Care Quality Commission

How CQC regulates:

NHS GP practices and GP out-of-hours services

Provider handbook

October 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 GP practices and GP out-of-hours services.

Our approach includes an inspection team led by an inspector with a GP on every inspection. It includes using Intelligent Monitoring to decide when, where and what to inspect, methods for listening better to people's experiences of care and using the best information across the system.

We inspect a number of GP practices, and the GP out-of-hours provider, in a clinical commissioning group (CCG) area at the same time.

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 to highlight where care is outstanding, good, requires improvement or inadequate.

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 as we put our approach into practice from 1 October 2014. However, the main aspects of our approach, such as the five key questions and the key lines of enquiry for each of these questions will remain constant. We will refresh this document to take into account the new fundamental standards regulations that are due to come into force in April 2015.

We will inspect all NHS GP practices and GP out-of-hours services by April 2016.

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.

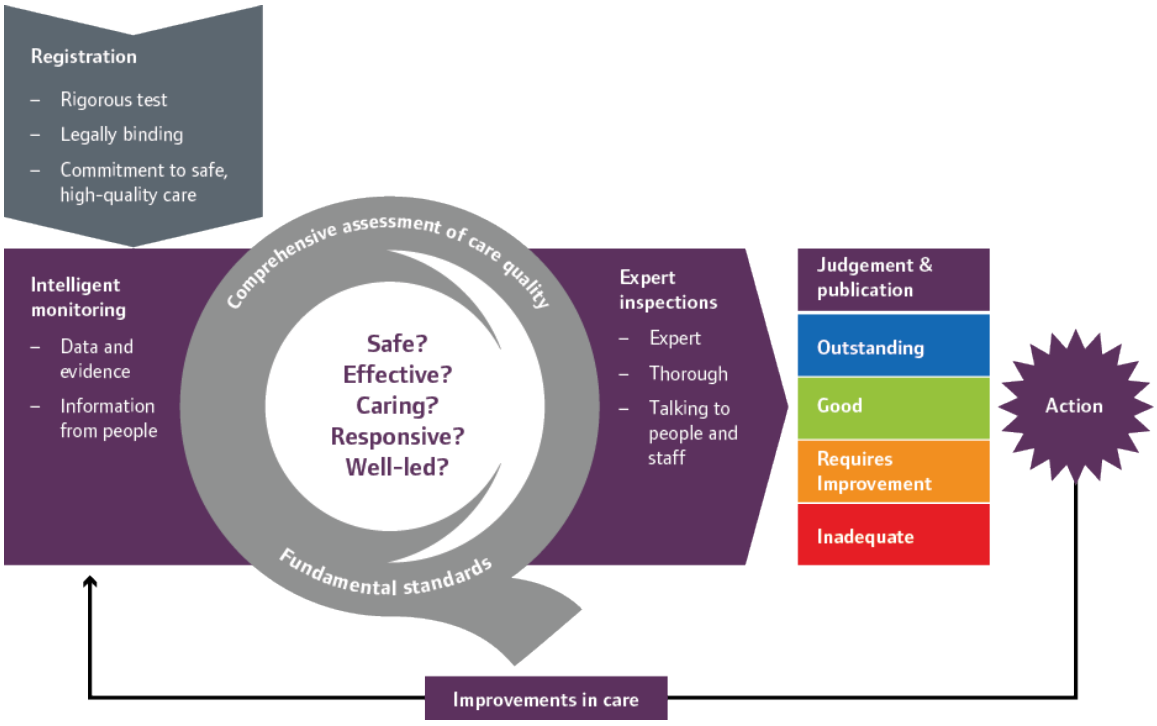
Our operating model

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).
- 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, which will be introduced in April 2015. We will issue guidance to help providers understand how they can meet these fundamental standards.

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.

Population groups

As well as focusing on the five key questions, we will always look at how services are provided to people in specific population groups. For every NHS GP practice we will look at the quality of care for the following six population groups:

- Older people
- People with long-term conditions
- Families, children and young people
- Working age people (including those recently retired and students)
- People whose circumstances may make them vulnerable
- People experiencing poor mental health (including people with dementia).

We have provided detailed definitions of these population groups in appendix A.

By looking at services for these groups of people, we can make sure our inspections look at the outcomes of care provided for all people, including those who are particularly vulnerable. It also means we can present information to the public about local services that are relevant to them. For example, someone with a long-term condition would be able to look at the quality of care provided by a practice for all people with long-term conditions registered with that practice.

We do not inspect GP out-of-hours services using these six population groups. We only do this when we inspect GP practices.

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 – are services 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.

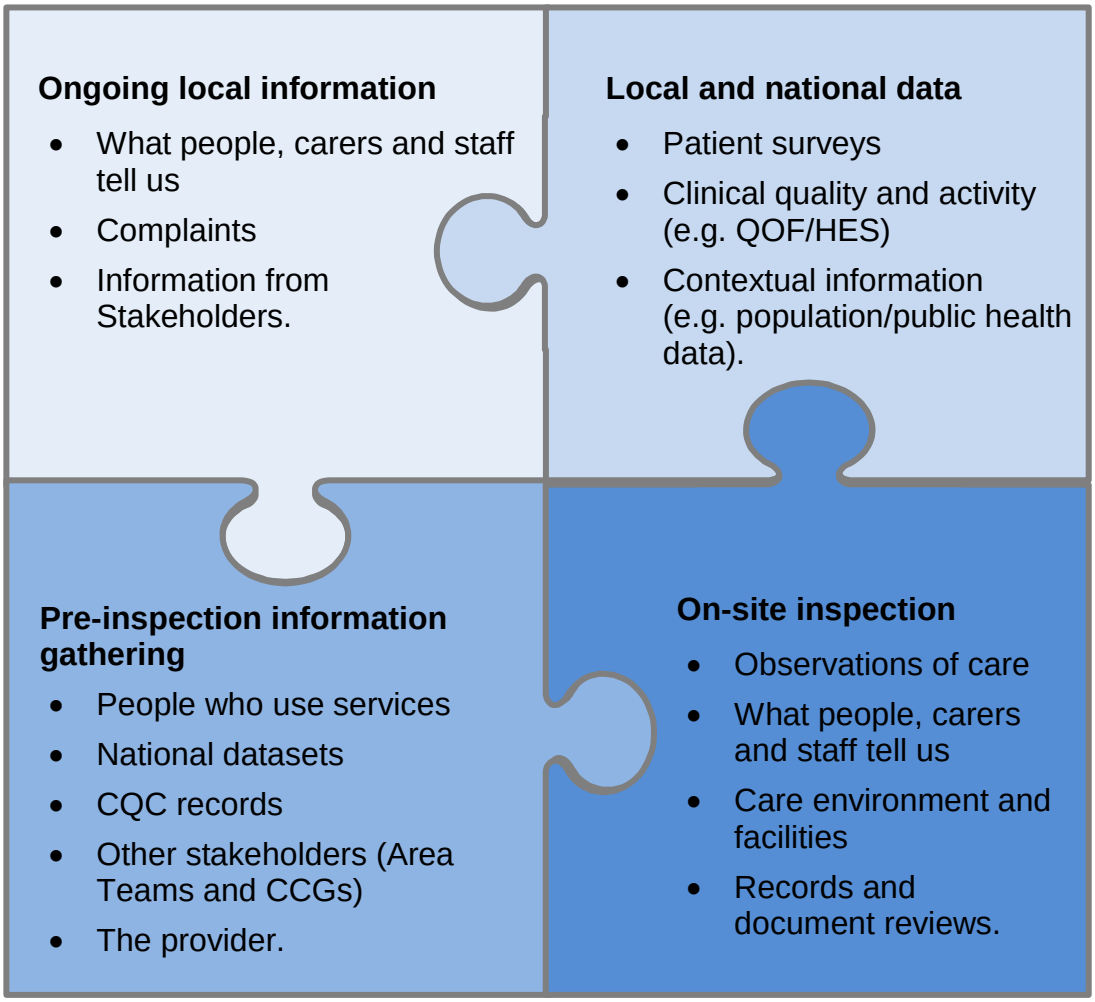
Each KLOE is accompanied by a number of questions that inspection teams will consider as part of the assessment. We call these prompts. The prompts are included in appendix B. Inspection teams will take into account the information gathered in the preparation phase and the evidence they gather during the inspection to determine which aspects of the KLOE they should focus on.

Please note: there are some differences in the prompts for GP practices and GP out-of-hours services, which are clearly marked in appendix B.

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

1. Information from the ongoing relationship management with the GP practice or GP out-of-hours service.
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 as set out in section 6.
4. Information from the inspection visit itself.

Figure 2: The four main sources of evidence



Our inspection teams will also use guidance for each of the population groups, which has been developed with internal and external specialists. It highlights key data items, specific prompts for the service, who should be interviewed and which areas should be inspected.

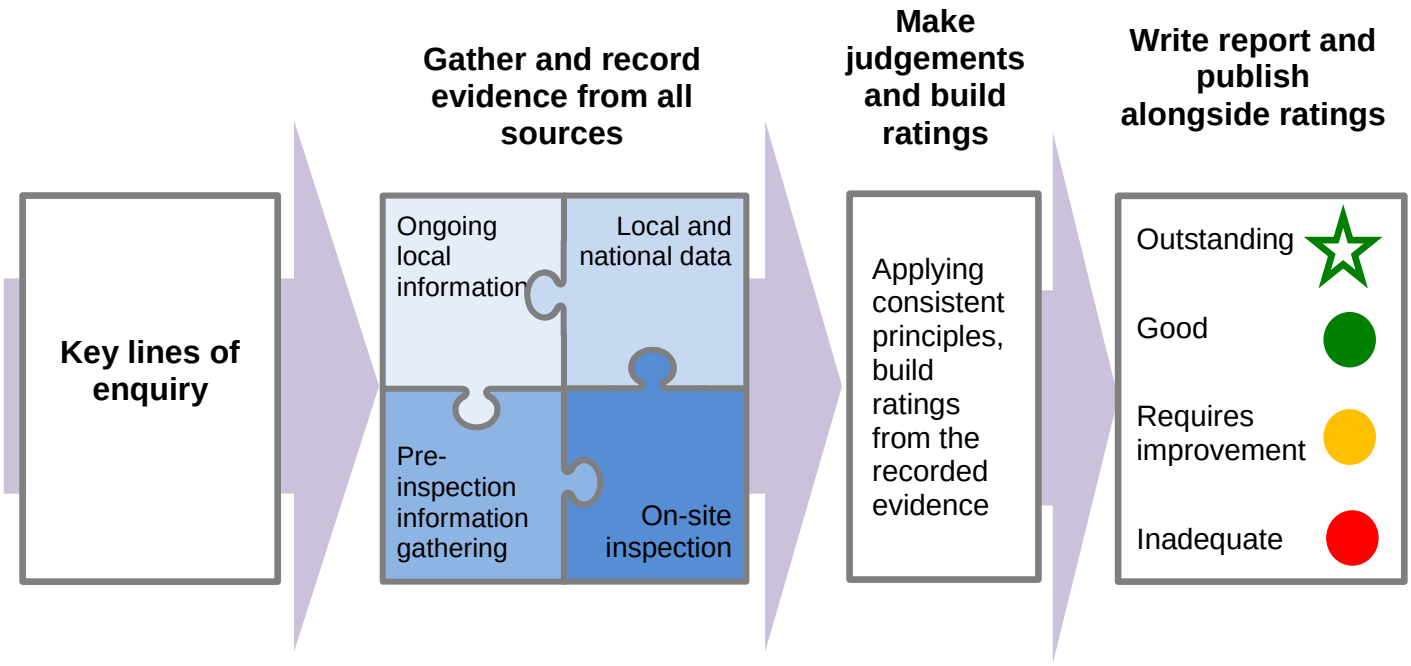
We will publish guidance on our website as it becomes available. We will not use this guidance in our inspections of GP out-of-hours services.

Ratings

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

As set out in figure 3 below, our ratings are 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 local 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 looks like for each of the five key questions. These are set out in appendix C.

These characteristics provide a framework which, together with professional judgement, guides our inspection teams when they award a rating. The inspection team use their professional judgement, 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 quality of care or on people's experiences 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.

A service does not need to demonstrate every one of the characteristics of good in order to be rated as good.

We will be proportionate in making the judgements and will consider the context within which a practice is working, and the specific circumstances of each GP practice or GP out-of-hours service.

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 mean that everyone using health and social care services receives good quality care.

To put this into practice, we have developed 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. Using a human rights approach that is based on rights that people hold rather than what services should deliver also helps us to look at care from the perspectives of people who use services.

These human rights principles are important in the delivery of GP and GP out-of-hours care. Everyone wants to be treated with dignity and respect when using GP practices or GP out-of-hours services. If people do not experience this, it may make them reluctant to use these services in the future. This can lead to a negative impact on people's health, particularly as GP practices are often the way through which other health services and social services are accessed.

Equality is a particularly important principle for primary care. Not only do GP practices need to address health inequalities for certain population groups – differences in health status and the social factors that influence health – but people from some groups may experience particular barriers in accessing GP services or may be at risk of experiencing prejudice or discrimination when they are using these services. Our new approach to regulating GP practices , based on looking at how services are provided to specific population groups, will enable us to look at both equality for people who use services and health inequalities.

Monitoring the use of the Mental Capacity Act

The Mental Capacity Act (2005) is a crucial safeguard for the human rights of people who might (or might be assumed to) lack mental capacity to make decisions, in particular about consenting 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. This refers specifically to the capacity to consent to, or refuse, proposed care or treatment.

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 mental capacity for 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.

In particular, we will look at how and when mental capacity is assessed and, where people lack mental capacity for 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.

Where it is likely that a person is deprived of their liberty in order to be given essential care or treatment, we will look for evidence that efforts have been made to reduce any restriction 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 this is reflected in our inspections. We have a specific KLOE about consent, which takes account of the requirements of the Mental Capacity Act and other relevant legislation, such as the Children Acts 1989 and 2004.

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 who use services 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 and local 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 have set out standard expectations for complaints handling that 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. Evidence sources may include complaints and whistleblowing policies, indicators such as a complaints backlog and staff survey results, speaking with people who use services, families and staff, and reviewing case notes from investigations.

2. Registration

Before a provider can begin to provide services, 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 appendices to this handbook 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, and make judgements about whether applicants are likely to meet these legal requirements.

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 will 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

Each registered provider of an NHS GP practice or GP out-of-hours service will have a member of CQC's inspection staff as their 'relationship owner'. In some cases there may be a relationship owner for each registered location, rather than for the provider. Their role will include reviewing any information received from or about the provider obtained from a number of sources and stakeholders. They will be supported by our intelligence teams who will analyse some of the information.

Our approach includes continuous monitoring of local data and intelligence and risk assessment.

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

- Local patient surveys or other patient experience data.
- Information about the number and types of complaints that 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 and helpline, and we are committed to carrying out public engagement aimed at encouraging members of the public, 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:

- Comments and feedback sent to CQC from individual people who use services and those close to them.
- Nationally collated feedback from people who use services and those close to them, for example available patient survey data, Health Ombudsman's evidence of complaints, information from NHS Choices and the NHS Friends and Family Test.
- Local Healthwatch.
- Organisations that represent or act on behalf of people who use services, including equality groups.
- NHS complaints advocacy services.
- Community, patient and carer groups including practices' patient participation groups (PPGs).
- Engagement activity specifically designed to encourage people to share their experiences of care.

Working with partner organisations

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

- NHS England Area Teams
- Clinical commissioning groups.

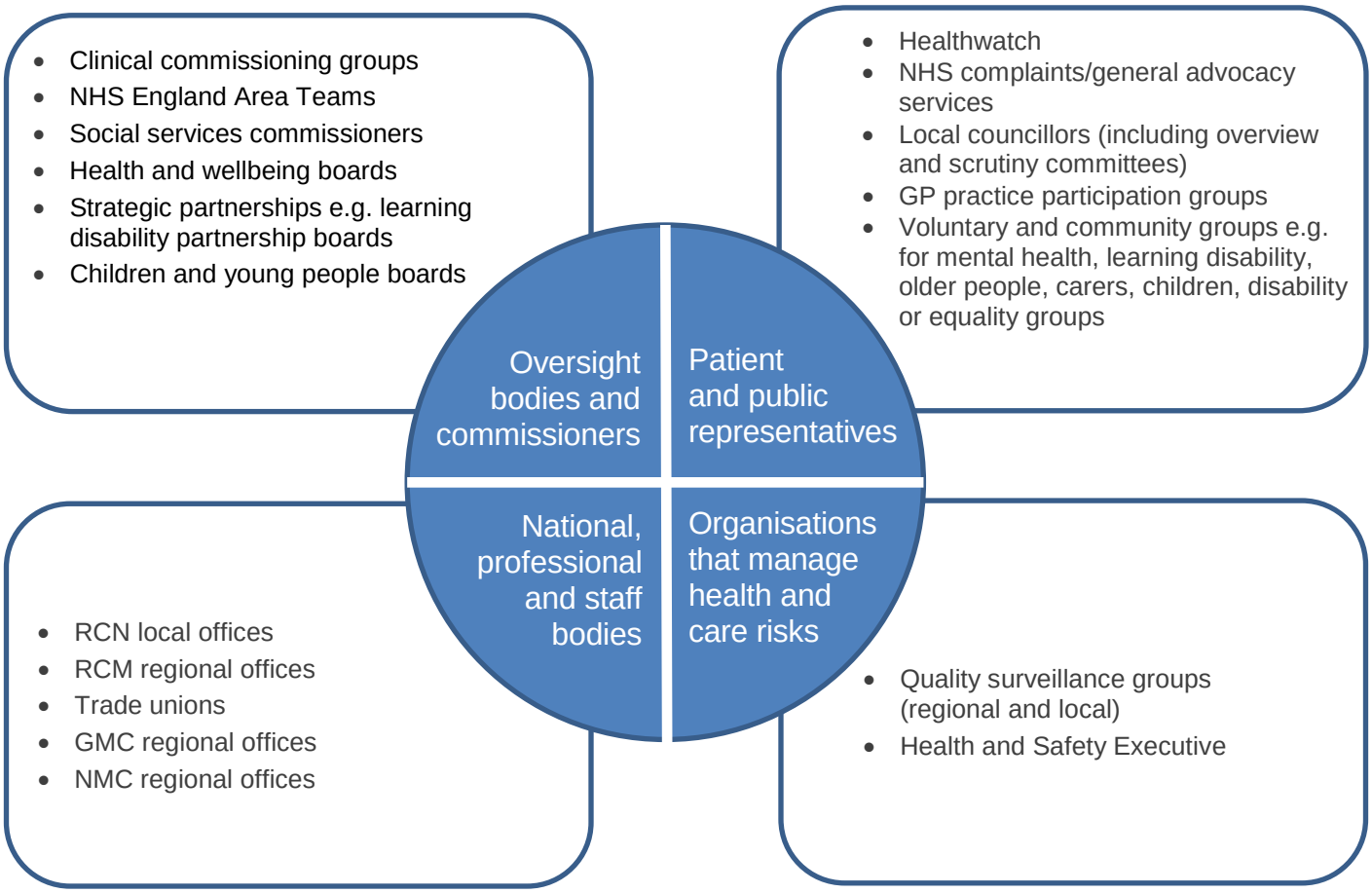
Our inspection managers lead the ongoing relationship with NHS England Area Teams and clinical commissioning groups.

We work with these organisations to gather information on a regular basis and in the lead up to an inspection.

We also work closely with:

- Professional regulators, such as the Nursing and Midwifery Council, the Health and Care Professions Council and the General Medical Council.
- The Royal Colleges.
- The Parliamentary and Health Service Ombudsman.
- Local medical committees.
- Local education and training boards.

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



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 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
- NHS complaints advocacy organisations.

4. Intelligent Monitoring

Our new, more comprehensive model includes ongoing Intelligent Monitoring of the risks that individual GP practices and GP out-of-hours providers are not providing either safe or high-quality care.

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 feedback and patient outcomes.

We have developed a set of indicators that we will use for GP practices, and our initial scoping work has identified the sources of information set out in table 1. We will continue to refine this list as our inspection programme progresses. We have carried out additional testing and engagement to determine the most useful indicators to inform our work, and we will align our definitions of indicators as far as possible with those used by our partner bodies, such as NHS England and Public Health England. To this end, the initial indicators will also be published on the NHS Choices website.

We use this information to give our inspectors some background and context about the areas of care that may need to be followed up along 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 at risk of providing poor quality care. We have used the indicators developed so far to create priority bandings, which we will use to help inform where we prioritise for inspection.

The indicators may 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 GP practice or out-of-hours provider and other organisations.

Table 1: Indicator sources

Outcome measures and safety events	Information from people who use services and the public	Information from and about staff
• Prescribing indicators – safe prescribing/effective prescribing indicators. • Safeguarding referrals and alerts. • Selected QOF indicators. • Secondary care activity: e.g. emergency admission rates for long-term conditions, A&E attendance rates, referral rates to secondary care. • Vaccination rates. • Screening uptake – e.g. breast, cervical cancers. • Patient safety incidents.	• Responses from General Practice Patient Survey. • People's experiences shared with CQC. • Feedback left on NHS Choices, and other feedback sites (e.g. www.Iwantgreatcare.org). • Complaints. • Feedback from local Healthwatch.	• Concerns raised by staff to CQC. • Fitness to practise referrals and cases.

5. Inspection

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

Type of inspection	Description
Comprehensive (section 6 and 7)	• Reviews the provider in relation to the five key questions leading to a rating on each on a four-point scale. • Assesses all six of the population groups (GP practices only). • Takes place at the same time as we inspect a number of practices in a CCG area. • Usually one day on site and usually announced. • At least once every three years
Focused (section 8)	• Follow up to a previous inspection, or to respond to a particular issue or concern. • May not look at all five key questions and six population groups. • Team size and composition depends on the focus of the inspection. • The inspection may be unannounced.

We will check the quality of NHS GP services and GP out-of-hours services within each clinical commissioning group (CCG) area. From October 2014 to April 2016 we will inspect a number of GP practices in each CCG, on a rolling six-month cycle, as well as inspecting the GP out-of-hours service. We are not inspecting the CCG itself.

Combined providers

CQC has developed a tailored approach to inspection for different types of health and social care services. One of these is the approach for GP practices and GP out-of-hours services set out in this handbook. Other examples are acute hospital services, community health services 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. NHS trusts are the most common example of this type of provider. Others include large social enterprises that provide a range of services to a local population, or an independent health provider with a range of services at one of its locations.

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 use our different approaches in combination to reflect the range of services that are provided.

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 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 are considering how we inspect practices that have merged, have become multi-site practices or have federated, and where they may share common leadership or systems and processes. We will test this over the coming months.

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 will influence what we look at, who we will talk to and how we will configure our team. The information we gather during this time before the inspection is also used as evidence when we make our ratings judgements.

As described in sections 3 and 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 compile three types of data pack for GP and GP out-of-hours inspections:

- **CCG level data pack**: This is primarily for inspection managers to use as part of the information sharing meeting with the CCG. The pack includes contextual information for the CCG as a whole and summary information for each of the locations being inspected. Relevant Area Teams and CCGs will be able to access this pack.
- **GP practice data pack**: This pack is primarily for inspectors to use to inform key lines of enquiry. It includes information specific to the GP practice location being inspected. The GP practice will be able to access this pack.
- **GP out-of-hours services data pack:** This pack includes information gathered through an information request to providers, CCGs and stakeholders, as well as contextual information. This data pack will be shared with the GP out-of-hours service being inspected.

The data packs are arranged around the five key questions and incorporate information from our Intelligent Monitoring, NHS England, Public Health England, the General Medical Council, Office for National Statistics and the Public Health Observatory. They will be used to identify questions, but not to make final judgements.

In a small minority of cases where we carry out a focused inspection at short notice, a data pack may not be available.

Gathering the views of people who use services in advance

A key principle of our approach to inspecting is to seek out and listen to the experiences of the public, people who use services and those close to them, including the views of people who are in vulnerable circumstances or who are less likely to be heard. The purpose of this is to better understand the issues that are of most concern to people to guide our inspection.

In the weeks before we start to inspect practices in a CCG area, we gather people's experiences of care through:

- Local discussions with local Healthwatch, local overview and scrutiny committees, NHS complaints advocacy services, and identified patient representatives at CCGs and within health and wellbeing boards.
- Publicising our inspections through a range of local channels, including through GP practices.

We are continuing to explore the best ways to gather the views of people who use services in advance of our inspections.

Gathering information from the provider

Before we begin inspecting in a CCG area we will write to practices and the GP out-of-hours service and ask them for some information. We will ask for documents and examples of information that will provide us with helpful pre-inspection insight.

GP practices and will have five working days to respond to our request. GP out-of-hours services will have 10 working days to respond to our request. This is because we ask for more information from GP out-of-hours services.

We will make clear what information to send, where to send information and who to contact with any queries or questions.

The information we will request is likely to include:

- An action plan that addresses the findings from any patient survey carried out.
- A summary of any complaints received in the last 12 months, any action taken and how learning was implemented.
- A summary of any serious adverse events for the last 12 months, any action taken and how learning was implemented.
- Evidence to show that the quality of treatment and services has been monitored. This includes evidence of two completed clinical audit cycles carried out in the last 12 months, and evidence of any other audits, with evidence of actions or outcomes taken as a result.
- Recruitment and training policies and procedures (for example, how staff are recruited and vetted before commencing work, arrangements for European Economic Area (EEA) and foreign doctors and what induction they receive).
- Number of staff by role (whole time equivalent).
- A copy of the current Statement of Purpose.

This list is not exhaustive and we may ask for further information depending on the information available to us.

Gathering information from stakeholders

We may also ask local organisations to provide information, including:

- CCGs and NHS England Area Teams.
- Local education and training boards (postgraduate deaneries).
- Local authorities.
- Other local health and social care services, including those provided by local authorities, hospitals, care homes and public health departments.
- Local GPs and other practice staff about the quality of out-of-hours services.

We may write to some of these stakeholders to ask for information.

We will also meet with the CCG and the NHS England Area Team before the inspections.

The inspection team

Inspections will be led by a CQC inspector with input from GPs and other professionals.

Inspection teams visiting individual practices within a CCG area will always include a GP and may include other specialist inspectors, such as practice nurses and/or practice managers. The lead CQC inspector is the main point of contact for inspections of individual GP practices and out-of-hours services. Our inspection team will vary in size, to reflect the size of the practice or GP out-of-hours service.

Teams may also include Experts by Experience. Experts by Experience are people who use, or care for someone who uses, a GP practice or GP out-of-hours service. 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.

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 trained 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. Further details on the Experts by Experience programme can be found on our website at www.cqc.org.uk/public/get-involved.

Announcing the inspections

Inspections are usually announced. We feel that this is the most appropriate way to make sure our inspections do not disrupt the care provided to people.

We will announce which CCG area we are visiting at least four weeks before we start to inspect practices in that area.

When we announce inspections, we will give two weeks' notice to individual GP practices. The inspector will phone the practice to announce the inspection and a letter will also be sent to confirm the date.

GP out-of-hours services will usually receive six to eight weeks' notice of their inspections. This is because we ask for more information from GP out-of-hours services than we will do from GP practices before we inspect, therefore more time is needed to collect and analyse this information.

After announcing the inspection and throughout the inspection process, the inspection lead and inspection planner will support and communicate with GP practices and out-of-hours services by letter, email and telephone to help them prepare for the day and know what to expect.

Unannounced inspections

We may also carry out unannounced inspections, for example if we have concerns about a practice or if we are responding to a particular issue or concern. This may be something identified at a previous inspection that we are following up or new information.

At the start of these visits, the team will meet with the practice's senior partner or senior manager on duty at the time and will feed back at the end of the inspection if there are any immediate safety concerns.

When we are following up concerns from a previous inspection, we will usually carry out an unannounced focused inspection.

Timetable

Inspection teams will spend a numbers of weeks (usually two, sometimes up to four) in a CCG area inspecting NHS GP practices and NHS GP out-of-hours services.

The inspections of GP practices and out-of-hours services within a CCG area will go through the following stages:

- Preparation.
- Planning and information sharing meeting with the NHS Area Team and CCG.
- Briefing and planning for the inspection team.

- Inspections of GP practices and GP out-of-hours services.
- Draft reporting and awarding a rating.
- Internal quality control.
- Factual accuracy – an opportunity for a provider and registered manager to check the accuracy of the report.
- Final reporting and rating published (including post-inspection meeting with the CCG and NHS England Area Team and follow-up).
- Provider will be offered the opportunity to request a review of their rating.
- If appropriate, a revised rating will be published.

Planning meeting with the NHS England Area Team and the CCG

An inspection manager will lead the inspections across a CCG area, and will be the main point of contact with the CCG and the NHS England Area Team throughout the inspection. We also have a regional GP adviser with oversight of our inspections across a CCG area to provide advice to the inspection manager and inspection teams.

Before the start of the inspection period, the inspection manager and regional GP adviser will meet with the CCG and NHS England Area Team(s) to discuss:

- The scope and purpose of the inspection.
- Who will be involved from CQC.
- Which GP practices and GP out-of-hours services we propose to inspect.
- How the inspections will be carried out, including our relevant powers.
- How we will communicate our findings from our inspections to the NHS England Area Team and the CCG.

The CCG and NHS England Area Team will be asked to provide an overview of the local context, what is working well or is outstanding, and where there are areas of concern or risk in GP practices and GP out-of-hours services. This information may influence our planned schedule.

Where appropriate, we use existing structures and meetings to hold these discussions.

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.

An inspection of an individual GP practice or GP out-of-hours service usually lasts for one day.

Inspections of GP out-of-hours services will include inspection time during the out-of-hours period as well as during the daytime. Where services are managed from one location across multiple sites, we are likely to visit a number of the sites during a comprehensive inspection.

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 during the site visit

We will gather the views of people who use services and those close to them by:

- Speaking individually with people.
- Using comment cards placed in reception areas and other busy areas to gather feedback from people who use services, their family and carers.
- Using posters to advertise the inspection and give an opportunity to speak to the inspection team. These will be put in areas where people who use services will see them.
- Exploring options for using digital routes for people of all ages to share their experience, through text messaging, social media, such as Twitter, and through mobile apps.
- Using the information gathered from our work looking at complaints and concerns from people who use services.

Where we include Experts by Experience on our inspections they will talk to people using services at the premises on the day of the inspection.

Gathering the views of staff

The inspection team will speak to staff. On all inspections, we are likely to speak to the following people:

- GP partners.
- Other GPs employed, including locums and trainee GPs.
- Practice managers/managers of out-of-hours services.
- Practice nurses.
- Healthcare assistants.
- Administrative staff.

In larger providers the inspection team may also hold focus groups with separate groups of staff.

The inspection team will offer to talk to current and former whistleblowers during the inspection period.

Other inspection methods and information gathering

Other ways of gathering evidence may include:

- Pathway tracking patients through their care.
- Reviewing records.
- Reviewing operational policies and supporting documents.
- Listening to how staff handle calls in GP out-of-hours services.
- Speaking with the patient participation group or patient reference group.

We recognise that there are particular sensitivities about medical records held by GP practices. The relationship between GPs, practice nurses and their patients is often a close and long-lasting one, with a very strong expectation of confidentiality. The GP practices' records may include very private and personal information, including information about relationships, mental health and sexual health. We have recently published information describing why we look at medical records during our inspections and how we will do this. A GP or nurse from the inspection team will usually review medical records. This information can be found here.

The start of the visit

At the start of each inspection of a GP practice or a GP out-of-hours service, the inspector will meet with the registered manager. If the registered manager is not available the inspector can meet with another senior member of staff, for example a partner. This introductory session will be short and will explain:

- Who the inspection team are.
- The scope and purpose of the inspection, including our relevant powers and the plan for the day.
- How we will escalate any concerns identified during the inspection.
- How we will communicate our findings.

At the start of the visit we ask GP practices and GP out-of-hours services to present to the inspection team their own view of their performance, particularly in relation to the five key questions and six population groups and to include any examples of outstanding care and practice. There is no specified format or media for this briefing; the provider can choose whichever format suits them. This should take no longer than 30 minutes.

We want providers to be open and share their views with us about where they are providing good care, and what they are doing to improve in those areas they know are not so good.

We will judge practices and GP out-of-hours services more harshly on 'well-led' if we find that they have not been open with us about issues of concern they already know about, and this will affect their rating.

Continual evaluation

Throughout the inspection the inspection team will review the emerging findings together. This corroboration will occur at least once during the inspection. 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 are identified. It also enables the team to identify which further evidence might be needed in relation to a line of enquiry and what relevant facts might still be needed to corroborate a judgment.

Feedback on the visit

At the end of the inspection visit, the inspector will provide feedback to the GP practice or GP out-of-hours service, usually to the registered manager. This is to give high level initial feedback only, illustrated with some examples.

The meeting will cover:

- Thanking the service for their support and contribution.
- Explaining findings to date, but noting that further analysis of the evidence will be needed before final judgements can be reached on all the issues.
- Any issues that were escalated during the visit or which require immediate action.
- Any plans for follow-up or additional visits (unless they are unannounced).
- Explaining that further analysis is required before we can award ratings.

- Explaining how we will make judgements against the existing regulations.
- Whether we need additional evidence or are likely to seek further specialist advice in order to make a judgement.
- Explaining the next steps, including challenging factual accuracy in the draft report, final report sign-off and publication.
- Answering any questions from the practice.

8. Focused inspection

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 service provider are to occur.

Focused inspections do not usually 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.
- Concerns that have been raised with us through other sources, such as information from Intelligent Monitoring, members of the public, staff or stakeholders.

Change of service provider

We may undertake a focused inspection when there will be a change in a service provider, such as a takeover or merger or an acquisition of a service.

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. These 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 population group 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 to 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 all the available evidence, using their professional judgement.

For each individual rating against a key question (for example, for responsiveness for working age people) the judgement is made following a review of the evidence under each key line of enquiry (KLOE). This evidence comes from the four sources of information: our ongoing relationship with the provider, Intelligent Monitoring, pre-inspection work, and information from the inspection visit itself. This 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

GP practices: what do we give a rating to?

For each **GP practice** we inspect, we will rate at four levels.

Level 1: Rate every population group for each key question.

Inspectors will consider both evidence that relates to individual population groups, and practice-level evidence that relates to all people using the service. The impact of practice-level evidence on the six population groups needs to be considered and this, along with evidence about a specific population group, will provide the basis for the ratings at this level. Evidence specific to different population groups may lead to different ratings being awarded for different population groups.

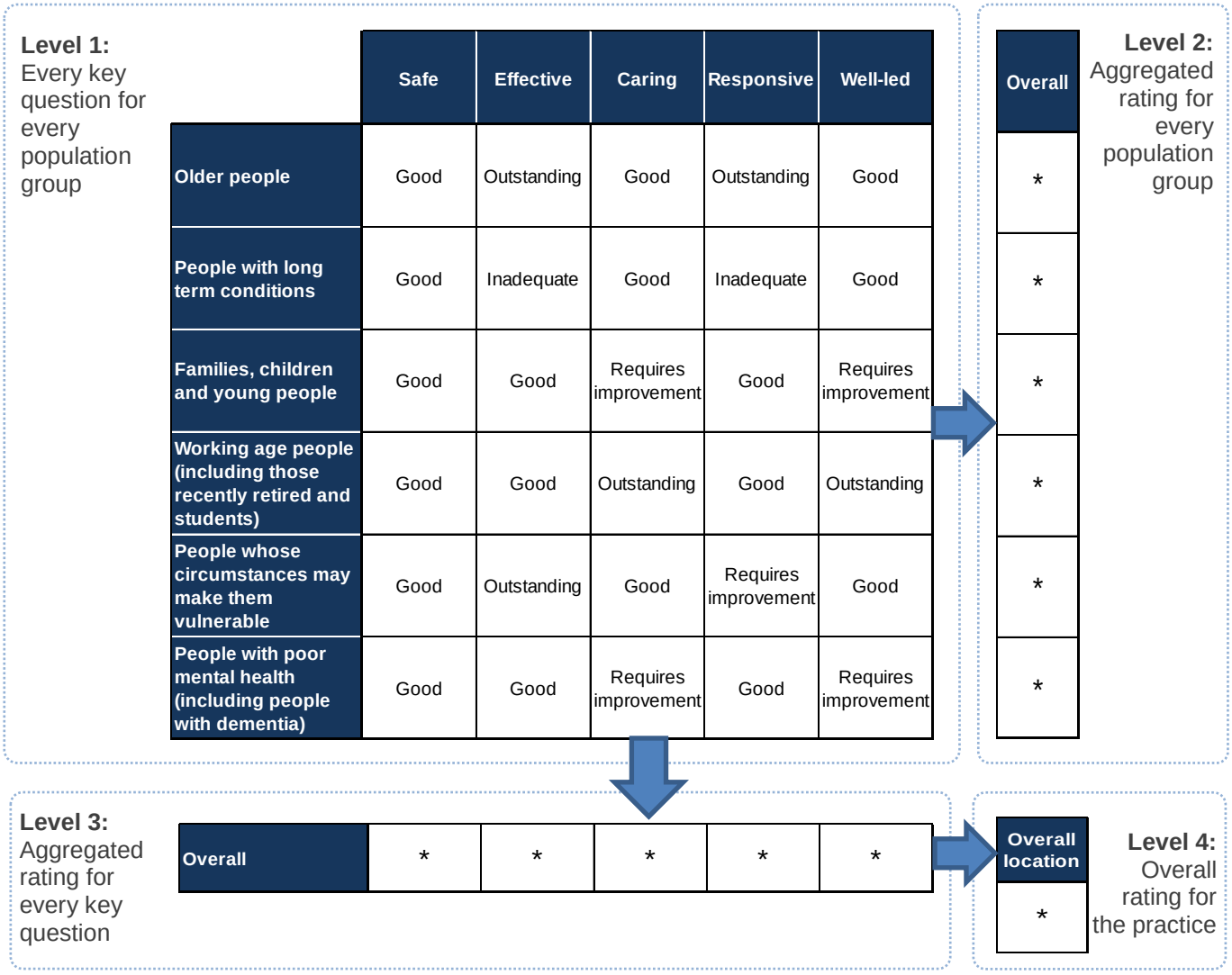
Level 2: An aggregated rating for each population group.

Level 3: An aggregated rating for each key question.

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

The following example shows how the four levels work together:

Figure 5: Rating at four levels for GP practices



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

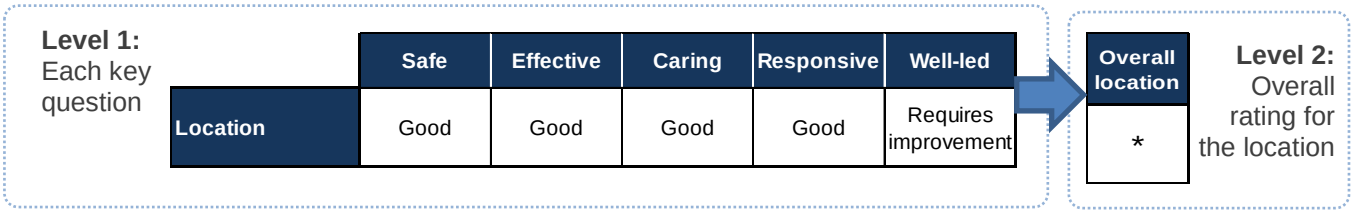
NHS GP out-of-hours services: what do we give a rating to?

For GP out-of-hours services, we rate at the following two levels.

Level 1: A rating for each of the key questions for the out-of-hours services as a whole.

Level 2: An overall rating for the out-of-hours services. This will be an aggregated rating informed by our findings at level 1.

Figure 6: Rating at two levels for GP out-of-hours services



Where we have evidence about the quality of GP out-of-hours services for specific groups of people, particularly where they may be in vulnerable circumstances, we will include this as part of our overall report following the inspection.

Sometimes, we won't be able to award a rating. This could be because:

- The service is new.
- We don't have enough evidence.
- The service has recently been reconfigured, such as being taken over by a new provider.

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

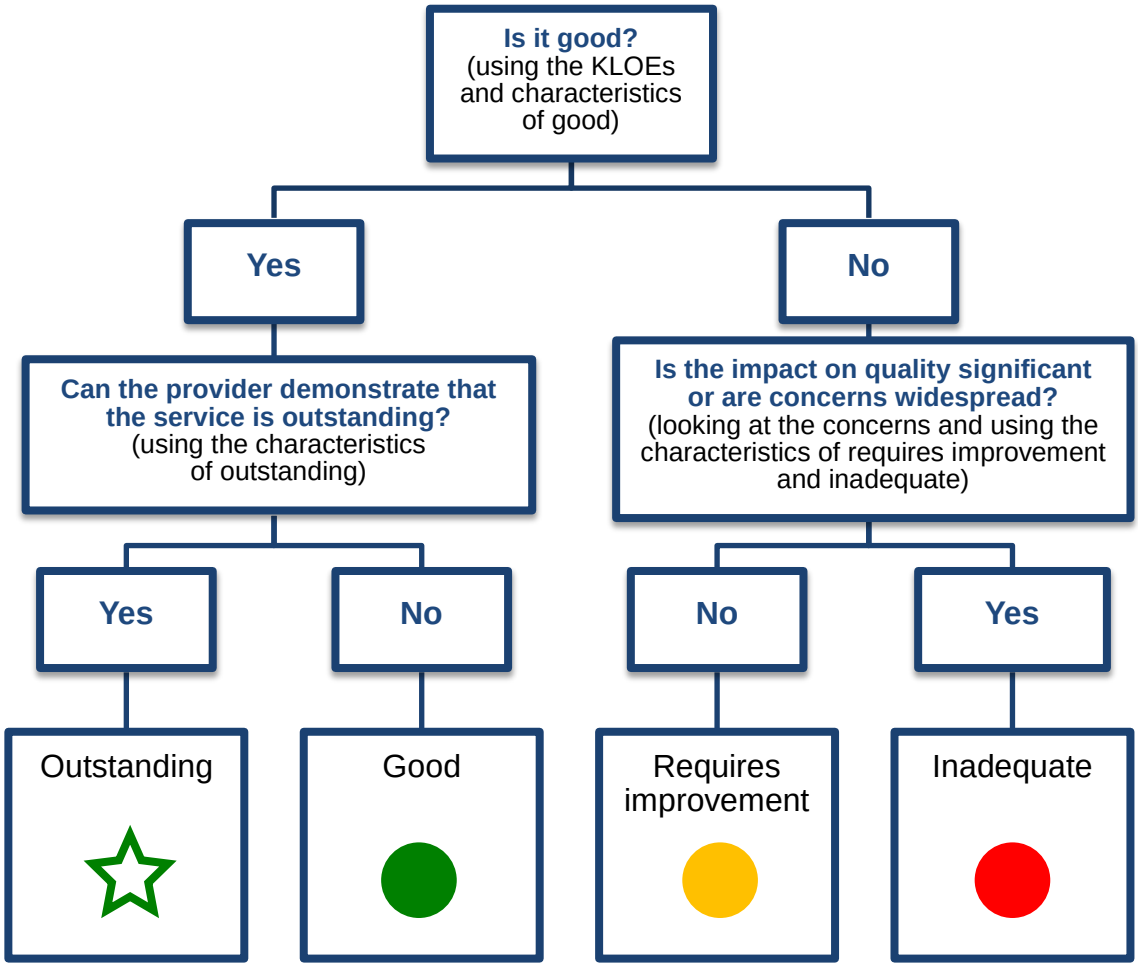
When awarding ratings for the five key questions and for, GP practices only, the six population groups, our inspection teams will review the evidence gathered against the KLOEs and use the guidance supplied to decide on a rating.

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 7) shows how this works.

Figure 7: 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 will be based on all of the available evidence.

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

- Where 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 large service.

Figure 8a: How we aggregate ratings – GP practices

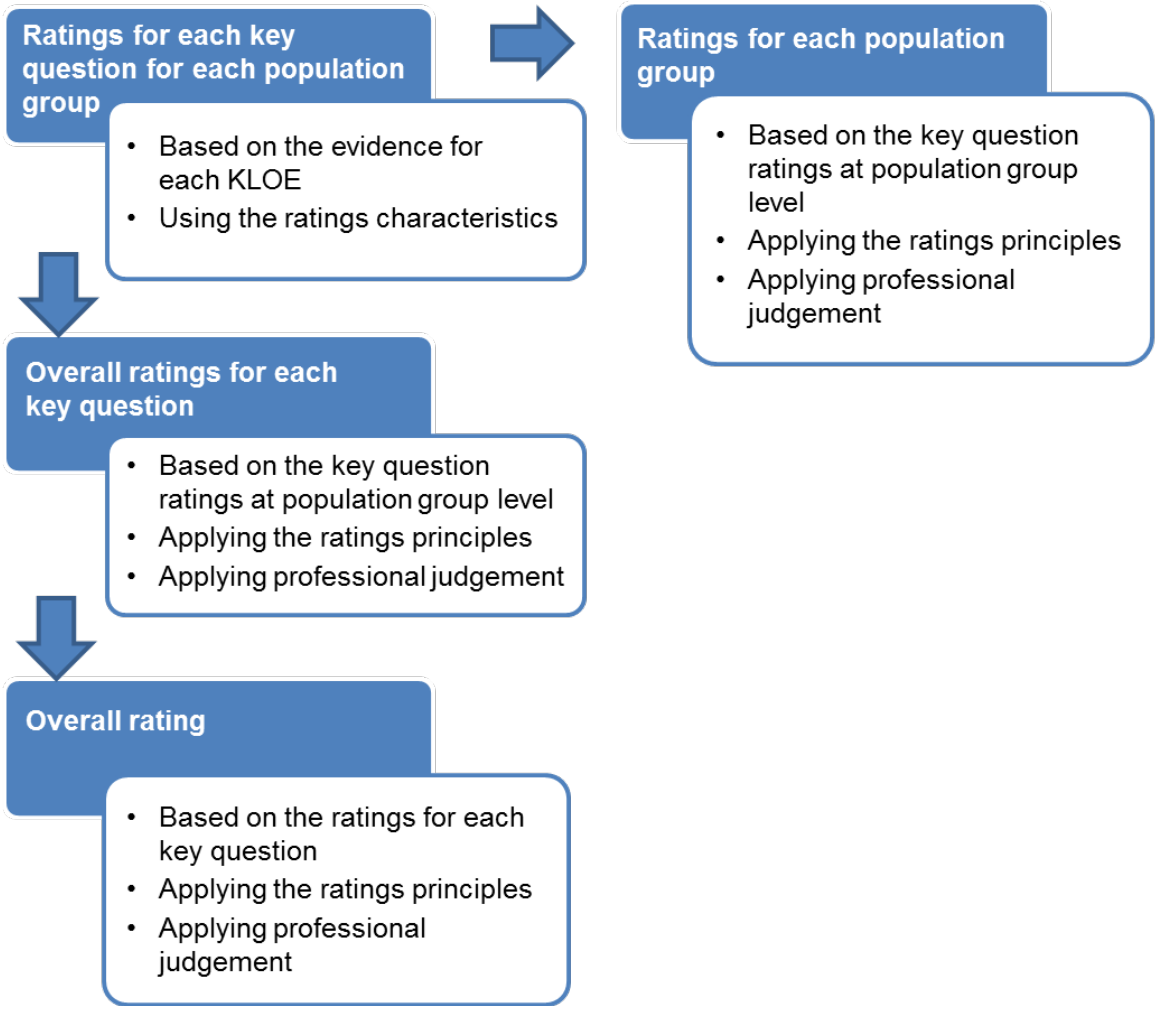
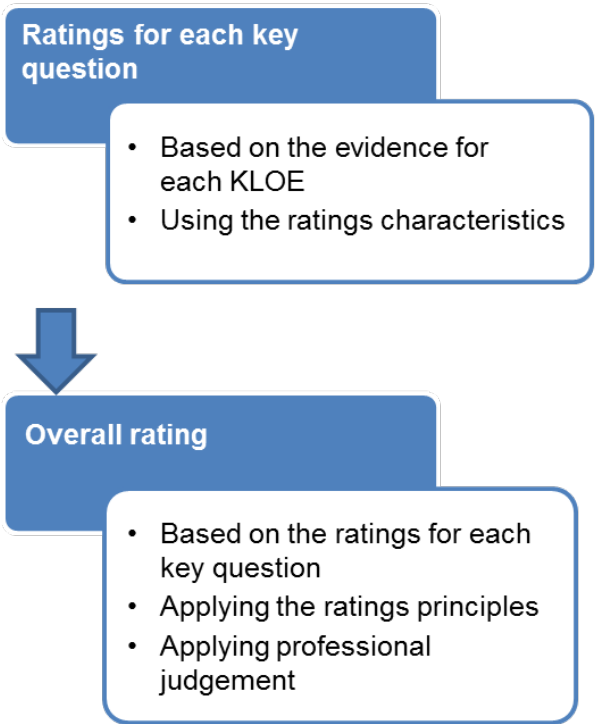


Figure 8b: How we aggregate ratings – GP out-of-hours services



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 report is high, ahead of it being shared with the organisation being inspected.

10. Reporting, quality control and action planning

Reporting

After each inspection we produce a report. The report is drafted in collaboration with members of the inspection team and is written in clear, accessible plain English. Our reports include our ratings judgements.

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 the core principles that underpins all our work. We have put in place an overall approach for CQC to embed 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.

We have made a commitment to strong internal quality control and assurance mechanisms, including panels that consider a sample of rating judgements to check consistency.

Following quality checks, the draft report is sent to the provider for comment in relation to factual accuracy. The report is finalised following any necessary changes and sent to the provider.

Action planning by GP practices and GP out-of-hours services

We expect individual GP practices and GP out-of-hours services to respond to areas of concern that we have identified and to make the recommended improvements. This is their responsibility and includes developing an action plan to address any concerns raised.

Post-inspection discussions with the NHS England Area Team and the CCG

The inspection findings from all inspected GP practices and GP out-of-hours services will inform the basis of a discussion at a meeting held between CQC, the NHS England Area Team(s) and the CCG. Where appropriate, we will use existing structures and meetings to hold these discussions, for example quality surveillance groups.

Individual practices are not usually invited to attend the meeting.

The purpose of this meeting is to discuss our overall findings in the CCG area with partners in the local health and social care system – organisations that are responsible for commissioning or supporting improvement of general practice in the local area.

Each meeting will consider:

- An overview of findings from the inspections across the CCG area, including key themes of good and poor practice.
- Identification of GP practices or GP out-of-hours providers where there are concerns, including a discussion about whether planned action to improve quality is adequate, or whether additional steps need to be taken. In some cases this discussion will take place separately from the broader discussion about our findings across the CCG area and will include the individual provider.
- What subsequent oversight and monitoring of GP practices or GP out-of-hours services will take place

Where existing meetings are not used, we will send a letter of invitation to the NHS England Area Team(s) and the CCG to attend the post-inspection meeting, along with an agenda and a copy of the final, or near-final report(s). If these reports have been published, we will send a link to the reports on our website.

Attendees will include:

- CQC Inspection Manager.
- CQC GP regional adviser.
- Other CQC staff involved in the inspections, as required.
- Representatives from the CCG.
- Representatives from the NHS England Area Team.
- Others as appropriate (for example, local Healthwatch, local education and training boards and local medical committee(s) representative).

Any area-wide action planning carried out by the CCG and the NHS England Area Team does not replace action planning carried out by individual practices to respond to any concerns we have or recommendations we make. Individual practices should have their own action plans as well. Once agreed, action plans should be shared with the CQC Inspection Manager and the GP regional adviser to ensure that all key areas highlighted during the inspection have been appropriately addressed.

Where GP practices and GP out-of-hours providers have been found to be providing inadequate care, further action may be taken. See section 11 for more information.

Publication

CQC will publish the inspection reports on our website after the end of the inspection. We encourage CCGs, NHS England Area Teams and individual practices and GP out-of-hours services to publish their action plans on their own website.

The Chief Inspector of General Practice will also summarise, within the inspection report, our key findings from the inspection.

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

We may also make recommendations, even when 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 and expect appropriate action to be taken by the provider and local partners.

We follow up any concerns or enforcement action we take. 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 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 requirement and the duty of candour

Two new requirements, the fit and proper person requirement and the duty of candour, will apply to GP practices and GP out-of-hours services from April 2015 subject to Parliamentary process and approval.

The fit and proper person test will place a clear duty on health and social care providers to make sure directors and board members (or their equivalents) meet criteria set out in the test. Organisations retain full responsibility for appointing directors and board members (or their equivalents). However, CQC will be able to intervene where it considers an individual is not a fit and proper person, and place a condition on a provider to remove the director (or equivalent) if there is evidence that they have previously been involved in failures to deliver good quality, safe care.

A new statutory duty of candour will be placed on all organisations registered with CQC, and for NHS GP practices from April 2015, subject to Parliamentary process and approval. This means that people, and where appropriate their families, must be told openly and honestly when unanticipated things happen, which cause them harm above a pre-determined threshold. 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 existing professional duty of candour on individuals. We will be considering this statutory duty as part of our assessment.

Responding to inadequate care

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

Working with NHS England, we are introducing a special measures framework within which CQC and NHS England Area Teams will work together to ensure a timely and coordinated response to GP practices that are providing inadequate care. This will ensure that practices are not allowed to continue to provide inadequate care to people indefinitely.

Over the next few months, we will be working closely with GP practices and organisations that represent them, as well as people who use services, to develop this approach.

We will begin to introduce special measures from October 2014. Initially, we will pilot the special measures regime to test our approach, working closely with NHS England. It will be fully implemented from April 2015.

Our proposals are that GP practices rated as inadequate for one or more of the five key questions or six population groups will be given a specified period for re-inspection. This will be no later than six months after the initial

rating is confirmed. This period will give the practice a fixed time during which they must demonstrate improvement, ahead of another CQC inspection.

If, after re-inspection, they have failed to make sufficient improvement, and are still rated inadequate for a key question or population group, CQC will place the practice into special measures following consultation with NHS England.

In a very small number of cases, a GP practice may have such significant problems that people who use services are at risk or there may be sufficiently little confidence in the practice's capacity to improve on its own. In this case, the practice will be placed straight into special measures. GP practices will be placed into special measures for a maximum of six months. Being placed into special measures will represent a decision by CQC that a practice has to improve within six months to avoid having its registration cancelled.

Where practices are rated as inadequate, information will be shared with the NHS England Area Team and the CCG at the earliest opportunity, and discussions will take place to determine the next steps for the practice.

NHS England is developing guidance for Area Teams and CCGs on how they should respond to, and work with, practices that receive an inadequate rating following an inspection. This will be published in October 2014.

Challenging the evidence and ratings

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

GP practices and providers of GP out-of-hours services can challenge the factual accuracy of reports and make representations about the evidence in Warning Notices. These steps will normally be the means by which providers will also challenge the ratings CQC has awarded, because ratings are awarded on the basis of the evidence about the quality and safety of their service.

The following routes are open to GP practices and providers of GP out-of-hours services to challenge our judgements.

Factual accuracy check

When GP practices and GP out-of-hours services 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. GP practices and GP out-of-hours services 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 registered persons the opportunity to make representations about the matters in the Notice. The content of the Notice will be informed by evidence about the breach that is in the inspection report. This evidence will sometimes have also contributed to decisions about ratings. Therefore, as with the factual accuracy check, representations that are upheld that also have an impact on ratings may result in relevant ratings being amended.

Under our process for factual accuracy checks and Warning Notice representations, unresolved issues can be escalated to managers in CQC who were not involved in the inspection.

Request for a rating review

Providers can ask for a review of their own ratings.

The only grounds for requesting a review is that the inspector did not follow the process for awarding them properly, as described in published policies and procedures. GP practices and GP out-of-hours services cannot request reviews on the basis that they disagree with the judgements made by an inspector, as such disagreements would have been dealt with through the factual accuracy checks and Warning Notice representations.

Where a GP practice or GP out-of-hours services 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.

GP practices and GP out-of-hours services will have a single opportunity to request a review of their inspection ratings. In the request for review form, they must say which rating(s) they want to be reviewed and all relevant grounds and circumstances. Where we do not uphold a request for review, practices and 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 a review will be handled by CQC staff who were not involved in the original inspection, with access to an independent reviewer.

The outcome of the review will be sent to the GP practice or GP out-of-hours service 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. GP practices and GP out-of-hours services 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 handled 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 website.

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

Appendix A: Population group definitions

Appendix B: Key lines of enquiry

Appendix C: Characteristics of each rating level

Appendix D: Ratings principles

Published October 2014

How to contact us

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Look at our website:	**www.cqc.org.uk**
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Follow us on Twitter: @CareQualityComm