:

Write to us at:

CQC consultation: How we inspect, regulate and rate
Care Quality Commission
Citygate
Gallowgate
Newcastle upon Tyne
NE1 4PA

On Twitter:

Use **#tellcqc** for your feedback and mention **@carequalitycomm**

Please send us your views and comments by **Friday 23 January 2015**.

Consultation questions

1. We have identified the core services that we will check during our inspections of ambulance services (see appendix A). These questions are for both NHS and independent ambulance services:

   - Do you agree that these are the right core services to look at?
   - Do you understand what we mean by these core services? If not, what is unclear?

   Issues to consider:

   We believe weighting core services equally is in line with our commitment to promote equality in the services we regulate and to uphold Equality Act legislation. Everyone who receives care and treatment should expect

to receive the same good quality care, irrespective of the type of service that they are using.

An exception might be where an ambulance service provides a core service to a smaller population than another core service; for example where an ambulance service provides patient transport services to 10% of the population they provide emergency and urgent services to. In this situation the inspection team would use their professional judgement to determine what weight to give the core service when aggregating ratings.

- Do you agree that, in general, core services should be weighted equally with the above exception?

2. These questions are for both NHS and independent ambulance services:

- Do you feel confident that the key lines of enquiry and the list of prompts will help our inspectors judge how safe, effective, caring, responsive and well-led NHS and independent ambulance services are?
- Is there anything missing?

3. These questions are for both NHS and independent ambulance services:

- Do you agree that the characteristics of 'outstanding' (in appendix C) are what you would expect to see in an outstanding NHS and independent ambulance service?
- Do you agree that the characteristics of 'good' (in appendices B and C) are what you would expect to see in a good NHS and independent ambulance service?
- Do you agree that the characteristics of 'requires improvement' (in appendix C) are what you would expect to see in an NHS and independent ambulance service that requires improvement?
- Do you agree that the characteristics of 'inadequate' (in appendix C) are what you would expect to see in an NHS and independent ambulance service that was inadequate?
- Do you agree that rating all ambulances will achieve the purposes described in the Nuffield report?

4. Do you think observing care in or from an ambulance is an appropriate way to gather evidence to inform the inspection?

5. Do you think that 30 days is an appropriate period of time to complete an unannounced visit of an NHS ambulance service?

These questions are specific to NHS ambulance services:

6. Do you agree that we should report on and rate core services at trust level?

7. Due to the large geographical areas covered by NHS ambulance services, do you think we should rate core services at area level within an NHS ambulance service? If so, how would we identify the areas, and what criteria could we use?

This question is specific to independent ambulance services:

8. If we rated independent ambulance services, what would be useful, a rating at location level or at core service level?

9. Do you think we should rate independent providers at corporate level? If so, how should we do this?

10. These questions are specific to independent ambulance services:
    - Do you think we should introduce special measures for independent ambulances?
    - What do you think this should involve?

11. As part of this consultation we have published a Regulatory impact assessment and an Equality and human rights duties impact analysis. We would also like your comments on these.

Note:

Please also see the separate appendix document to this handbook, which contains important information:

Appendix A: Core service definitions

Appendix B: Key lines of enquiry

Appendix C: Characteristics of each rating level

Appendix D: Ratings principles

Published November 2014

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