CareQuality Commission

How CQC regulates:

# NHS acute hospitals

## Provider handbook

September 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.

### Our principles

- We put people who use services at the centre of our work.
- We are independent, rigorous, fair and consistent.
- We have an open and accessible culture.
- We work in partnership across the health and social care system.
- We are committed to being a high performing organisation and apply the same standards of continuous improvement to ourselves that we expect of others.
- We promote equality, diversity and human rights

# Contents

# Introduction

This handbook describes our approach to regulating, inspecting and rating NHS acute hospitals.

Our approach builds on our consultation, *A new start*, which proposed radical changes to the way we inspect and regulate NHS acute hospitals.

Our approach includes using a national team of expert hospital inspectors and clinical and other experts, including people with experience of receiving care (Experts by Experience). We 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 are in-depth and we also inspect in the evenings and at weekends when we know people can experience poorer care. Our inspectors 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 rate services. These ratings will help people to compare services and will highlight where care is outstanding, good, requires improvement or inadequate.

We also undertake other inspection and regulation activities that are not covered in this handbook, such as thematic inspections and joint inspections with Ofsted and HM Inspectorate of Prisons. We coordinate this activity to reduce the burden on providers.

Our approach has been developed over time and through consultation. We have worked with the public, people who use services, providers and organisations with an interest in our work to develop our approach.

We will continue to learn and adapt how the approach is put into practice from 1 October 2014, for example how we include a focus on particular care pathways or conditions in our inspections. However, the overall framework, including our five key questions, our core services, the key lines of enquiry and ratings characteristics, will remain constant. We are planning to refresh this document to take into account the new fundamental standards regulations that are due to come into force in April 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.

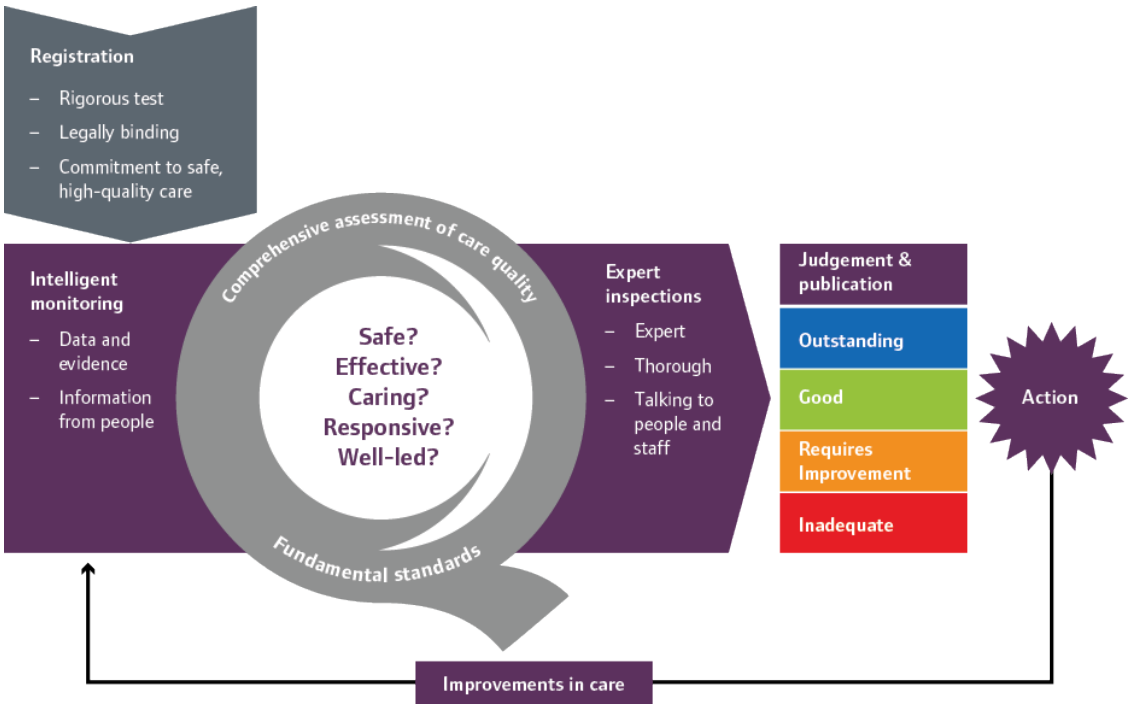
## Our operating model

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

We will not inspect all the acute services within a trust. We have identified eight services that we will always inspect, irrespective of risk, at every NHS acute hospital where they are provided. These are known as the core services:

- Urgent and emergency services
- Medical care (including older people's care)
- Surgery
- Critical care
- Maternity and gynaecology
- Services for children and young people
- End of life care
- Outpatients and diagnostic imaging.

We selected these core services as they are seen as carrying the greatest risk and cover the majority of services that people use. We set out our definitions of these core services in the separate appendix A.

Our inspections will normally be limited to these core services. However, if we identify particular services, specialist areas or pathways of care where we have concerns, or where we believe the quality of care could be outstanding, and they are not covered by these core services, we may look at one or two of 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.

We will not always be able to visit every ward or part of a 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 received a complaint, there has been a safeguarding alert or we have heard from a whistleblower.
- We have not inspected for a long period or have not previously inspected at all.
- Where the quality of care may be outstanding.

For acute specialist trusts, we will only inspect the elements of the core services that are appropriate for the services they offer. In some cases it may be necessary to introduce a specialist core service, for example, transition services for trusts that specialise in the treatment of children and young people. The additional core services we have identified to date are set out in appendix A.

## Care pathways

We are committed to including a focus on care pathways and particular patient groups as part of our inspection of acute 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 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.

Our teams will also use guidance that provides detailed areas of focus for each of the core services, in addition to the KLOEs and prompts. This guidance has been developed with internal and external specialists and reflects aspects that are of particular interest to the public and professionals.

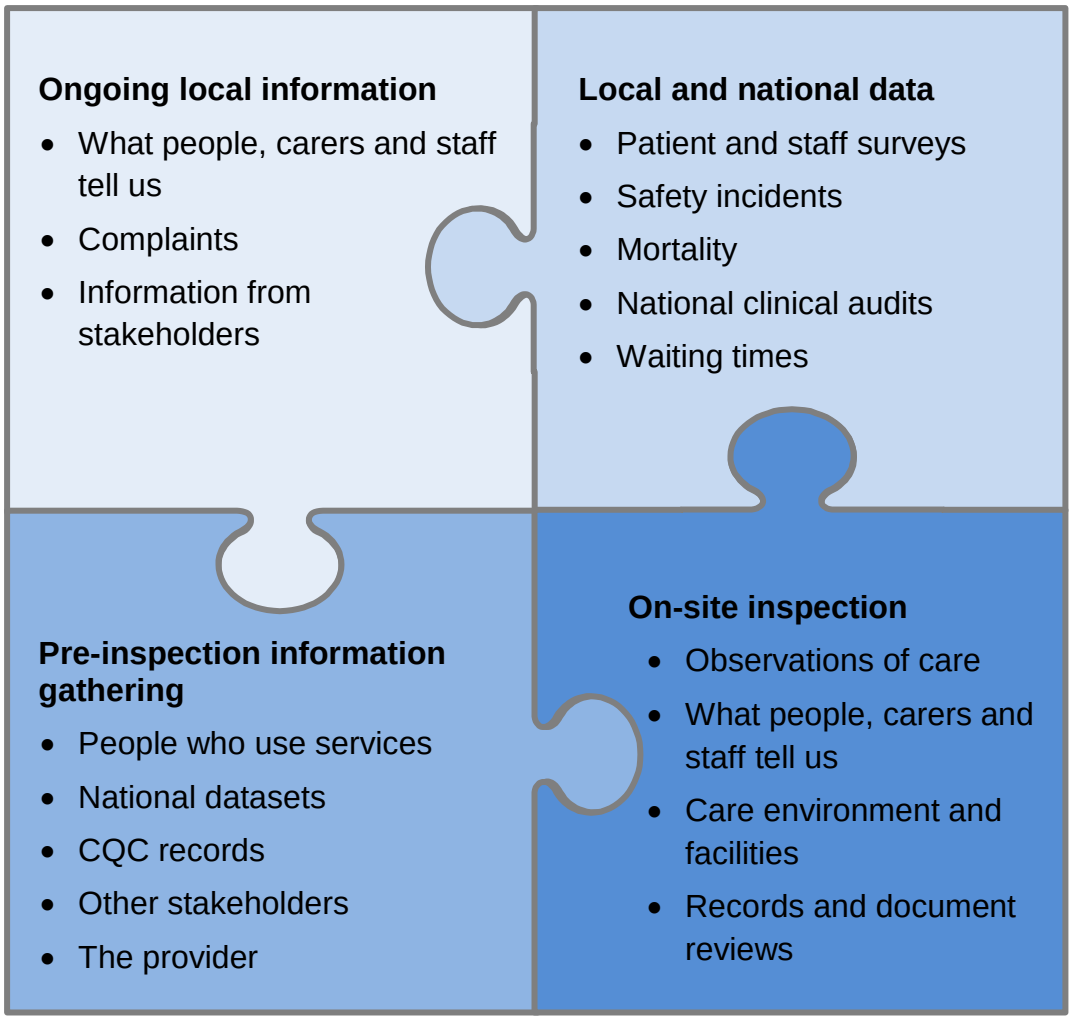
The guidance highlights key data or audit items, specific prompts for the service, who should be interviewed and what areas should be inspected. New national priorities or policy directions will be reflected in this guidance as they emerge.

We will publish this guidance on our website as it becomes available.

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, case note tracking of complex patients, 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**



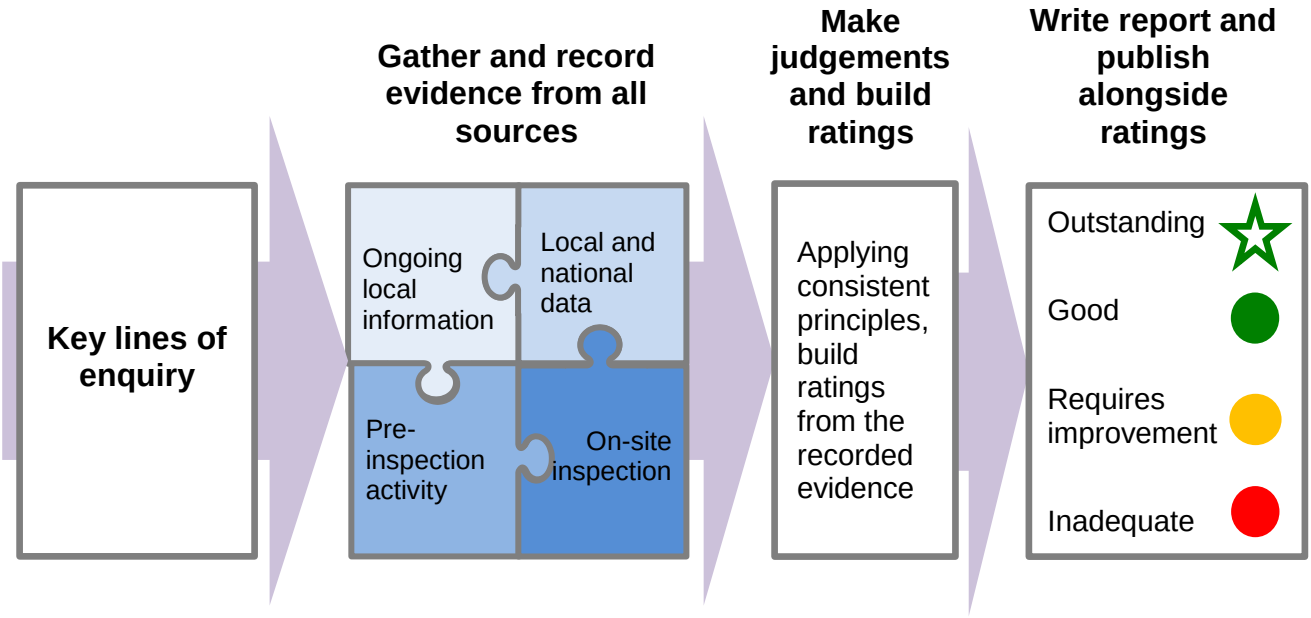

## Ratings

Ratings are an important element of our approach to inspection and regulation.

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

We 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, 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 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.

Ratings are discussed in more detail in section 9.

## 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, also helps us to look at care from the perspectives of people.

Human rights are important in all our key questions – for example, safe, effective clinical practice is necessary to protect people's right to life, and both the leadership of hospitals and the frontline service delivery need to promote equality, dignity and respect for people. In acute hospitals, there may be challenges in ensuring human rights that rely on responding to the needs of individuals. Because of the large numbers of patients moving through services, many spend only a short period in 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 acute hospital services – such as patient data, surveys and, importantly, 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 acute hospitals are performing is by gathering and understanding the experiences and views of people. Our approach enables us to gather more evidence from people who use services, including ways of finding out the experiences and outcomes of acute 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. The MCA clearly applies where a service works with people who may have cognitive difficulties due to dementia, an acquired brain injury or a learning disability, but providers must also recognise that a person may lack the mental capacity to make a specific decision at the time it needs to be made for a wide range of reasons, which may be temporary, and know how they should then proceed.

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.

We have a duty to monitor the Deprivation of Liberty Safeguards in all hospitals and care homes in England, and check on their use when we inspect places where they are used. Hospitals and care homes must tell us about the outcome of any application to deprive someone of their liberty using the Safeguards or by an order of the Court of Protection.

Where it is likely that a person lacking mental capacity to consent to the arrangements is deprived of their liberty to be given essential care or treatment, we will look for evidence that efforts have been made to reduce any restrictions on freedom, so that the person is not deprived of their liberty. Where this is not possible we will check that the deprivation of liberty has been authorised as appropriate, by use of the Deprivation of Liberty Safeguards, the Mental Health Act 1983, or by an order of the Court of Protection.

The importance of working within the empowering ethos of the wider MCA is 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 and when mental capacity is assessed, how mental capacity is maximised and, where people lack mental capacity to make a decision, how that decision is made and recorded in compliance with the MCA.

We will look for evidence that restraint, if used to deliver necessary care or treatment, is in the best interests of someone lacking mental capacity, is proportionate, and complies 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 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, based on work we have undertaken with the Patients Association. 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 case notes from investigations.

# 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 assesses 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 ensures that our registration inspectors 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.

Judgements are 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.

These judgements will not stifle innovation or discourage good providers of care services, but 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 are vital to our inspection approach. These relationships allow CQC better access to qualitative as well as quantitative information about services, particularly local evidence about people's experience of care. Local relationships also provide opportunities to identify good practice and to work with others to push up standards.

## Working with providers

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 includes 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 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.

## 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
- The NHS Friends and Family Test
- PLACE reports (patient-led assessment of the care environment).

**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**

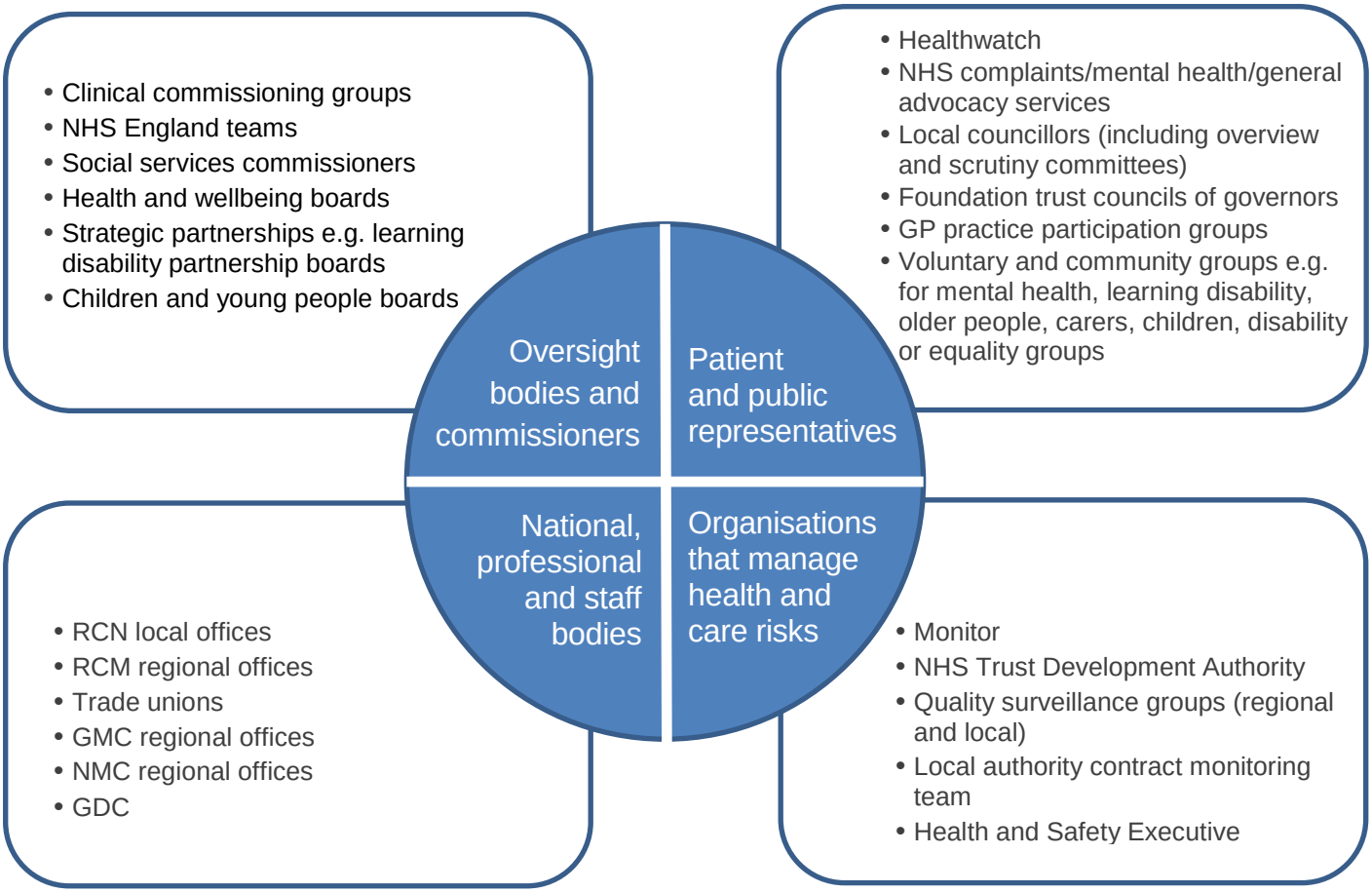
- Feedback on services submitted through CQC's online "share your experience" form or through telephone calls to our national call centre.
- Engagement activity specifically designed to encourage people to share their experiences of care.

## Working with local organisations and community groups

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

- Local health overview and scrutiny committees
- Quality surveillance groups
- Health and wellbeing boards
- Local Healthwatch
- Local authorities
- Clinical commissioning groups
- NHS complaints advocacy organisations.

**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
- Professional regulators such as the Nursing and Midwifery Council, the Health and Care Professions Council and the General Medical Council
- The Royal Colleges.

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 have worked closely with Monitor and the NHS Trust Development Authority to develop a single overarching framework for judging whether or not an NHS service is 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 do not undertake 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. Our assessment includes 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 interview the director of finance and others and review key documents such as board meeting minutes and the annual audit letter.

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

# 4. Intelligent Monitoring

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 an NHS acute trust or a specialist NHS trust. 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 hospitals that are at risk of failing.

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 to create priority bands for inspection. This priority banding puts trusts into one of six bands, with an extra category to reflect that a trust has recently been inspected.

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 trust and other organisations.

You can access the latest version of the indicators and individual reports for acute and specialist NHS trusts at www.cqc.org.uk/public/hospital-intelligent-monitoring. We will continue to improve and refine the indicators that we use in Intelligent Monitoring as we learn which are the most useful to inform our work.

Where our Intelligent Monitoring identifies risks, we will follow these up as part of our inspection process.

# 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**<br>(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.<br>• Assess all of the core services, where they exist.<br>• Large inspection team.<br>• Typically, two to four days announced site visit plus unannounced visits.<br>• At least once every three years. |
| **Focused**<br>(Section 8) | • Follow up a previous inspection or respond to a particular issue or concern.<br>• Team size and composition depends on the focus of the inspection.<br>• Length of site visit and whether it is announced or unannounced is flexed.<br>• As frequent as required. |

## Inspecting the non-acute services provided by the organisation – combined inspections

CQC has developed a tailored approach to inspection for various different types of health and social care services. One of these is the approach for acute hospitals as set out in this handbook. Other examples are community health services, mental health services, GP practices and residential social care services.

We recognise that many providers have a wide range of services that will sit in more than one of our inspection approaches. Where such arrangements exist 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 are 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.

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.

## Acute specialist trusts

A number of NHS acute trusts specialise in the services they provide, for example they only provide services to children or only provide cancer services.

The approach described in this handbook will also be applied to these trusts. We will adjust the process to take into account the different circumstances of specialist trusts, for example, the information we ask for, how we gather the views of people who use the service and the members of the inspection team.

## Services provided by third party providers

An NHS trust will often have an arrangement in place where a third party organisation provides part or all of a core service, often on the trust's premises. Where this is the case, it is essential that the services provided by the trust 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 trust's inspection. However, they will consider the care pathways between the service and the trust's own 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 is also used as evidence when we make our ratings judgements.

As described in section 3 and section 4, we 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 collate our analysis into a data pack to be used by the inspection team. Our inspectors use this information along with their knowledge of the service and their professional judgement to plan the inspection.

The provider has an opportunity to review the data pack for accuracy and raise queries on the data.

## Gathering information from people who use services and stakeholders

Before 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.

## 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 request from a provider varies depending on the type of services offered, but will include information about:

- Management and governance structures
- Numbers 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 trust 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.
- **Case tracking patients with complex needs or those who are in vulnerable circumstances**: Reviewing case notes of selected patients builds a picture of how well providers care for patients with more complex needs, with particular vulnerabilities or from different groups in society.
- **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 requiring investigation:** This enables us to explore how well a provider reports, investigates and learns from serious incidents requiring investigation (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.
- **Information flows:** These determine what key information flows there are in a trust and how effective they are, to help us understand whether clinicians have access to the right data at the right time to make informed clinical decisions and also to understand whether managers have access to the right data to ensure quality care is provided.

## The inspection team

Depending on the size of the trust, a typical inspection team has up to 50 members and includes:

- Inspection Chair (a very senior clinician, or manager with knowledge of quality and safety in hospitals)
- CQC Head of Hospital 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.

The experts we use reflect the services provided by the trust and the areas of focus for the inspection, for example, this may include doctors, nurses, therapists, social workers and governance experts.

## Planning the focus of the inspection

The planning of the inspection involves:

- 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 of the trust 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.
- Ensuring that we follow up any outstanding compliance actions and Warning Notices, and any improvement plans for trusts 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 Hospital Inspection and the inspection planner are 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.

# 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)
- Unannounced visits
- Closing the inspection visit
- Additional site visits (if required).

## Briefing and planning session

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

### Trust presentation

At the start of the site visit the trust 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 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 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 hospitals is to seek out and listen to the experiences of the public, people who use 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 public listening events.
- Holding focus groups with people who use services and those close to them.
- Holding drop-in sessions.
- Using comment cards placed in reception areas and other busy areas to gather feedback. Comment cards will also be available at listening events and focus groups.
- Using posters to advertise the inspection to allow people an opportunity to speak to the inspection team. These will be put in areas where people will see them.
- 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.

We 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.

## Gathering the views of staff

The inspection team will interview individual directors and staff at all levels. We will usually interview the following people:

- Chair
- Chief executive
- Medical director
- Director of nursing
- Chief operating officer
- Director of finance
- Non-executive director responsible for quality/safety
- Board director responsible for end of life care

- Service leads for each of the core services (for example, clinical director, nursing lead and directorate manager)
- Complaints lead
- The senior lead for human resources.
- Senior information and risk owner (SIRO).

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:

- Consultants and other medical staff
- Junior doctors
- Registered nurses and midwives / sisters and matrons
- Student nurses and healthcare assistants
- Allied health professionals
- Administrative and support/other staff
- Foundation trust councils of governors.

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

## Other inspection methods/information gathering

Other ways of gathering evidence will include:

- Observing care
- Pathway tracking people through their care
- Inspecting care environments
- Reviewing records
- Reviewing policies and documents.

## Continual evidence evaluation

Throughout the inspection the Inspection Chair and Head of Hospital Inspection/team leader continually reviews the emerging findings with the inspection team. 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 judgement or, where appropriate, a rating.

Continual evaluation is also an opportunity to make connections across different areas of inspection where there may be common themes, such as lack of audits, and which might raise questions about governance structures overall.

## Feedback on the announced visit

At the end of the announced inspection visit, the Inspection Chair and Head of Hospital Inspection/team leader will hold a feedback meeting with the chief executive, the chair and other members of the provider's board. 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 trust's staff for their support and contribution.
- Explaining 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 trust.

## 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 often involve fewer members 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 trust's senior operations lead on duty at the time, and at the end will feed back if there are any immediate safety concerns.

# 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
- Where certain changes in the provider occur.

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 undertake 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 three months after a comprehensive inspection or soon after a provider has notified us that they have taken the action needed.
- Concerns that have been raised with us outside an inspection through other sources such as information from Intelligent Monitoring, MHA monitoring visits, members of the public, staff or stakeholders.

## Changes in the service provider

When there is a planned merger, acquisition or takeover of a trust or hospital, 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 co-ordinate our evidence gathering and site visits with Monitor or the NHS Trust Development Authority to reduce the burden on trusts.

## 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 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 base their judgements on the available evidence, using their professional judgement. For each individual rating (for example, safety in maternity 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 consider the weight of each piece of relevant evidence. In most cases we 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 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 location we inspect, we rate performance at four levels:

**Level 1:** Rate every core service for every key question

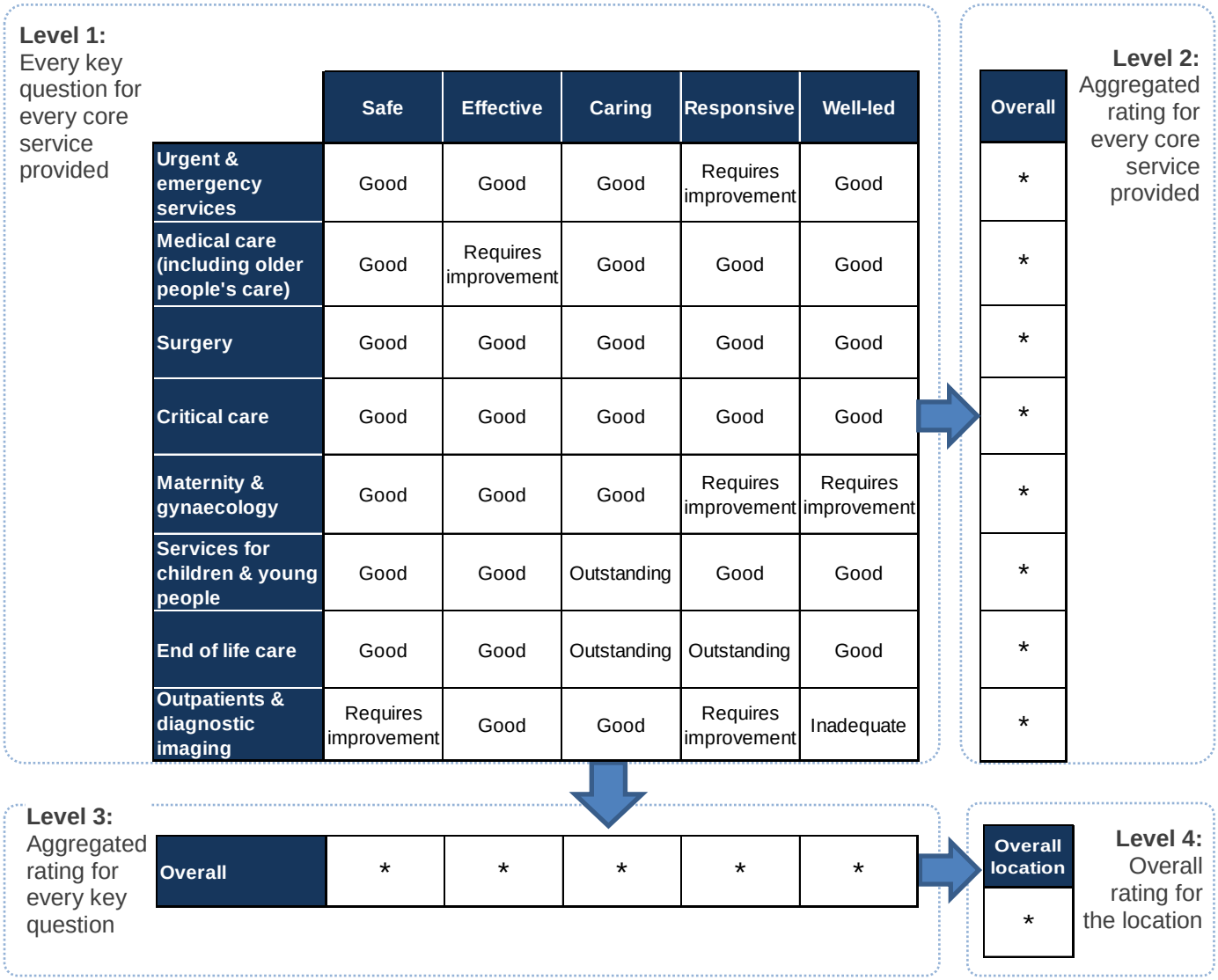
**Level 2:** An aggregated rating for each core service

**Level 3:** An aggregated rating for each key question

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

The following example shows how the four levels work together:

## Figure 5: The levels at which acute hospital services are rated

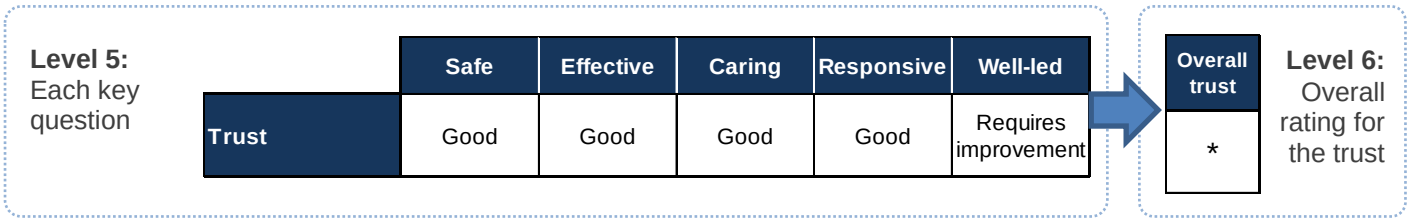



* These will be aggregated ratings (outstanding, good, requires improvement or inadequate), which will be determined using the ratings principles (see below).

For the trust, we rate performance at the following two levels:

Level 5: Each of the key questions. 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 don't 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 term '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

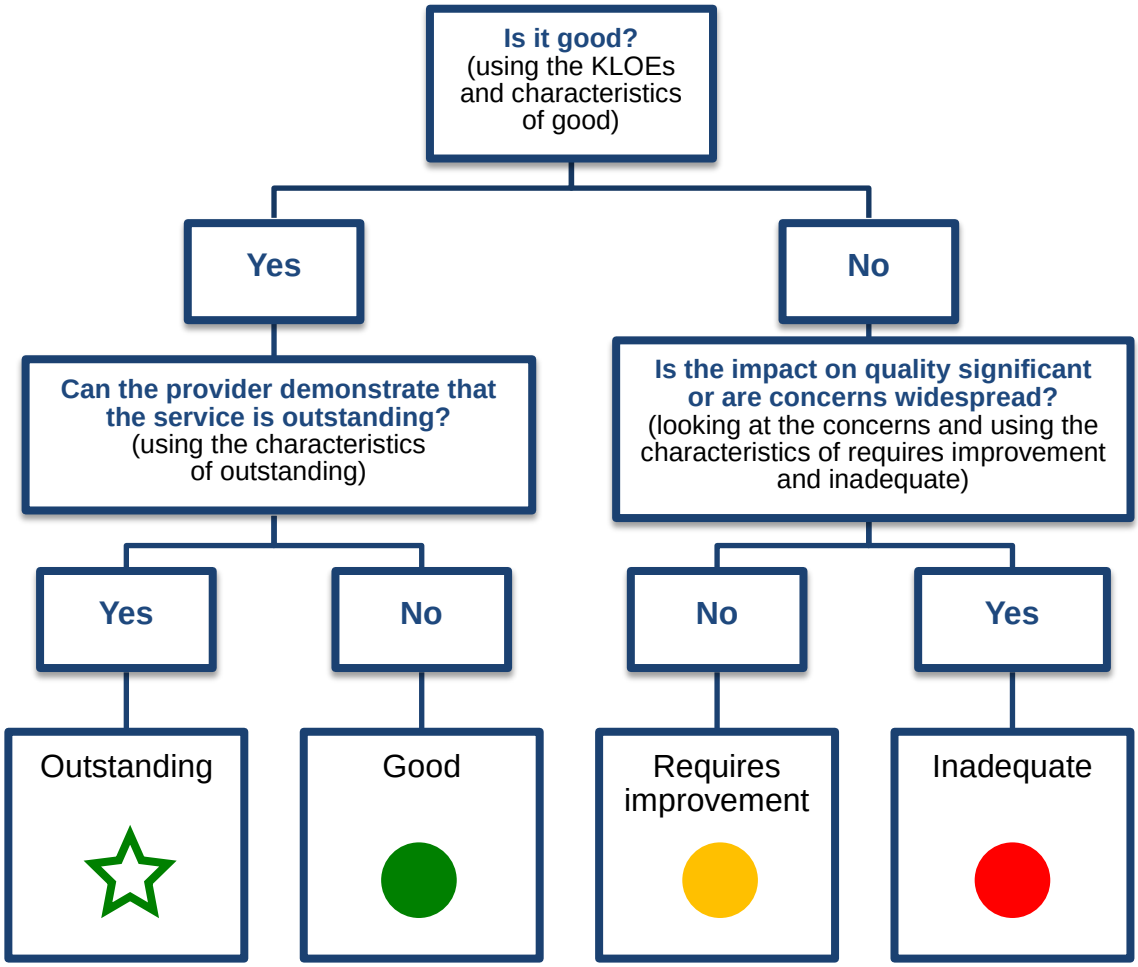
When awarding ratings of the five key questions at service level, our inspection teams consider the evidence they have gathered for each of the KLOEs and use the guidance supplied to decide on a rating.

In deciding on a rating, the inspection team 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

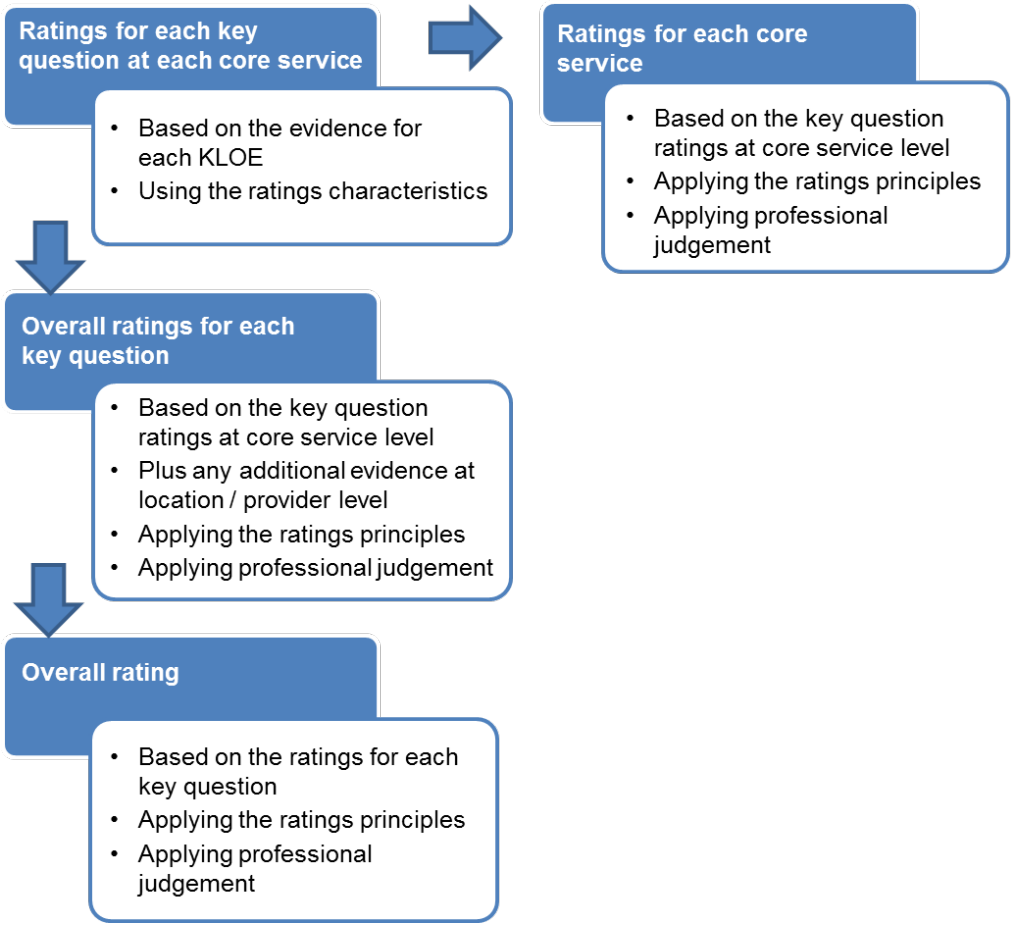
When aggregating ratings, our inspection teams follow a set of principles to ensure consistent decisions. Our principles are set out in appendix D.

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.

## Aggregating ratings for a combined inspection

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

1. For each service type, aggregate the underlying ratings of each service type (for example, acute, community health, mental health) 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.

# 10. Reporting, quality control and action planning

## Reporting

For each inspection, we produce a report to cover all the locations we have visited and a report for the provider overall. The report includes all the ratings. The report will be clear, accessible and written in plain English.

Our reports focus on what our findings about each of the five key questions mean for the people who use the service. We describe the good practice we find as well as any concerns we have. In our reports we 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 including CQC's legal, policy, intelligence and enforcement teams.

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 with local partners

The inspection findings inform the basis of a discussion at a quality summit. This is 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 are issued to the provider before the quality summit.

The plan of action is 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 Hospital Inspection or team leader for the inspection visit
- Clinical 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 nursing)
- Monitor/NHS Trust Development Authority
- Local Healthwatch
- NHS England Area Team representative
- Local authority representatives (including overview and scrutiny committees and health and wellbeing boards)
- Representatives from relevant clinical commissioning groups
- Health Education England representative
- Others as appropriate (for example, a Health and Safety Executive representative).

The CQC representative chairs the first part of the quality summit, and presents the inspection team's findings. The second part of the summit is not normally led by CQC. It will usually be chaired by a representative from Monitor, the NHS Trust Development Authority or the trust itself, depending on the findings of the inspection. The provider is given an opportunity to respond to the findings of the report. The focus is then 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 are 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, ratings and data pack 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 have identified concerns we decide what action is appropriate to take. The action we take is 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 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 general 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 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.

We follow up any concerns or enforcement action. If the necessary changes and improvements are not made, we can escalate our response, gathering further information through a focused inspection. However, we always consider each case on its own merit and we do 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 will issue guidance to help providers to understand how they can meet the new regulations and, when they do not, what actions CQC will take. We will publish an update to this handbook to reflect the new regulations.

### New requirements: fit and proper person and duty of candour

Two new requirements, the fit and proper person requirement and the duty of candour, will apply from mid November 2014 (or very closely after this date subject to Parliamentary approval) to NHS bodies (NHS trusts, NHS foundation trusts and special health authorities).

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.

## Responding to inadequate care

As well as using our enforcement powers, CQC will also work with other organisations, including other regulators and commissioners, to ensure action is taken on concerns that we identify.

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. We will not normally take any further enforcement action.

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.

## 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 are 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 are invited to provide feedback on its factual accuracy. They can 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. 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 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 have also contributed 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 cannot request reviews on the basis that they disagree with the judgements made by CQC, as such disagreements would have been 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 must say which rating(s) they want to be reviewed and all relevant grounds. Where we do not uphold a request for review, providers cannot 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'll 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.

**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



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## How to contact us


| | |
|---|---|
| Call us on: | **03000 616161** |
| Email us at: | **enquiries@cqc.org.uk** |
| Look at our website: | **www.cqc.org.uk** |
| Write to us at: | **Care Quality Commission**<br>**Citygate**<br>**Gallowgate**<br>**Newcastle upon Tyne**<br>**NE1 4PA** |

Follow us on Twitter: @CareQualityComm