Care Quality Commission

How CQC regulates:

Primary care dental services



Provider handbook

March 2015

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 values

- Excellence – being a high-performing organisation
- Caring – treating everyone with dignity and respect
- Integrity – doing the right thing
- Teamwork – learning from each other to be the best we can

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Foreword

This handbook on how CQC will regulate primary care dental services is really important to me, as I passionately believe that everyone in our society deserves safe, high-quality, accessible primary dental care regardless of their circumstances.

There are a number of organisations involved in monitoring the quality and safety of dental services and dental care professionals. We all have a mutual interest in ensuring that patients receive high-quality, safe dental services from professionals and organisations that are competent and meet national standards. I am extremely pleased that these organisations, including the General Dental Council (GDC), NHS England, NHS Business Services Authority, Healthwatch England and CQC, have agreed to work closer together to review the approach to dental regulation and inspection across England, assess current arrangements and determine an effective model for regulation for the future.

In August 2014, we published a statement, *A fresh start for the regulation and inspection of primary care dental services*. Our statement set out our priorities for developing a new approach for primary care dental services. Our main priority is to carry out an assessment of the quality of primary care dental services leading to a judgement about whether they provide people with care that is safe, effective, caring, responsive and well-led, based on whether the regulations are being met.

This handbook, for primary care dental providers, sets out how we will do this for 2015/16, and how we will work with our partners. The future model from 2016 onwards will be influenced by the joint work of the GDC, NHS England, NHS Business Services Authority, Healthwatch England and CQC.



Professor Steve Field CBE FRCP FFPHM FRCGP
Chief Inspector of Primary Medical Services

Introduction

This handbook describes our approach to regulating and inspecting primary care dental services.

Our new approach builds on our publication, *A new start*, which proposed radical changes to the way we regulate, inspect and monitor care and our consultation on our draft provider handbook for primary care dental services.

By primary care dental services, we mean those dental services that are predominantly provided by dentists on the 'high street', including services that may visit people in their home if access to a practice is difficult, and any out-of-hours emergency dental services. These services come under the regulatory remit of CQC's Chief Inspector of Primary Medical Services.

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?

Unlike other sectors that CQC regulates, we will not be giving a rating to primary care dental services in 2015/16, although we reserve the option to do so in the future.

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.

1. Our framework

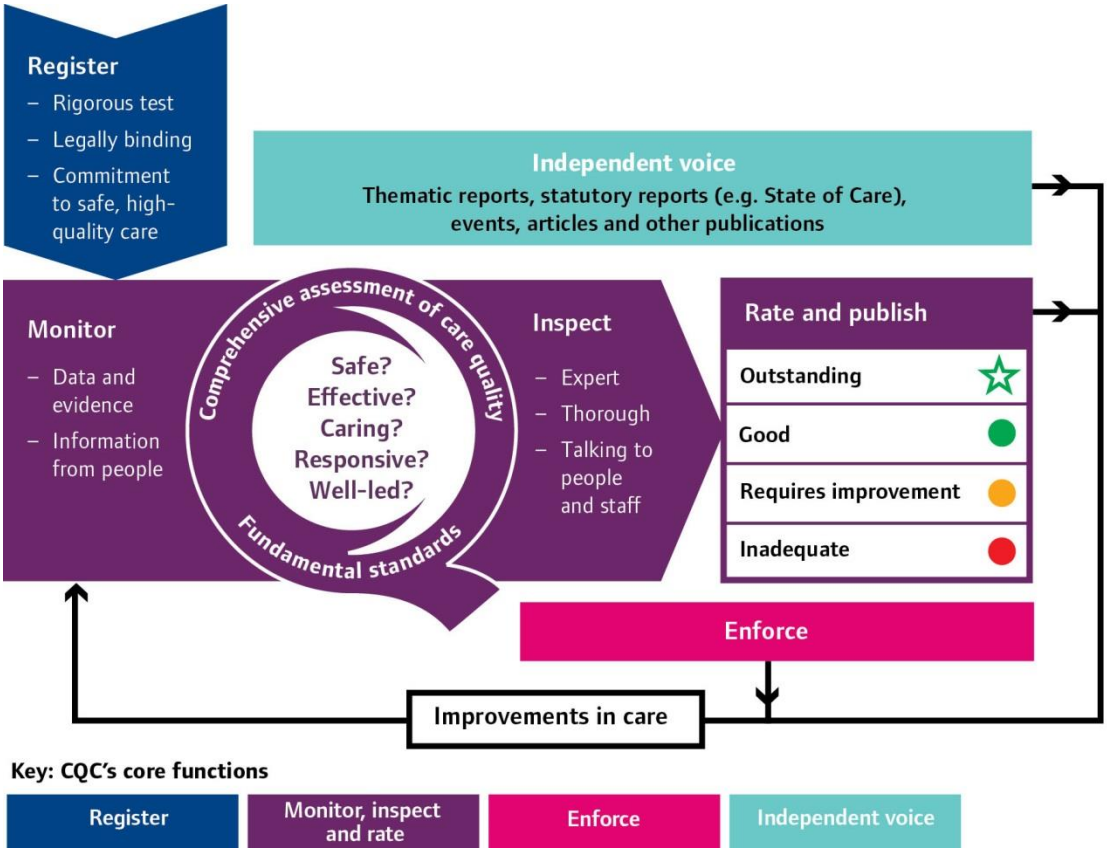
Our operating model

Although we inspect and regulate different services in different ways, there are some principles that guide our operating model across all our work. The diagram on the following page 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.
- Continuous monitoring of local data, shared intelligence and risk assessment.
- Taking action against those who provide services but fail to secure registration before doing so.
- Involving specialist advisers to accompany our dental inspectors where we identify specific concerns.
- Using feedback from people who use services and the public to inform our judgements about services.
- Providing information for the public on our judgements about care quality.
- 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.
- Using our independent voice to speak about what we find on behalf of people who use services.

Our model is underpinned by the new fundamental standards that come into force on 1 April 2015. We have published *Guidance for providers on meeting the regulations* to help providers understand how they can meet the new regulations.

Figure 1: CQC's overall operating model



Please note that this is the overall CQC operating model and, unlike some sectors that CQC regulates, we will not be rating primary care dental services from 2015/16, although we may do so in the future.

Applying the operating model to primary care dental services

We will carry out an assessment of the quality of primary care dental services leading to a judgment about whether they provide people with safe, effective, caring, responsive and well-led care, based on whether the regulations are being met.

Although we are adopting the principles and many of the key elements of the overall operating model in our new approach to inspecting primary care dental services, some of the detail will be different to the methods we use when regulating other sectors. On the basis of previous inspections we have found that, compared with these other sectors, dental services present a lower risk to patients' safety. Our stakeholders also agree that the majority of dental services are safe and that the quality of care is good. Therefore, we will inspect 10% of providers based on a model of risk and random inspection, as well as inspecting in response to concerns, and we will not provide a rating for primary care dental services in 2015-16, although we reserve the option to do so in the future.

We will look for notable practice to promote learning and encourage improvement, as well as make sure that dental practices meet the requirements set out in the regulations (including the new fundamental standards of care coming into force this April). In accordance with CQC's operating model, we will ask if practices are safe, effective, caring, responsive and well-led, and will report our findings under the five key questions.

To support this we will use Key Lines of Enquiry (KLOEs) and provide examples of what we would expect to see to demonstrate that no regulations have been breached and therefore that services are safe, effective, caring, responsive and well led, based on the regulations. To enable this, the KLOEs map to the regulations to ensure that we can identify breaches of the fundamental standards.

The KLOEs are set out in appendix A.

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

Registering those that apply to CQC to provide services

Before dental providers can begin to provide services, they must apply to CQC and secure registration for the regulated activities they intend to deliver. Providers must satisfy CQC that they will be able to meet 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 well-led care.

Intelligent use of data, evidence and information to monitor services

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. We will collect and analyse data about dental practices from a range of sources including information from people who use services, other regulators and oversight bodies, local organisations, other stakeholders and service providers. The information we gather is also used as evidence when we make our judgements against the fundamental standards of care.

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.

Inspection

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

Type of inspection	Description
Comprehensive	• Will be carried out at 10% of registered practices in 2015/16. • Addresses all five key questions CQC asks of services (safe, effective, caring, responsive, well-led). • Usually takes one day at the practice. • Likely to include a specialist adviser. • Usually announced two weeks before the inspection.
Focused	• Follow-up to a previous inspection, or to respond to a particular issue or concern. • Will not address all five key questions CQC asks of services (safe, effective, caring, responsive, well-led). • Team composition and size will depend on the concern(s). • May be conducted in partnership with one of our partners (for example, NHS England). • May be unannounced.

We will carry out comprehensive inspections at 10% of all practices, and select practices for inspection on both a random and a risk-based basis.

Whether selected for inspection or not, all primary care dental providers registered with CQC (approximately 10,000 practices) must meet the fundamental standards. We will develop Intelligent Monitoring for dental practices during 2015 to support our approach of continually monitoring the services we don't inspect.

The 10% of practices selected for a comprehensive inspection will include a sample of:

- Corporate providers
- Partnerships
- Individual providers
- NHS only
- Private only
- Both NHS and private.

We use indicators to help select practices that may be at greater risk of not meeting the fundamental standards. The indicators include the following:

- Providers that have been registered for more than 18 months and have not been inspected.
- Any concern or risk identified about a provider from previous inspections, or from intelligence or information gathered.
- Any concern or complaint we have received about a provider that relates to the fundamental standards; when there is a safeguarding alert; or when a member of staff (including whistleblowers) contacts us with concerns relating to a possible breach of the fundamental standards.

Making judgements

We will make judgements using all the available evidence gathered from three main sources:

- Information from the ongoing relationship with the dental practice.
- Information gathered in the weeks before the inspection.
- Information from the inspection visit.

To help inspection teams carry out their role and to ensure consistency in our inspection approach, we have developed a set of KLOEs, which are listed in appendix A. These include examples of what we would expect to see in demonstration that the characteristics of each key question, and the fundamental standards, are being met. The KLOE's and examples of evidence are not an exhaustive list, or a 'checklist'. We will take into account the context of the practice when we look for evidence. We will consider the amount and depth of evidence that we need to assess and will gather sufficient evidence to be able to reach a robust judgement.

When making our judgements we consider the weight of each piece of relevant evidence. In most cases we need to verify our evidence with other sources to support our findings. When we have conflicting evidence, we will consider 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

Unlike some sectors that CQC regulates, we will not be rating primary care dental services from 2015/16 although we may do so in the future. It would be unfair and a disadvantage to other providers to rate only the 10% of providers that we inspect.

Enforcement

Where we have identified concerns, we will 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 of regulation, including the fundamental standards, we have a wide range of enforcement powers given to us by the Health and Social Care Act 2008.

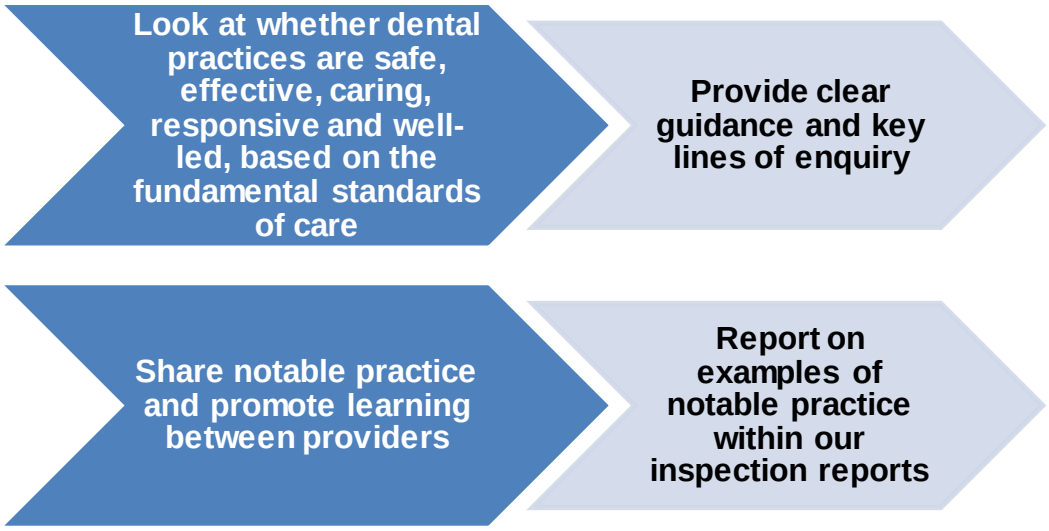
Our Enforcement policy describes our powers in detail and our general approach to using them.

Encouraging improvement

Our approach is to carry out an assessment of the quality of primary care dental services leading to a judgement about whether the care which is being provided is safe, effective, caring, responsive and well-led. Although we will not be testing the effectiveness of care delivered at individual practitioner level, we will expect dental practices to demonstrate how they provide safe and effective care to patients and how they assure themselves about patient outcomes. This is part of our role in encouraging services to improve. We will be clear about our expectations of practices through our guidance that underpins the regulations, including the fundamental standards of care.

Additionally, our role in encouraging improvement in the primary care dental sector will be to share notable practice and promote learning between providers. During inspections, we will look at what providers do over and above the fundamental standards to assure themselves that patients receive good outcomes. We will ask the provider at the start of an inspection to tell us about any notable practice they have adopted. We will highlight notable practice in our reports, with the intention of enabling other practices to learn from what works well. These examples will be verified by our specialist dental adviser as part of our quality assurance processes to ensure accuracy and consistency, and enable us to build up a portfolio of examples.

Figure 2: How we will encourage improvement



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.

We know that certain groups can have difficulty in accessing primary care dental services. For example, disabled people or those with mobility issues can face physical barriers in accessing dental practices particularly if the building is old and building restrictions mean that reasonable adjustments to access cannot be made. Homeless people may experience barriers in accessing free NHS dental treatment because they may not have the required evidence to prove exemption from NHS fees.

We also know that some groups in society, such as those who are HIV positive, face particular stigma when using primary care dental services. Attempts have been made to improve the availability of NHS dental services in many parts of the country; although there is some evidence to suggest that the use of dental services varies between different ethnic groups. The UK has become highly multi-cultural at quite a rapid pace and there are concerns that some dentists are not fully prepared or understand the possible implications, particularly around consent.

We have developed a human rights approach to regulation. This looks at a set of human rights principles in relation to the five key questions CQC asks of services. These principles are: fairness, respect, equality, dignity, autonomy, right to life and rights for staff. We have developed definitions of these principles through public consultation and linked these to the Human Rights Act 1998 and the Equality Act 2010.

People who use services have told us that these principles are very important to them. 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 perspective of people who use services.

Our human rights approach is integrated into our approach to inspecting and regulating primary care dental services, as this is the best method to make sure we promote equality and human rights in our work. We have identified the most important fundamental standards relating to equality and human rights and have integrated the human rights principles into our inspection prompts, inspection methods, learning and development for inspection teams and into our policies around making judgements and enforcement.

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 dental service provides treatment to patients 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.

There may be occasions when people with more complex issues are referred to specialist services such as community dental services or dental hospitals.

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.

It is unlikely that restraint will be used in primary care dental services, because the patient would be assessed as requiring specialist treatment from either a community dental service or dental hospital. However, if it is used to deliver necessary care or treatment, we will look for evidence to ensure it is in the best interests of someone lacking mental capacity, is proportionate and complies with the MCA. For example, in some circumstances sedation to enable necessary treatment may be in the best interests of a person lacking mental capacity to consent. For this to be lawful, it must be clear from the records that this is the least restrictive option that can be identified to deliver necessary treatment. Primary care dental services are unlikely to be responsible for seeking authorisation of a deprivation of liberty. However, dental staff must be aware that if they are providing care or treatment to a person who is subject to

an authorisation for deprivation of liberty, this authorisation does not authorise specific treatment, which must be given using the wider provisions of the Mental Capacity Act. Where it is likely that a person is deprived of their liberty to enable them to receive 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 prompt 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 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 by telephone, and providing opportunities to share concerns with inspectors when they visit a service.
- Asking national and local partners (for example, NHS Area Teams 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 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 and procedures, reviewing indicators, such as a backlog of complaints, and speaking with people who use services, carers, families and staff.

2. How we work with others

Good 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 notable practice and to work with others to raise standards. Our inspection managers will be responsible for maintaining local relationships with stakeholders.

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. We are committed to engaging with the public to encourage people to share their views and experiences with us; this includes people who use services and those close to them, carers and advocates. We do this through raising awareness among the public, working with local Healthwatch organisations, dental care professionals, providers, Experts by Experience and through public events.

Working with other regulators and oversight bodies

As part of our ongoing relationship with our stakeholders, and to help focus our inspection activity, we will ask NHS Area Teams (the commissioner of NHS dental services) to share information about providers. Specifically before an inspection, we will ask NHS Area Teams if they have recently visited the practice and what the outcome of the visit was, particularly if they have any areas of concern. If we receive information of concern as part of our ongoing regulatory oversight or identify concerns through inspection that we think require NHS England to take action, we will share this information with the NHS Area Team. If we identify concerns about the fitness to practise of any member of the dental team, we will share these with the General Dental Council.

Working with local organisations

CQC has a statutory duty to have regard to the views of local Healthwatch organisations as part of our wider statutory responsibility to involve people who use services in our work. Each local Healthwatch organisation acts as a voice for any member of the public in its area who wants to influence the commissioning, provision or delivery of care services. As part of our inspection planning, we will write to local Healthwatch organisations and local overview and scrutiny committees to ask them to share with us any issues or concerns they wish to raise about individual practices. The information they provide will help direct the focus of our inspection.

Working with providers

Each registered location of a primary care dental practice will have a member of CQC's inspection staff as their 'relationship owner'. 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 may analyse some of the information.

Our approach to inspection includes continuous monitoring of local data and intelligence and risk assessment. In our signposting statement, *A fresh start*, we committed to making better use of shared intelligence and to taking a collaborative approach with our partners to monitor dental care standards. We will develop our approach to intelligent monitoring within the primary care dental sector during 2015. This work will be influenced by the Regulation of dental services programme board, referred to in our signposting statement as the Tripartite Programme Board, on the future of dental regulation in England.

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:

- Information about the number and types of complaints and compliments that people make about their care and how these are handled.
- The results of the Friends and Family Test.

Working with corporate providers

CQC defines any provider operating more than 20 locations as a 'corporate provider'. This can include smaller providers where necessary, based on individual circumstances. Corporate providers in England operate services across all the health and social care sectors that CQC regulates.

CQC maintains oversight of corporate providers to inform central, regional and local regulatory activity. We meet regularly with corporate providers to exchange information, provide updates and receive feedback on CQC's regulatory approach and to discuss the organisation's performance.

From 1 April 2015, the Deputy Chief Inspector with responsibility for Primary Care Dental Services, along with the heads of inspection, will play a key role in developing the relationship with dental corporate providers and coordinating inspection activity.

3. 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 judgements. We will analyse data from a range of sources, including information from people who use services, information from other stakeholders and information that providers send to us.

Gathering people's views in advance of our inspections

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 leading up to an inspection, we gather people's experiences of care through:

- Discussions with local Healthwatch and local overview and scrutiny committees.
- Publicising our inspections through a range of channels such as displaying information in the dental practice and asking the provider to let people know that we will be inspecting and to share their experiences with us.

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 start the inspection, we will write to practices to ask them for some information. Practices will have five working days to respond to our request. We will make clear what information to send, where to send it and who to contact with any queries or questions.

The information we will request is likely to include:

- Quality monitoring information, such as information about compliments and complaints.
- Information about staff employed.
- An up-to-date statement of purpose.
- Information about membership of any accreditation/good practice scheme.

Gathering information from stakeholders

We will write to NHS Area Teams, local Healthwatch organisations and overview and scrutiny committees to ask for information. We may also meet with the NHS Area Team.

The inspection team

We are anticipating that most of our comprehensive inspections will be carried out on one day by a CQC inspector with support from a Specialist Adviser. This support may include attendance at the inspection or providing advice remotely.

To ensure that we gather sufficient and robust evidence to support our judgements, in some circumstances an inspection may be supported by any or all of the following:

- A larger inspection team.
- Team members with specific skills or experience.
- Spending more time in the service.

Circumstances that may indicate the need for any of the above include:

- The complexity of a service.
- Increased levels of risk to patient safety.
- Conflicting information about the experiences of people using the service.

Inspection teams may also include Experts by Experience. Their main role is to talk with people who use services and tell us what they say. Many people find it easier to talk with an Expert by Experience than an inspector. Experts by Experience can also talk with carers and staff. Experts by Experience are people who have experience of using a particular type of service or who care for someone who uses a service we regulate. For example, in primary care dental inspections, we may involve an Expert by Experience if we need to talk to people whose circumstances make them vulnerable or people with complex needs that may make access more difficult.

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.

When we announce inspections, we will give two weeks' notice to providers. The inspector will phone the practice to announce the inspection, which will then be followed up in a letter. After announcing the inspection and throughout the inspection process, the lead inspector and inspection planner will support and communicate with the dental practice by letter, email and telephone to help them prepare for the day and know what to expect. We also provide guidance about what to inspect on an inspection.

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 be due to new information.

At the start of these visits, the team will meet with the most senior person in charge at the time and will feed back to them at the end of the inspection – particularly 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.

Planning meeting with the NHS Area Teams

CQC's local inspection managers will be the main points of contact with NHS Area Teams before the inspection period. They will contact the NHS Area Team(s) to discuss:

- The scope and purpose of the inspection.
- Who will be involved from CQC?
- Which practices 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 Area Team.

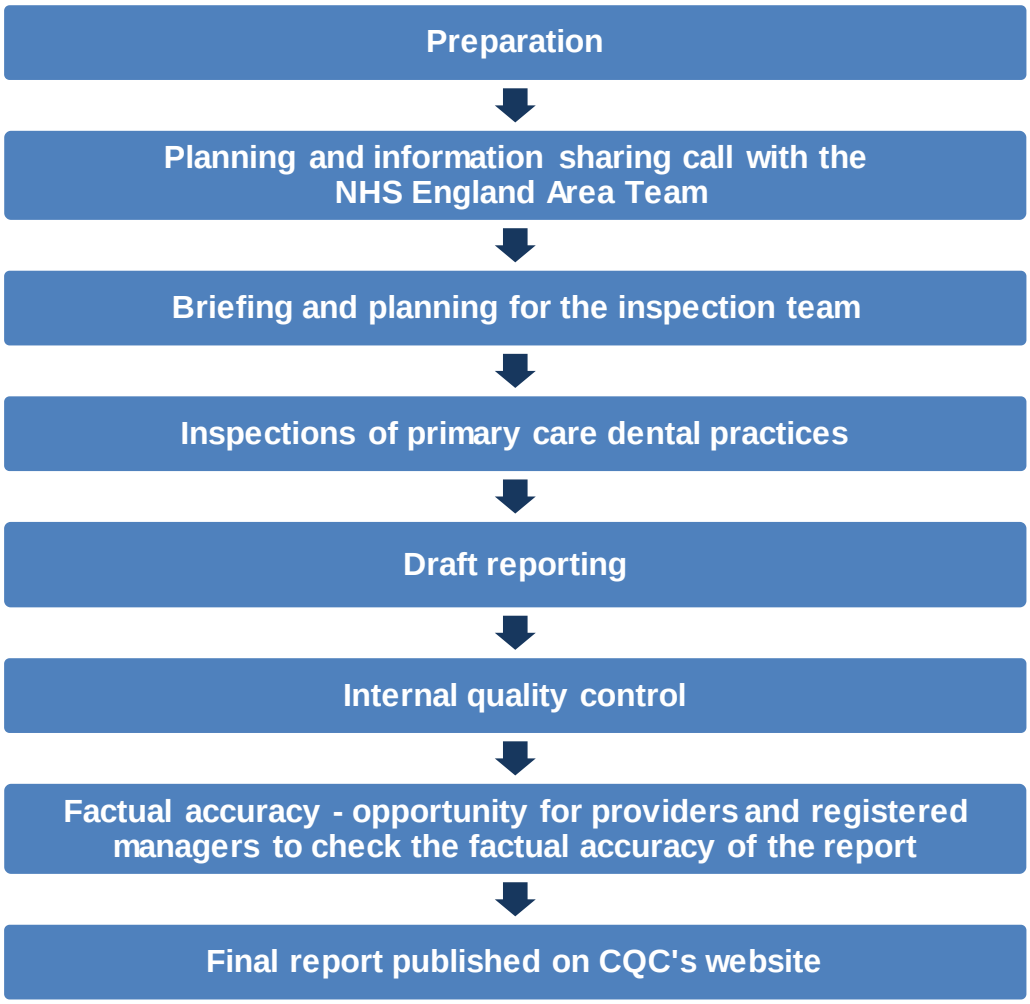
We will then follow up with a letter asking the NHS Area Team to provide information about recent contract visits and areas of concern. The local inspection managers, along with the NHS Area Team, will determine if they need a face-to-face meeting to discuss the information supplied before the inspection.

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

Timetable

Inspections of primary care dental services will go through the following stages:

Figure 3: Stages of a primary care dental inspection



4. Practice visits

Practice visits are a key part of our regulatory framework, giving us an opportunity to talk to people who use services, staff and other professionals to find out their experiences. They allow us to observe the physical premises as well as how the practice implements systems and processes in delivering the regulated activities. They also enable us to observe care, if appropriate and necessary, and to review people's dental records to see how their needs are identified and managed.

The start of the visit

At the start of the practice site visit, 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:

- How CQC regulates primary care dental practices.
- 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.

We will ask the practice to share with us any concerns they have identified themselves in their ability to meet the requirements of the regulations (including the new fundamental standards) and, what they are doing about it. We will also ask them to share with us any notable practice that they think goes beyond the requirements of the regulations.

There is no specified format or presentation template for this briefing – the provider can choose whichever format suits them. This should take no longer than 30 minutes.

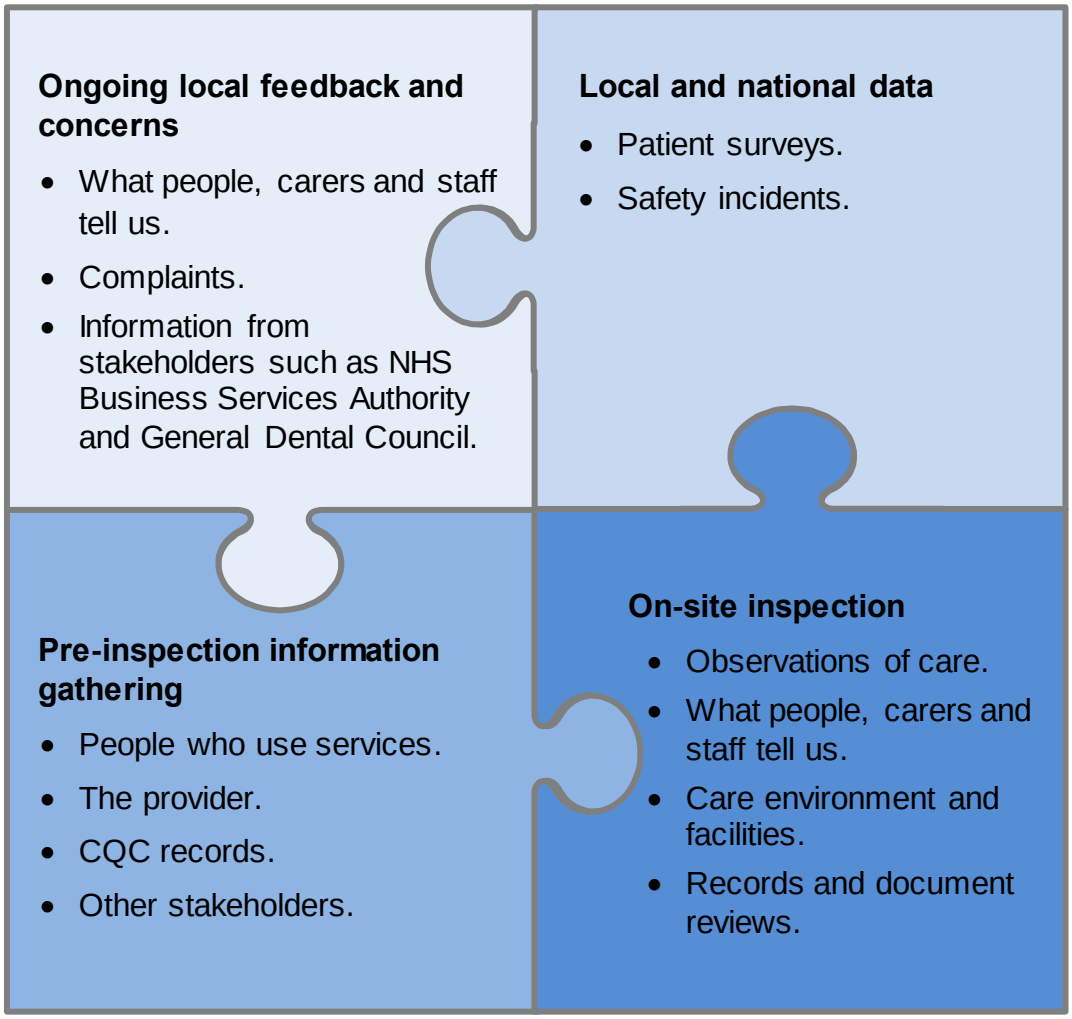
We want providers to be open and share their views with us about where they are providing good care, and what they are doing to improve in areas they know are not so good.

Gathering evidence

Inspection teams will use evidence from four main sources. These are:

- Information from the ongoing relationship management with the dental practice.
- Other nationally available and local information that can inform the inspection judgement.
- Information from activity carried out during the pre-inspection phase.
- Information from the inspection visit itself.

Figure 4: The four main sources of evidence



The inspection team will use the KLOEs (see appendix A), and any concerns identified through the preparation work, to structure their site visit. They collect evidence against the five key questions using the methods described below.

Gathering the views of people who use services

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 to gather feedback from people who use services, their family and carers.
- Using posters to advertise the inspection and provide an opportunity to speak to the inspector or any other members of the inspection team. These will be put in areas where people will see them.
- Exploring options for using digital routes for people of all ages to share their experience, through text messaging, social media, 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:

- Dental nurses.
- Individual dentists.
- Practice managers.
- Reception staff.

The inspection team will offer to talk to current and former whistleblowers during the inspection period. This may be during the practice site visit or on the telephone.

Other inspection methods and information gathering

Other ways of gathering evidence may include:

- Reviewing parts of the dental records.
- Reviewing operational policies and supporting documents.
- Observing processes such as decontamination.
- Looking at the premises and facilities.

Continual evaluation

If the inspection is being carried out by a team, the lead inspector will review the emerging findings with the team throughout the day. This keeps the team up to date with all issues and enables them to shift the focus of the inspection if they identify new areas of concern. It also enables the team to identify any further evidence or facts that might still be needed.

Feedback on the visit

At the end of the inspection visit, the inspector will provide feedback to the registered manager or most senior person in charge, as agreed at the start of the inspection. 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 the 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 that require immediate action.
- Any plans for follow-up or additional visits (unless they are unannounced).
- Explaining how we will make judgements.
- Whether we need additional evidence or are likely to seek further specialist advice.
- Explaining the next steps, including factual accuracy checking of the draft report, final report sign-off and publication.
- Answering any questions from the practice.

5. Focused inspection

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.
- Concerns that have been raised with us through other sources, such as information from our stakeholders, members of the public, staff.

Change of service provider

When there is a change in the legal entity of the service provider, such as a sale, merger or an acquisition of a service, we may undertake a focused inspection depending on the level of risk to patients and the safety and quality of care.

The focused inspection process

Although they are smaller in scope, focused inspections broadly follow the same process as a comprehensive inspection. The reason for the inspection determines many aspects, such as the scale 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.

As a focused inspection is not an inspection of the whole of a provider, we will not necessarily address all the five key questions; safe, effective, caring, responsive and well-led.

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

6. Reporting, quality control and action planning

Reporting

After each inspection we produce a report on what we found. To do so is a legal obligation under section 61 (3) of the Health and Social Care Act 2008. The report is drafted in collaboration with members of the inspection team (where applicable) and is written in clear, accessible, plain English.

Our reports focus on our findings against the five key questions CQC asks of services. We want to help providers to continually improve, so our reports will include information about any improvement we think the provider could make, even if they meet the fundamental standards of care. We will also include information about notable practice. If we identify any breaches in the fundamental standards we will clearly set out the evidence about the breach.

Quality control

We engaged widely with stakeholders and dental providers when developing this handbook and heard that there were some concerns about our ability to be consistent in making judgements. Consistency is one of the core principles that underpin all our work. We have put in place an overall approach across 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 and consistent quality assurance processes.

Following quality checks, we send the draft report to the provider to comment in relation to its factual accuracy. The report is published following any necessary changes.

Action planning

We expect practices 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.

Publication

CQC will publish the inspection reports on our website after the end of the inspection. We encourage dental practices to publish their report, including any action plans, on their own website.

7. Enforcement and actions

Types of action and enforcement

From April 2015, new regulations, including the 'fundamental standards', come into force. These are more focused and clear than the previous regulations about the care that people should expect to receive.

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 of regulation, including the fundamental standards, we have a wide range of enforcement powers given to us by the Health and Social Care Act 2008.

Where appropriate, if the provider is able to improve the service on its own and the risks to people who use the service are not immediate, we will expect the provider to make improvements. We will do this as part of our powers under Regulation 17(3) of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014. This will be reflected in our inspection report and judgement of the five key questions that CQC asks of services.

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

We include in our report any concerns, recommended improvements or enforcement action taken, and expect the provider to take appropriate action.

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.

New regulations: fit and proper person requirement and the duty of candour

Two new regulations, Regulation 5: Fit and proper persons: directors and Regulation 20: Duty of candour, apply to all providers from 1 April 2015.

The intention of Regulation 5 is to ensure that people who have director level responsibility for the quality and safety of care, and for meeting the fundamental standards, are fit and proper to carry out this important role. It applies to all providers that are not individuals or partnerships. Organisations retain full responsibility for appointing directors and board members (or their equivalents). CQC may intervene where it has evidence that a provider has not met the requirement to appoint and have in place fit and proper directors, using the full range of enforcement powers.

The intention of Regulation 20 is to ensure that providers are open and transparent with people who use services and other 'relevant persons' (people acting lawfully on their behalf) in general in relation to care and treatment. It also sets out some specific requirements that providers must follow when things go wrong with care and treatment, including informing people about the incident, providing reasonable support, providing truthful information and an apology. This statutory duty on organisations supplements the existing professional duty of candour on individuals.

We have published guidance for providers on meeting the regulations, which provides information on how we look at these regulations to make judgements at registration and on inspection.

Responding to inadequate care

We will intervene if people are at risk of harm or providers appear not to be meeting the regulations, including the fundamental standards. We will start with whatever level of intervention will achieve our purpose of protecting people who use the service, or holding providers and individuals to account, or both.

In addition to our statutory powers, we also work with other regulatory and oversight organisations to ensure that they take action on any concerns that we have identified, where that is more proportionate or likely to be more effective than CQC acting on its own.

As well as using our enforcement powers, CQC will also work with other regulators and oversight bodies, such as the General Dental Council and NHS England, to ensure that action is taken to address concerns that we identify.

Challenging the evidence

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

Providers can challenge the factual accuracy of reports and make representations about the evidence in Warning Notices. Primary care dental services can challenge our judgements in the following ways.

Factual accuracy check

When we send a copy of the draft report to providers, we invite them to provide feedback on the factual accuracy. Providers can challenge the accuracy and completeness of the evidence. Practices 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.

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.

Complaints about CQC

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

Providers should make complaints to the person that they have 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's website.

Appendix A: Key lines of enquiry

The key lines of enquiry (KLOE) for inspectors relate to CQC's five key questions that we ask of services. By asking these questions it helps us to make a consistent judgement. We have focused particularly on the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014, although inspectors may also consider evidence against the Care Quality Commission (Registration) Regulations 2009. We have mapped these KLOEs to the regulations. Although providers will have a variety of ways to demonstrate how they are meeting the regulations, we have included some examples. They are not meant to be an exhaustive list or a 'checklist'. Providers must also refer to our guidance for providers on meeting the regulations.

Safe

By safe, we mean that people are protected from abuse* and avoidable harm.

*Abuse can be physical, sexual, mental or psychological, financial, neglect, institutional or discriminatory abuse.

Health and Social Care Act 2008 (Regulated Activities) Regulations 2014

- Safe care and treatment **Regulation 12**
- Safeguarding service users from abuse and improper treatment **Regulation 13**
- Fit and proper persons employed **Regulation 19**
- Staffing **Regulation 18**
- Premises and equipment **Regulation 15**
- Duty of candour **Regulation 20**
- Good Governance **Regulation 17**
- Person-centred care **Regulation 9**
- Need for consent **Regulation 11**

	Key line of enquiry	Examples of what we should see to demonstrate that the service is safe – based on safety related regulations
S1	What systems, processes and practices are in place to ensure all care and treatment is carried out safely?	• There is a clear understanding and reporting of RIDDOR (Reporting of Injuries, Diseases and Dangerous Occurrences Regulations 2013) and COSHH (Control of Substances Hazardous to Health). • Staff understand their responsibilities to raise concerns, to record safety incidents, concerns and near misses, and report them internally and externally where appropriate. • The provider complies with relevant patient safety alerts, recalls and rapid response reports issued from the Medicines and Healthcare products Regulatory Authority (MHRA) and through the Central Alerting System (CAS).
S2	How are lessons learned and improvements made when things go wrong?	• Patients are told when they are affected by something that goes wrong, given an apology and informed of any actions taken as a result. • The provider identifies and analyses clinical errors, incidents, errors and near misses involving all relevant staff and patients where applicable. • Lessons are learned and communicated to make sure action is taken to improve safety.
S3	What systems, processes and practices are in place to keep people safe and safeguard them from abuse?	• Staff understand the reporting system for raising concerns, such as safeguarding, whistleblowing, complaints and feel confident to do so and, fulfil their responsibility to report concerns. • Staff know how to identify, report and respond to suspected or actual abuse. • Individual records are written and managed in a way to keep people safe. This includes ensuring people's records are accurate, complete, eligible, up to date, stored and shared appropriately.

S4	How are risks to individual people who use services assessed, and their safety monitored and maintained?	• There are sufficient numbers of suitably qualified and competent staff (this includes appropriate recruitment processes), and the provider considers how the service uses the skills of other members of the dental team. • Staff are able to identify and respond appropriately to signs of deteriorating health and medical emergencies.
S5	How well are potential risks to the service **anticipated** and **planned** for in advance?	• Risks to safety from service developments and disruption are assessed, planned for, and managed in advance.
S6	What systems, processes and practices are in place to protect people from unsafe use of equipment, materials and medicines?	• Premises and equipment are clean, secure, properly maintained and kept in accordance with current legislation and guidance such as, The Health and Social Care Act 2008 Code of Practice on the prevention and control of infections and related guidance, HTM 01-05 and HTM 04-01, National Patient safety Agency (NPSA) guidance and safe sharps directive to keep people safe. • Providers meet the requirement of relevant legislation to ensure that premises and equipment are properly purchased, used and maintained such as, Ionising Radiation Regulations 1999 and Ionising Radiation (Medical Exposure) Regulations 2000 (IRMER), Sharps regulations 2013, HTM 07-01 (healthcare waste). • There are appropriate arrangements for managing medicines which include obtaining, prescribing, recording, handling, storage and security, dispending safe administration and disposal. • There are sufficient quantities of instruments/equipment to cater for each clinical session which takes into account the decontamination process.

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.

Health and Social Care Act 2008 (Regulated Activities) Regulations 2014

- Person centred care **Regulation 9**
- Duty of candour **Regulation 20**
- Consent **Regulation 11**
- Staffing **Regulation 18**
- Safe care and treatment **Regulation 12**
- Fit and proper persons employed **Regulation 19**

	Key line of enquiry	Examples of what we should see to demonstrate that the service is effective – based on effective related regulations
E1	Are people's needs assessed and care and treatment delivered in line with current legislation, standards and evidence based guidance?	• People's care and treatment is planned and delivered in line with evidence based guidelines, standards, best practice and current legislation. These include NICE, Faculty of General Dental Practice (FGDP), Selection Criteria for Dental Radiography, Standards for Conscious Sedation in the Provision of Dental Care. Report of the intercollegiate Advisory Committee for Sedation in Dentistry 2015 and Guidelines for Domiciliary care by the British Society for Disability and Oral Health, FGDP Clinical Examination and Record-Keeping: Good Practice Guidelines, GDC standards for the Dental Team, Department of Health Delivering Better Oral Health toolkit. • There is evidence of a comprehensive assessment to establish individual needs and preferences. This Includes: o An up-to-date medical history. o Explanation of the presenting complaint or purpose of the appointment.

		○ A clinical assessment and information about the costs of treatment including any options or choices. • Discrimination on the grounds of age, disability, gender reassignment, pregnancy and maternity status, race, religion or belief are avoided when making care and treatment decisions.
E2	Do staff have the skills, knowledge and experience to deliver effective care and treatment?	• Staff are supported to deliver effective care through opportunities to undertake training, learning and development and through meaningful and timely supervision. • Learning needs of staff are identified. • Members of the dental team are up-to-date with their Continuing Professional Development (CPD) and supported to meet the requirements of their professional registration.
E3	Are there effective arrangements in place for working with other health professionals to ensure quality of care for the patient?	• There are clear guidelines for referring patients to specialist colleagues based on current guidelines. • When people are referred to another dental service, all information that is needed to deliver their ongoing care is appropriately shared in a timely way.
E4	Is people's consent to care and treatment always sought in line with legislation and guidance?	• The provider has made information and support available to help people understand the care and treatment options. This includes information about the cost of treatment (where appropriate). • Staff understand and apply the legislation and guidance, including the Mental Capacity Act 2005 and the Children's Acts 1989 and 2004. • Staff can demonstrate when people may require support in obtaining consent and work within the ethos of the Mental Capacity Act 2005. • People report that they are supported to make decisions.

Caring

By caring, we mean that staff involve and treat people with compassion, kindness, dignity and respect.

Health and Social Care Act 2008 (Regulated Activities) Regulations 2014

- Consent **Regulation 11**
- Dignity and respect **Regulation 10**
- Person-centred care **Regulation 9**

	Key line of enquiry	Examples of what we should see to demonstrate that the service is caring – based on caring related regulations
C1	Are people treated with kindness, dignity, respect and compassion while they receive care and treatment?	• People report that they are treated with dignity and respect at all times. • The environment is conducive to supporting people's privacy. • Staff take time to interact with patients and those close to them in a respectful, appropriate and considerate manner. • Staff recognise and respect people's diversity, values and human rights.
C2	How are patients and those close to them involved as partners in their care?	• People report that they felt the dentist or other members of the dental team listened to them and involved them in making decisions about their care and treatment. • Treatment is fully explained including the cost of treatment, and people report they are given enough time to think and ask questions about their consent to care and treatment.
C3	Do people who use services, and those close to them, receive the support they need to **cope emotionally** with their care and treatment?	• People report that staff respond to pain, distress and discomfort in a timely and appropriate way.

Responsive

By responsive, we mean that services are organised so that they meet people's needs

Health and Social Care Act 2008 (Regulated Activities) Regulations 2014

- Complaints **Regulation 16**
- Person centred care **Regulation 9**
- Duty of candour **Regulation 20**
- Dignity and respect **Regulation 10**
- Good governance **Regulation 17**

	Key line of enquiry	Examples of what we should see to demonstrate that the service is responsive – based on responsive related regulations
R1	Are **services planned** and delivered to meet the needs of people?	• The facilities and premises are appropriate for the services that are planned and delivered. • Appointment times are scheduled to ensure people's needs and preferences (where appropriate) are met. • Providers make reasonable adjustments such as to the environment, choice of dentist or treatment options to enable people to receive care and treatment. • The provider takes into account of the needs of different people on the grounds of age, disability, sex, gender reassignment, race, religion or belief, sexual orientation, pregnancy and maternity • There is evidence that the provider gathers the views of patients when planning and delivering services.
R2	Do services take account of the **needs of different people**, including those in	• All reasonable efforts/adjustments are made to enable patients to

	vulnerable circumstances?	receive their care or treatment. • People report they have access to, and receive, information in the manner that bests suits them and that they can understand. • There is evidence of reasonable effort and action to remove barriers when people find it hard to access or use services.
R3	Can people access care and treatment in a **timely** way?	• Waiting times, cancellations and delays are minimal. • People have timely access to urgent treatment. • People report that they are aware of how they can access emergency treatment, including out of normal hours.
R4	How are people's concerns and complaints listened and responded to, and used to improve the quality of care?	• There is a complaints system in place, which is publicised, accessible, understood by staff and people who use the service. • There is openness and transparency in how complaints are dealt with. • Information is provided about the steps people can take if they are not satisfied with the findings or outcome once the complaint has been responded to. • People report that they know how to complain, that the system is easy to use and staff treat them compassionately and give help and support they need to make a compliant.

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.

Health and Social Care Act 2008 (Regulated Activities) Regulations 2014

- Complaints **Regulation 16**
- Good governance **Regulation 17**
- Duty of candour **Regulation 20**
- Staffing **Regulation 18**
- Fit and proper persons: directors **Regulation 5**
- Fit and proper persons employed **Regulation 19**
- Safeguarding service users from abuse and improper treatment **Regulation 13**
- Safe care and treatment **Regulation 12**

	Key line of enquiry	Examples of what we should see to demonstrate that the service is well-led – based on well-led related regulations
W1	Do the governance arrangements ensure that responsibilities are clear, quality and performance are regularly considered, and risks are identified, understood and managed?	• Staff are supported and managed at all times and are clear about their lines of accountability. • Where required, there is a registered manager in post who understands their responsibilities and is supported. • Staff are supported to meet their professional standards and follow their professional code of conduct. • Care and treatment records are complete, legible and accurate, and are kept secure. • Records relating to employed staff include information relevant to their recruitment. • There is an effective approach for identifying where quality and/or

		safety is being compromised and steps are taken in response to issues. These include audits of radiological images, clinical notes, Legionnaires' disease, infection prevention and risks, incidents and near misses and autoclave checks.
W2	How does the leadership and culture reflect the vision and values, encourage openness and transparency and promote delivery of high quality care?	• The provider has systems in place to support communication about the quality and safety of services and what actions have been taken as a result of concerns, complaints and compliments. • Candour, openness, honesty and transparency and challenges to poor practice are the norm.
W3	How is quality assurance used to encourage continuous improvement?	• Audit processes function well and have a positive impact in relation to quality governance, with clear evidence of action to resolve concerns. • Information about the quality of care and treatment is actively gathered from a range of sources. • Staff report that information is shared for continuous learning and improvement.
W4	How are **people** who use the service, the **public** and **staff engaged** and **involved**?	• The provider has processes in place to actively seek the views of people who use the service and those close to them, and should be able to provide evidence of how they take these views into account in any related decisions. • Staff report that the provider values their involvement and that they feel engaged and say their views are reflected in the planning and delivery of the service. • Staff and the provider understand the value in staff raising concerns.

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** **Citygate** **Gallowgate** **Newcastle upon Tyne** **NE1 4PA**



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