Primary medical services pilot

Testing our current inspection methods with GP practices and other primary medical services

November 2012

Contents

Executive summary

The regulation of providers of NHS primary medical services is being aligned with that of other health and social care services under the Health and Social Care Act 2008. This legislation means that providers of health and adult social care have to be registered with the Care Quality Commission (CQC).

This requires all providers of primary medical services (excluding providers of NHS out-of-hours services who had to register from the 1 of April 2012) to be registered with CQC from 1 April 2013. Once these providers are registered with us we will monitor them to check whether they continue to meet essential standards of quality and safety.

We are currently consulting on our strategy for 2013 to 2016 which includes proposals that will significantly change how we regulate in the future. For example we propose to make greater use of information and evidence to achieve the greatest impact and to differentiate our model to reflect differences in services. The outputs from the consultation will inform the new strategy that will be published in early 2013.

The recommendations in this report are based on our current approach to monitoring whether providers continue to meet essential standards. However, these recommendations and our approach are likely to differ in the future as we change our regulatory approach in line with our revised strategy.

We currently monitor compliance by continuously assessing all of the information we hold about providers and by carrying out inspections that involve a visit to services where the provider is delivering the care they are registered for. When inspecting we check to see whether the essential standards of quality and safety are being met by talking to people using the service, staff, observing practice and looking at documents where necessary.

We carried out a pilot with primary medical services to test our methods for checking whether providers are meeting essential standards. The outputs from the pilot enable us to refine our current methodology and develop new methods, where necessary, to ensure our approach is effective and appropriate. The pilots were also used to:

- Identify what training and guidance is required for our staff to understand and inspect the sector.
- Understand what additional guidance is required for primary medical services.
- Continue building working relationships and educate the sector about CQC.
- Test out our planning assumptions and resource requirements.

The pilot involved 42 providers of primary medical services from rural and urban areas, different PCT catchment areas and of differing sizes. The

distribution of the participants was 25% based in London region and 75% in South region. Twelve inspectors carried out inspection visits for each provider participating in the pilot over a four week period.

The pilot also involved local stakeholders. This included representatives from Local Medical Committees (LMCs), Patient Participation Groups (PPGs), and Primary care trusts (PCTs). Representatives from these groups attended the introductory and feedback events as well as participating in the pilot inspections where appropriate. Local Involvement Networks (LINks) and Overview and Scrutiny Committees were also contacted and asked to submit any information they deemed useful.

The pilot tested all aspects of our inspection methodology. Feedback was collated from the inspectors, participants and stakeholders involved in the pilot. The outputs were analysed resulting in the following recommendations which will be taken forward and implemented by April 2013 in preparation for monitoring providers of primary medical services.

Recommendations

Notice of the inspection
• Primary medical services should be given a 48 hour notice period for scheduled inspections • Primary medical services should be given no notice period for responsive inspections
Training
• Consider the additional areas identified and incorporate relevant guidance where necessary • Develop the training material on primary medical services further taking account of all the lessons learnt from the pilot and training all our inspectors in advance of April 2013 • Ensure we have effective quality assurance mechanisms in place, which will have additional focus in the early stages of regulating the sector • Ensure that our bank of specialist staff includes people with expertise in primary medical services so we have a specialist resource to draw upon
People's views
• Explore further what methods are appropriate for gathering people's views in primary medical services. Produce guidance for our staff as part of our existing programme of work on developing more methods to capture people's voices
Staff's views
• To use the current interview methodology and update the guidance

to include primary medical services • To develop a 'preparing for inspection leaflet' for primary medical services so that staff know what to expect from an inspection
Frequency and number of essential standards of quality and safety to be checked
• An inspection should consist of inspecting a minimum of five outcomes selected from across the chapter headings (excluding the suitability of management chapter) in the Guidance about Compliance: Essential standards of quality and safety • Inspections every two years for primary medical services
Quality and Risk Profile (QRP)
• Continue developing the QRP for primary medical services and revise the guidance document for providers and inspectors • Explore the suggested additional data sources to identify whether they are appropriate • Continue developing the process for sharing the QRP with providers of primary medical services
Relationships and information sharing with stakeholders and local representative groups
• Continue to build working relationships with local Healthwatch organisations, taking account of lessons learnt from working with LINks and our approach to information sharing • Continue to explore relationships with OSCs and the information they can share with us • Continue discussions with Shared Lives (formerly NAAPs) and representatives of PPGs considering how we can work with PPGs more effectively to develop methodology and guidance for inspectors and PPGs to use from April 2013 • Develop a plan that details how we are going to take forward the work with these organisations and representative groups • Establish information sharing practices with Local Area Teams, as they emerge as the commissioners of Primary Care
Criminal Records Bureau checks
• We will be clear on what our expectations are with regards to CRB checking for existing and new members of staff in primary medical services to ensure the sector and our inspectors are clear and we are consistent in our approach
When to schedule an inspection visit
• Inspection guidance to include the need for an inspector to check a providers website when planning a primary medical service inspection visit

Branch surgeries
• Consider how information about branch surgeries can be captured in the statement of purpose and what this means for how we inspect
Engagement
• Develop an engagement plan for communicating with the sector to explain what our inspection methodology will be • Allocate resource for engaging with the sector between December – April 2013 • Develop tools to support staff engagement with the sector to ensure consistency in our messaging
Medical records
• Review the current guidance about consent, recording and retention of evidence to take account of primary medical services

Introduction

The regulation of providers of NHS primary medical services is being aligned with that of other health and social care services under the Health and Social Care Act 2008. This legislation means that providers of health and adult social care services have to be registered with the Care Quality Commission (CQC).

The aim of regulation is to ensure that people can expect all health and adult social care services to meet essential standards of quality, to protect their safety and to respect their dignity and rights wherever care is provided. We publish up-to-date information about those that we register on our website, to help the public make informed choices about health and social care services.

The Health and Social Care Act (Regulated Activities) Regulations 2010 set out different timescales for when providers from different sectors have to be registered with CQC. These regulations included time-limited exemptions for NHS primary medical services, which are defined as those whose sole or main purpose is providing medical services under one of the following contracts or agreements:

- General Medical Services (GMS)
- Personal Medical Services (PMS)
- Alternative Provider Medical Services (APMS)
- NHS Act 2006 Section 3 (contracts with the Secretary of State).

In the initial timetable for registration, all providers of primary medical services were required to register with CQC by April 2012. However, following a Department of Health consultation, the Government decided that providers of NHS general practice and most other primary medical services do not need to be registered until 1 April 2013. This excluded providers of GP out-of-hours services who had to be registered by 1 April 2012.

All GP out-of-hours providers have been registered with us since 1 April 2012. GP practices and all other primary medical services are going through the registration process which was initiated in July and will be completed by 31 March 2013. Once a provider is registered with us we monitor whether they continue to meet essential standards.

We do this in a way that centres on the views and experiences of people using services. We focus on the experiences people have when they receive care and the impact it has on their health and wellbeing. This includes clinical outcomes as well as ensuring people are safe.

Our inspectors continuously review all available information and intelligence we hold about a provider. We seek information from people who use services and public representative groups, and from organisations such as other regulators. We also carry out inspections. These involve a visit to services where the provider is delivering the care that they are

registered to deliver. When inspecting we check to see whether the essential standards are being met by talking to people using the service and to staff, observing practice and looking at documentation where necessary.

We are currently consulting on our strategy for 2013 to 2016 which includes proposals that will significantly change how we regulate in the future. For example we propose to make greater use of information and evidence to achieve the greatest impact and to differentiate our model to reflect differences in services. The outputs from the consultation will inform our new strategy that will be published early in 2013.

The recommendations in this report are based on our current approach to monitoring whether providers continue to meet essential standards. However, these recommendations and our approach are likely to differ in the future as we change our regulatory approach in line with our revised strategy.

The Essential Standards of Quality and Safety

The Health and Social Care Act 2008 (Regulated Activities) Regulations 2010, and the Care Quality Commission (Registration) Regulations 2009 describe the essential standards of quality and safety that people who use health and adult social care services have a right to expect.

These are described in more detail in the *Guidance about compliance: Essential standards of quality and safety*, which help providers comply with the regulations.

There are 28 essential standards described in the *Guidance about compliance*. However we usually focus on the 16 that relate most directly to quality and safety of care when checking whether providers are meeting essential standards. These are listed in the table below.

Chapter	Outcome	Regulation	Regulation Descriptions
Involvement and information	1	17	Respecting and involving people who use services
	2	18	Consent to care and treatment
Personalised care, treatment and support	4	9	Care and welfare of people who use services
	5	14	Meeting nutritional needs
	6	24	Cooperating with other providers
Safeguarding and safety	7	11	Safeguarding people who use services from abuse
	8	12	Cleanliness and infection control
	9	13	Management of medicines
	10	15	Safety and suitability of premises
	11	16	Safety, availability and suitability of equipment
Suitability of staffing	12	21	Requirements relating to workers
	13	22	Staffing
	14	23	Supporting staff
Quality and management	16	10	Assessing and monitoring the quality of service provision
	17	19	Complaints
	21	20	Records

The essential standards are grouped into chapters. The chapters include standards that focus on similar aspects of care. An inspection generally involves checking at least one standard from each chapter, not all 16.

Purpose of the pilot

CQC has developed and piloted methods for checking whether services are meeting the essential standards for each health and adult social care

sector that has registered with us. The outputs from the pilots have resulted in refinements to our methodology and the development of new methods to ensure our approach is effective and appropriate. The pilots were also used to:

- Identify the training and guidance required for our staff to understand and inspect the sector
- Understand what sector specific guidance was required
- Continue building working relationships with relevant stakeholders and raise awareness in the sectors about CQC.
- Test out our planning assumptions, resource requirements and inspection methodology.

A pilot was carried out for primary medical services with the same aims.

Method

The pilot involved an inspector carrying out an inspection to check whether essential standards were being met. An inspection was carried out for each participant involved in the pilot.

Participants - providers

A letter requesting volunteers for the pilot was circulated to Local Medical Committees (LMCs) in the London and South region for them to forward on to their members. We also invited members of our provider reference group to participate. We currently have an anonymous online provider reference group that gives providers of NHS general practice and other primary medical services the opportunity to engage in our work. They can take part in online surveys, discussion forums and polls. They are also invited to review and comment on guidance and methodology when necessary. We received a lot of responses from providers interested in participating. 45 providers from across the two regions were selected from rural and urban areas, different PCT catchment areas and of differing sizes. The distribution of the participants was 25% based in London and 75% in the South region.

Although we selected 45 providers only 42 completed the pilot. As such the numbers in this report reflect the 42 providers that completed the pilot only.

The participants consisted of 40 GP practices and two walk-in centres. The provider types were:

Provider type	No
Organisation	2
Partnership	38
Individual	2
Total	42

The number of locations for each provider were:

Number of locations	No
One	31
Two	9
Three	1
Four	1
Total	42

Participants - inspectors

Twelve CQC inspectors volunteered to support the pilot, five based in London and seven from the South region. All 12 inspectors that took part in the pilot had substantial inspection experience but they were not skilled specifically in inspecting primary medical services.

The inspectors received training prior to carrying out the inspections. They accessed an e-learning module and guidance on primary medical services and attended a half-day training session on the pilot methodology.

CQCs National Professional Advisor for primary medical services Professor David Haslam was also available throughout the pilot to provide support.

Approach

The pilot involved inspectors carrying out inspections to check whether the services included in the pilot were meeting essential standards. As described earlier our inspectors usually check a sample of the 16 essential standards most directly related to quality and safety.

We held introductory events for representatives from the services participating in the pilot as well as other key stakeholders, such as LMCs and patient participation groups (PPGs). People at the event felt it would be beneficial if the person nominated by the service to represent them were available on the day of the inspection. This way the representative would be informed and able to share their views and opinions on how the inspection went. This approach was agreed for the pilot.

All nominated representatives provided their availability and the inspectors scheduled their visits to coincide with this.

Notice of the inspection

Generally our inspections are unannounced; the provider is not informed in advance of the inspection. However, some sectors are given short notice, for example dentists are given 48 hours notice.

Short notice inspections are only used for providers where an unannounced inspection may have an adverse impact on the delivery of care. Where concerns have been identified and we are responding to these concerns with an inspection we will usually carry out an unannounced inspection to any type of service.

The pilot tested different notice periods; providers received either no notice or short notice of their inspection. A range of short notice periods were tested; 48 hours, five days and following discussions with our stakeholder advisory group a ten day notice period.

Notice period	No of providers
No notice	12
48 hours	15
5 days	12
10 days	3
Total	42

People's views

People's views and experience of the care they receive is at the centre of our inspection approach. Therefore it was important we tested how we collect the views and experiences of people using primary medical services. Inspectors were asked to gather people's views of the care they receive during each of their inspections.

Staff views

The views of staff, their understanding of what to do in certain situations, their training, support mechanisms and understanding of the service they work for are also important sources of information. Discussions and interviews with staff are used to gather information when carrying out inspections. This was also tested as part of the pilot.

Frequency and number of essential standards of quality and safety to be checked

Inspectors check whether services are meeting a sample of essential standards.

To test what is an appropriate number of essential standards to include in an inspection inspectors checked either four or five standards per inspection.

Number of essential standards checked	Number of providers
Four	19
Five	23
Total	42

All 16 essential standards were checked across the pilot inspections excluding outcome 5 – Meeting nutritional needs, as it is deemed less relevant for primary medical services.

Quality and Risk Profile

Quality and risk profiles (QRPs) are an internal tool for gathering together key information that is available about a provider. The information is associated with the essential standards and analysed to assess performance across providers. The results of the analysis for each essential standard are combined to produce a risk estimate. This suggests where there is a potential risk that a provider is not meeting an essential standard. Inspectors use QRPs when they are planning an inspection and deciding which standards to check. The QRP is not a judgement about compliance. It is information that assists an inspector to reach a judgement.

A QRP was produced for each provider that participated in the pilot. The information used to populate the QRP included:

- Quality and Outcomes Framework (QOF);
- Hospital Episode Statistics (HES);
- Quality Management Analysis System (QMAS)
- GP Patient Survey
- Information from Committee of General Practice Education Directors (COGPED)

- Comments from the NHS Choices website

The inspectors had access to the QRPs in advance to assist with the planning of the inspection. We also gave a copy of the QRP to the providers so that they knew what information the inspector had access to when planning the visit.

Relationships and information sharing with stakeholders and local representative groups

Relationships and information sharing protocols already exist with some stakeholders and representative groups. CQC has a statutory duty to work with Local Involvement Networks (LINks), and to work with other local bodies including Overview and Scrutiny Committees (OSCs) which represent and work with local populations to improve care services. Local compliance teams meet regularly with LINks and OSCs to receive information from them on services. Relevant information is included in the providers' QRPs which an inspector will check when planning an inspection. This information was not available to inform the QRPs for the pilot but will be used when the information sharing protocols are established.

Prior to the visits CQC contacted LINks and OSCs to request relevant information about the pilot participants. They were invited to submit any information that could provide an insight in to whether the services were meeting essential standards. Any information submitted by these organisations was given to the inspector in advance of their inspection for them to use in preparation.

In addition to existing relationships with LINks and OSCs there are patient participation groups (PPG) that have been established in many GP practices. These groups have the potential of being a useful source of information. We are in the preliminary stages of establishing relationships with PPGs and wanted to use the pilots to explore this relationship. Where a PPG existed and they had a representative willing to participate in the pilot, the inspector contacted them to gather their views either by telephone, or in person during or following the inspection visit.

We are in the preliminary stages of developing ways of working with the National Commissioning Board and local commissioning boards as well as discussing how we link with clinical commissioning groups. We are developing joined up ways of working and effective information sharing methods.

Timescales

We used the pilot to test our planning assumptions. Inspectors recorded how long it took them to complete each element of their inspection, including planning, inspecting and producing the report. The average time for completing an inspection was 20.5 hours. The average inspection visit, (the time an inspector was on site), was seven hours, we expect that this

will vary in the future when inspectors are more knowledgeable about PMS depending upon risk and issues identified during the inspection .

Information sharing protocol

Information collected and examined during the pilot was 'real life' information about providers and people who use services. We produced a protocol for the pilot to guide the use and sharing of this information.

Findings

This section presents the key findings and recommendations resulting from the feedback following the completion of the inspection phase of the pilot.

Notice of the Inspection

Participants felt that both unannounced and short notice inspections had a limited disruption to patient care in most settings. Flexibility of the inspector on the day was the main factor that ensured patient care was not adversely affected.

However, the inspections had been scheduled over a short time period for the pilot and the availability of practice managers had been arranged in advance. Therefore it was almost guaranteed a practice manager would be available for all pilot inspection visits. This will not be the case when inspections are being scheduled from April 2013.

Providers and inspectors reported that having the practice manager available to coordinate the inspection and access information made the visit more effective and reduced disruption to patient care. The management and delivery of primary medical services on an appointment basis can make it very difficult to speak to individuals and access information without having a key person available to help with this. For example, when inspecting a single-handed GP practice if a member of staff is not available for support it would significantly hinder the ability to carry out the inspection without affecting patient care. As a single-handed GP would have no other support to help coordinate the inspection or speak to the inspector. The inspector would have to rely on the GP making time available to support them which would limit the time they were available to see people using the service.

Where concerns were identified it was generally thought an unannounced inspection was appropriate. Most participants agreed a short notice period would be beneficial to ensure an inspection is as effective as possible without having any unnecessary impact on patient care.

Most participants had carried out limited preparatory work specifically for the inspection. The services that had prepared focussed on educating staff about CQC and what to expect during the inspection.

A summary of the comments are listed below:

- It would be useful to know what areas the inspector would be looking at in advance of the inspection
- It is unlikely a provider can make any significant changes in 48 hours.

- It would be difficult for an inspection to be carried out if someone was not available to help coordinate the inspection
- The longer notice period the more anxious it would make staff who would be wondering if they have done everything they can to prepare
- A notice period allows practice managers to get temporary staff in to free up the practice manager
- Two visits could be carried out, one unannounced to talk to people and one announced to talk to staff
- Single-handed practices will find it difficult to organise time to meet and speak to the inspector without impacting on patient care

Our response:

- We expect providers to be meeting the essential standards at all times. In line with our principle of unannounced or short notice inspections we do not disclose what outcomes we will inspect in advance of the inspection
- To allow primary medical services, in particular single-handed GPs, the opportunity to arrange suitable support to ensure patient care is not adversely impacted we are recommending a notice period of 48 hours this limits the opportunity to make changes solely for the inspection, but is long enough to allow arrangements to be made to ensure patient care is not adversely impacted
- Where an inspector is unable to gather all the information they need on the day of the inspection they can follow up information requests, speak to people over the phone or if necessary return to the practice at a later time

Recommendations:

- Primary medical services should be given a 48 hour notice period for scheduled inspections
- Primary medical services should be given no notice period for responsive inspections

Training

The participants in the pilot felt inspectors were knowledgeable and had a good understanding of primary medical services. Practices thought our inspectors were professional, approachable and supportive whilst being suitably robust. The inspectors were thorough when carrying out their inspections and gathered sufficient evidence to reach a decision about each practice's compliance/non-compliance with the essential standards.

The inspections reflected our approach of putting people at the centre and focussed on the experience of people and the care they receive rather than just reviewing documentation and processes. This approach was seen to be proportionate. The inspector was interested in understanding how the practice was being managed and care delivered.

Inspectors felt their experience of inspecting and knowledge of the essential standards provided a good basis for the inspection. The skills they use when carrying out inspections in secondary care settings provides them with a good insight and knowledge base for primary medical services. The training and guidance were useful and provided an insight in to primary medical services. Where there were gaps in the information we will revise guidance materials. The use of different terminology was highlighted as an area that needed to be considered, language used in primary medical services needs to be reflected in our guidance.

The reports were checked using our usual quality assurance methods to ensure consistency in judgements. Our National Professional Advisor provided additional input, where required, to ensure the decisions being made were appropriate for primary medical services. This proved to be a useful sounding board for our inspectors and managers when checking judgements.

A summary of suggested additional topics to be included in the training material listed below:

- Detail about referral systems
- CRBs
- Role of commissioners
- Infection control requirements in general practice
- Training requirements for GPs
- Information included in medical records

Our response

- We understand the importance of equipping our staff with tools and training to carry out a proportionate and appropriate. inspection. Inspectors must be able to gather robust evidence to reach an appropriate judgement and take proportionate action, where necessary, in any setting.

- We must be credible. We achieve this by equipping our inspectors with the knowledge skills and experience to carry out their work.
- We have developed e-learning and detailed guidance on primary medical services which has been tested as part of this pilot and will be revised to reflect the findings. We also have a National Professional Advisor for primary medical services who has been very involved in the development of the training material to date.
- Inspectors will continue to use the judgement framework when making decisions about whether a provider is meeting essential standards. The Judgement Framework is a tool to help promote consistency when making decisions. Inspectors' decisions are reviewed as part of CQCs quality assurance checks.

Recommendations:

- Consider the additional areas identified and incorporate relevant guidance where necessary
- Develop the training material on primary medical services further taking account of all the lessons learnt from the pilot and training all our inspectors in advance of April 2013
- Ensure we have effective quality assurance mechanisms in place, which will have additional focus in the early stages of regulating the sector
- Ensure our bank of specialist staff includes people with expertise in primary medical services so we have a specialist resource to draw upon

People's views

It is important to gather people's views and we used a number of different methods to do this with varying levels of success. The pilot has provided some useful lessons that will be a good basis to further explore how to best gather people's views in primary medical services.

Some of the difficulties included knowing who wanted to speak to the inspector and when was best to speak to them. Capturing the views of people that were willing to speak to the inspector at a time that was appropriate to them was problematic.

Some inspectors spoke to people before their appointments, whilst others spoke to people afterwards. When the inspectors spoke to people before their appointments they were anxious about missing their appointment. When speaking to people after their appointment generally resulted in them having to wait to speak to the inspector.

Some inspectors approached people in the waiting room, whilst other inspectors got the practice nurse or GP to ask people if they wanted to speak to the inspector after their consultation when they were leaving. The pilots showed that when speaking to people, it was important to be aware they may be anxious or unwell depending on why they were visiting the GP. If inspectors approach people in the waiting room it would be hard to know who may be anxious. Asking the practice nurse or GP to direct someone to the inspector allows practices to be selective about who speaks to the inspector.

Ensuring people are available can also be problematic as providers have different surgery schedules. Inspectors had to schedule their time carefully to ensure they had time to speak to people and staff.

People were usually happy to speak to inspectors however we need to develop an approach to ensure inspectors are able to gather a sufficient number of people's views in a timely manner.

A summary of the comments are listed below:

- Need to be aware that the majority of people visiting their practice are unwell
- Most people when asked were happy to speak to an inspector.
- It would be advisable to speak to people after they have seen the doctor/nurse so that they are not anxious about missing their appointment and are more engaged
- It is important to have a private area in which to speak to people so they are at ease and can discuss what they want without being concerned others can hear
- Information or leaflets should be available to leave with people who use services

- Have a sign to put up in reception or the waiting area informing people that CQC is carrying out an inspection
- Ask reception staff to inform people that an inspection is being carried out and that an inspector is available to speak to
- Consider issues regarding language, especially in practices where the demographics have a high population of different cultures and individuals that speak different languages
- The time of day that an inspection takes place and the particular clinics taking place at that time will affect the types of people an inspector sees on the visit
- Doctors or nurses should ask people at the end of their consultation if they would like to speak to an inspector
- Reception staff can collect phone numbers of people that want to speak to inspectors who can be contacted after the inspection visit
- Inspectors could phone a number of people on the register, possibly primed beforehand by the practice, to get a range of people from the practice register
- Questionnaires can be made available for people to fill in on the day of the inspection or complete and return to CQC at a later date

Our response:

- People's views are important to us and we used a number of methods to capture them. The pilot showed our current methods need to be adapted for primary medical services
- Where there is a language barrier inspectors will use services and tools available to them. This includes the use of our translation and telephone interpreting service.

Recommendations:

- Explore further what methods are appropriate for gathering people's views in primary medical services. Produce guidance for our staff as part of our existing programme of work on developing more methods to capture people's voices

Views of staff

Individual interviews, group discussions, ad hoc conversations and follow up telephone calls were all methods used by inspectors to gather staff views. In most cases inspectors were allowed enough time to speak to the staff they needed to. Inspectors needed to take a flexible approach to their day to ensure they worked around staff schedules. This did not hinder the inspector from speaking to staff, but did impact on inspectors having the opportunity to speak to people on occasion.

The only preparatory work that had been done by most providers was to inform staff that an inspection would be taking place by CQC and provide them with an understanding of what we do. This helped when speaking to staff as they understood the purpose of the interview.

We spoke to a range of staff with practice manager, GP, practice nurse and reception staff the most frequently interviewed. As discussed earlier, both providers and inspectors agreed that it was important to have the practice manager or a suitable alternative available during the inspection.

The essential standards that were being inspected had an influence on which staff members we spoke to. For example, outcome 7 (safeguarding) may prompt a discussion with the vulnerable children and adults lead, while outcome 6 (co-operating with other providers) may prompt a discussion with the district nursing team and health visitors. The inspectors found the practices website a useful source of information when deciding who they needed to speak to.

Participants felt that knowing which essential standards the inspector would be looking at and who the inspector would like to speak to in advance of the inspection would be helpful. However, this is not in line with our approach and where staff cannot be contacted during the inspection visit the inspector can follow up with the individual later.

Most members of staff were willing to speak to the inspector. In some cases staff not interviewed were disappointed they had not had an opportunity to speak to the inspector.

A summary of comments are listed below:

- The practice manager should be there and is a key member of staff to speak to
- The essential standards that are being checked influence which members of staff need to be interviewed
- The provider website has useful information about who would be an appropriate person to speak to when planning a primary medical services inspection
- Some staff were disappointed when the inspector did not speak to them
- Reception staff were pleased that their views and opinions had been taken account of as part of the inspection

Our response:

- We recommend a short notice period which should allow the provider to identify a suitable individual to assist the coordination of the inspection
- When planning an inspection inspectors review all available information including the provider's website. This information is used to identifying who they need to speak to. We share the list of people with the practice on arrival so the individuals can be informed. Where a member of staff is not available on the day, the inspector will contact them after the visit
- If staff feel they would like to speak to an inspector, but they have not been included on the list of interviewees, they can raise it at the time of the inspection. The inspector will accommodate this request, either at the time of the visit or afterwards if that is more appropriate
- CQC has a process to support whistleblowing with a dedicated whistleblowing team at our National Customer Services Centre. Staff can contact our helpline at any time and provide information about any significant concerns which we will respond to in an appropriate manner

Recommendations:

- To use the current interview methodology and update the guidance to include primary medical services
- To develop a 'preparing for inspection leaflet' for primary medical services so that staff know what to expect from an inspection

Frequency and number of essential standards of quality and safety to be checked

We concluded that inspecting four or five essential standards enabled us to get an understanding of a provider as a whole. This was a manageable number to review in the time taken to complete the inspection. Providers felt the feedback and reports for this many standards provided an understanding of their service and sufficient information.

For larger providers some inspectors found it difficult to look at five standards thoroughly. However we recognise that this was a new sector for inspectors which increased the time taken to carry out an inspection.

The standards that we checked also impacted on the length of time taken for an inspection. Evidence gathering can be more time consuming for some essential standards compared to others. Some are more technical focussing on practical matters while some are more people focussed.

Inspections normally focus on at least one standard from each of the five chapters. However for this pilot, inspectors were asked to cover all 16 standards (except for outcome 5) at least once so they could not always cover one from each of the five chapters during each inspection.

Providers noted that they are subject to a lot of scrutiny already, and if concerns arise there are many different bodies that would be in a position to identify this and inform CQC.

The frequency of inspections would determine how long it would usually take for all essential standards to be checked. Generally inspections every two years was thought to be appropriate for primary medical services, as long as a responsive inspection can be carried out at any time where concerns are raised.

Some concerns were raised about it potentially taking longer than six years to inspect all 16 essential standards.

A summary of comments are listed below:

- Four or five essential standards seem sufficient
- The size of the practice and the essential standards being checked impacts on the time it takes an inspector to complete their inspection
- It was generally agreed that outcome 5 – nutrition was least important
- Need to check a range of essential standards that cover each chapter
- Annual inspections would be too frequent
- Inspections every two years would be appropriate with the option of a responsive inspection when there are concerns
- Inspecting every two years could take over six years to check all 16 essential standards
- CQC needs to demonstrate value for money with the frequency of its inspections

Our response:

- Inspectors need to take account of the size and complexities of a practice when planning their inspection. An inspection plan should be focussed on inspecting essential standards where there is potentially greater risk (identified from reviewing the QRP and any other relevant information)
- Only where outcome 5 – nutritional needs has been specifically identified as needing to be checked will it form part of an inspection
- Inspections every two years is proposed to maintain regular checks but to reduce unnecessary requirements on a sector that has regular scrutiny from other sources. Working relationships with strategic partners need to develop to ensure effective information sharing. Where concerns are identified a responsive inspection should be triggered
- To ensure all 16 essential standards are checked in a reasonable timeframe and that an inspection provides a broad overview of the practice it is recommended a minimum of five essential standards are checked during an inspection

Recommendations:

- An inspection should consist of inspecting a minimum of five outcomes from across the chapter headings (excluding the suitability of management chapter) in the *Guidance about Compliance: Essential standards of quality and safety*
- Inspections every two years for primary medical services, subject to outcomes from the consultation on CQC's strategic review.

Quality and Risk Profile (QRP)

The feedback about the QRP was that it was useful to be used as a guide. Inspectors felt it provided an overview and assisted them where they had no previous knowledge about the service. However the timeliness of the data was highlighted as an issue and the need to include local information as well as national information was raised.

Providers commented that they would like the QRP to be shared with them in advance of an inspection as this allows them to check the accuracy of the data and to prepare examples where things have changed from what is presented in the QRP. Providers would also like clearer guidance to help them interpret the QRP. The guidance should also make it clear that we have no current plans to make QRPs public documents. The majority of the information collated in a QRP is public information, however, the analysis applied to the data and its interpretation has not been designed for public use.

A summary of the comments are listed below:

- Some data was outdated, the practices had more up-to-date QOF data
- NHS Choices website displays one persons opinion and interpretation
- Helpful as a guide but needs to be followed up with more recent and local information
- If we don't think the data is robust enough to share with providers we shouldn't use it to inform our inspections
- Additional data sources might include 360 degree monitoring, PPG (patient participant group) surveys, PCT statistical complaints
- RAG rating can cause anxiety if a red is shown
- Would want to be able to inform CQC about any inaccuracies in the data

Our response:

- We use the most up-to-date nationally available datasets, and we work with data suppliers to ensure we have the most up to date data available. In the case of the QoF data, there will be a short period each year between QoF submissions from practices and its availability to CQC (and other stakeholders)
- We will only share the QRP with the provider that it relates to, the inspector that has the provider on their portfolio and other regulatory and statutory partners
- The QRP was produced manually for the purpose of the pilot. However, this will be automated from April 2013. This will allow for more systematic quality assurance checks

Recommendations:

- Continue developing the QRP for primary medical services and revise the guidance document for providers and inspectors

- Explore the suggested additional data sources to identify whether they are appropriate
- Continue developing the process for sharing the QRP with providers of primary medical services

Relationships and information sharing with stakeholders and local representative groups

The additional information that was provided proved useful. Although the Local Involvement Networks (LINks) for the area had limited information on primary medical services during this period they were able to share some survey work. This may change over time and may well vary in other regions. CQC will continue to have a working relationship with LINks in each area until the end of March 2013 and the statutory duty carries over when local Healthwatch comes into being in April 2013. It is important to develop some specific guidance based on current practice on how local CQC staff and LINks should work together in the field of primary care.

The Overview and Scrutiny Committees (OSCs) in the pilot areas did not provide any information about the practices involved in the pilot. We found that the information they hold does not refer to individual GP practices. However, this was a small sample, there is wide variation as to how local authorities scrutinise local health services including primary care. This is likely to change in the coming months with the introduction of new scrutiny arrangements, new commissioning arrangements and Health and Wellbeing Boards. CQC is currently conducting a national project on how to improve our work with scrutiny committees and local councillors.

Inspectors had varying success contacting and seeking information from patient participation groups (PPGs). Only 50% of practices involved had a PPG. They were managed either as a virtual online community or as an independently chaired group that is advised and supported by the practice. The online community approach was the most common for practices participating in the pilot. This approach offered limited information but needs exploring further.

Where a practice had an independently chaired group the inspector contacted either the chair or another representative for a telephone or a face to face interview. The information gathered was useful and was used to reach a decision about whether the service was meeting the essential standards.

Currently practices that have a patient participation group receive a payment as part of their directed enhanced services. However it is not clear whether this option will be included in 2013-14 directed enhanced services.

A summary of comments are listed below:

- Further work needs to be done with scrutiny committees and groups in local authorities about how to work with them
- Briefings about CQC, who we are, what our purpose is and how we can work together should be provided to PPGs as they have had no contact from the regulator until now
- It might be helpful to have a PPG in attendance at an inspection to offer support to people that are being interviewed

- PPGs carry out surveys that provide local information and can be used to support the national information in the QRP
- A face to face interview is preferred for a PPG representative to a telephone interview

Our response:

- CQC will continue to work with LINks and with local Healthwatch.
- CQC will work with a group of LINks to develop guidance on how CQC and local Healthwatch should work together after April 2013 – using examples of current LINk work
- CQC has developed links with the National Association for Patient Participation (NAPP), which is an organisation that works with PPGs. We held an event with NAPP and PPG representative groups to increase understanding and develop engagement
- We have begun discussions with the NHS Commissioning Board to consider how we will work together in the future. This includes consideration of how we will link with local area teams and clinical commissioning groups

Recommendations:

- Continue to build working relationships with local Healthwatch organisations, taking account of lessons learnt from working with LINks and our approach to information sharing
- Continue to explore relationships with OSCs and understand what information they can share with us
- Continue discussions with Shared Lives and representatives of PPGs considering how we can work with PPGs more effectively to develop methodology and guidance for inspectors and PPGs to use from April 2013
- Develop a plan that details how we are going to take forward the work with these organisations and representative groups
- Establish information sharing practices with local area teams as they emerge as the commissioners of primary care

Additional factors

CRBs
Practices take a different approach with regards to CRB checking when employing new staff. For example, because a GP is on the performers list some practices do not ask for a CRB check to be completed prior to employing them whereas other practices still carry out their own CRB checks on staff. CQC is not responsible for enforcing who should be CRB checked. It is the responsibility of practices to determine which of their staff require CRB checks, to what level and then to carry out the appropriate checks. However, our staff need clear guidance about what to expect when checking practices' compliance with the essential standard, 'outcome 12 – Requirements relating to workers' so we are consistent when making judgements. This will need to take into consideration changes to the criminal records and barring system taking place as a result of the Protection of Freedoms Act 2012.
Recommendation: We will be clear on what our expectations are with regards to CRB checking for existing and new members of staff in primary medical services to ensure the sector and our inspectors are clear and we are consistent in our approach

When to schedule an inspection visit
The management and organisation of primary medical services varies significantly. The scheduling of clinics and the day these run were very different across the participants. Therefore the time an inspection begins or the day it should be carried out should be planned using the information available to the inspector. A useful source of information was the practices website to help determine when would be appropriate.
Recommendation: Inspection guidance to include the need for an inspector to check a provider's website when planning a primary medical service inspection visit

Branch surgeries
Inspectors did not know how many or where branch surgeries were when planning there inspection. This meant the inspection plan only allowed time to visit the location(s) listed. To ensure the practice delivers appropriate care across the practice it would be sensible to check branch

surgeries on occasion or where information suggests it is needed.

Currently we do not record this information unless they are registered as a separate location.

Recommendation:

- Consider how information about branch surgeries should be captured in the statement of purpose and what this means for how we inspect

Engagement

Participants of the pilot and LMCs are keen to understand what the outputs from the pilot will mean for them. In addition we are receiving a lot of requests to speak at events and local practice and LMC meetings to discuss the pilot and describe the compliance methodology.

It is important that we continue engaging with the sector. This will help alleviate any unnecessary anxieties and continue building good working relationships.

Recommendation:

- Develop an engagement plan for communicating with the sector to explain what our inspection methodology will be
- Allocate resource for engaging with the sector between December – April 2013
- Develop tools to support staff engagement with the sector to ensure consistency in our messaging

People's records

Because this was a pilot inspectors did not have the right to access people's records as the providers are not yet registered with us.

Where an inspector needed to look at someone's records to enable them to gather the evidence they required to reach a judgement they explained the purpose and sought written consent directly from people. A copy of the consent form was kept for our records and in the person's records at the practice.

Once providers are registered with us we have the legal power to access people's records without seeking consent, although we would seek consent to do this where possible. Section 64 of the Health and Social Care Act 2008 is clear that personal and medical records should be provided where necessary for the purpose of our regulatory functions.

Guidance currently exists that describes how staff should determine whether it is appropriate to access medical records. Staff are trained in this approach.

Recommendation:

- Review the current guidance about consent, recording and retention

of evidence for primary medical services

Experts by experience

Our inspectors are sometimes supported by experts by experience when carrying out compliance inspections. These are people who have personal experience of using health, mental health and/or social care services, or who have experience of caring for someone who uses these services.

Experts by experience receive special training to prepare them for when they are supporting an inspector. They are tasked with gathering the views of people using services that are being inspected which they do in a number of ways:

- Accompanying the inspector on an inspection visit to talk to people using the service on site
- Telephoning people who use services and/or carers
- Attending group discussions with people who use services and/or carers

The feedback sessions held for participants of the pilot offered an opportunity to discuss experts by experience methodology and gather their views about whether or not this approach would be effective for primary medical services.

The main issue raised during these discussions was how to define an expert by experience for services that are accessed by everyone. They would need to be generalists, however experts by experience are selected because they have personal experience of a specific service area. It was proposed that experts by experience may be an effective methodology if we were carrying out themed inspections focusing on a specific area of primary medical services. For example, how people with learning disabilities access care and treatment in primary medical services.

It was also noted that the additional support experts by experience offer would be beneficial allowing the inspector more time to focus on different areas while the expert by experience carried out observations and gathered the views of people using services.

However participants where not in favour of the term experts by experience because of the similarity to the terminology the expert patients programme.

Recommendation:

- Continue to explore whether using experts by experience would be an effective way of gathering the views of people using primary medical services, particularly when carrying out themed inspections

Lessons to learn

One of the outcomes from the pilot was to provide learning to the sector. The inspections identified some areas where providers were not meeting the essential standards and this section reflects on those areas and provides some additional guidance that may be helpful for other providers.

The table below lists the essential standards checked and whether they were met or not. Where the provider did not meet the essential standards the judgement framework was applied. This determined whether a minor, moderate or major impact was identified, these are defined as:

Minor impact – people who use the service experienced poor care that had an impact on their health, safety or welfare or there was a risk of this happening. The impact was not significant and the matter could be managed or resolved quickly.

Moderate impact – people who use the service experienced poor care that had a significant impact on their health, safety or welfare or there was a risk of this happening. The matter may need to be resolved quickly.

Major impact – people who use the service experienced poor care that had a serious current or long-term impact on their health, safety and welfare, or there was a risk of this happening. The matter needs to be resolved quickly.

Further detail about this can be found in the *Judgement framework* that can be accessed via our website.

Essential standard	Meeting standard	Not meeting standard & impact
Outcome 1 – Respecting and involving people who use services	19	0
Outcome 2 – Consent to care and treatment	12	1 Minor
Outcome 4 – Care and welfare of people who use services	15	0
Outcome 6 – Cooperating with other providers	13	0
Outcome 7 – Safeguarding people who use services from abuse	12	3 Minor
Outcome 8 – Cleanliness and infection control	6	5 Minor 1 Moderate
Outcome 9 – Management of medicines	6	1 Minor
Outcome 10 – Safety and suitability of premises	11	0
Outcome 11 – Safety, availability and suitability of equipment	10	1 Moderate
Outcome 12 – Requirements relating to workers	7	3 Minor
Outcome 13 - Staffing	11	0
Outcome 14 – Supporting workers	9	2 Minor
Outcome 16 – Assessing and monitoring the quality of service provision	10	0
Outcome 17 - Complaints	14	0
Outcome 21 - Records	9	0

The majority of practices were found to be compliant with most of the essential standards we inspected. There were some common areas where we found non-compliance.

Outcome 7 – safeguarding people who use services from abuse.

We found three practices were non-compliant with this outcome. In all three cases this was in relation to their arrangements for safeguarding vulnerable adults. In these practices staff were appropriately trained in child protection and were aware of how to identify and respond if they came across children they had concerns about. They also had appropriate and effective arrangements to work with other local organisations when there were concerns about children. However, they did not have similar arrangements in place for adults so our inspectors were not confident that adults being seen in the practices were appropriately safeguarded.

Outcome 8 – Cleanliness and infection control.

We found six practices non-compliant with this outcome. This was because they did not have appropriate systems in place to prevent the spread of infection or they did not maintain an appropriate level of cleanliness. For example, these practices had not carried out risk assessments and did not have plans in place to prevent, detect and control the spread of an infection. We recognise that risk assessments and plans will be different to

those in secondary care but they are still an essential part of infection control practice. In some cases we saw practices were not as clean and as hygienic as would be expected and there was no evidence of appropriate cleaning procedures or schedules to ensure that the practices were kept clean.

Outcome 12 – requirements relating to workers

We found three practices to be non-compliant with this outcome. The reasons for this non-compliance were that there was no evidence of appropriate checks being done during recruitment. This included essential checks such as checks that staff were registered with the GMC or the NMC. In some cases practices had no evidence of any consideration of whether new staff required Criminal Record Bureau checks and at what level. In some cases staff that would be eligible for such a check had not had a check.

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Balham Park Surgery

Church End Medical Centre

Gallions Reach Healthcare Centre

Green Lane Surgery

Hassengate Medical Centre

Herne Hill Group Practice

Mawney Medical Centre

Newbury Group Practice

Old Court House Surgery (The)

Rahman & Rahman Partnership

Rosewood Medical Centre (The)

Rushey Green Group

St. Bartholomew's Surgery

Streatham Common Group Practice

Temple Fortune Health Centre

Tulasi Medical Centre

Upminster Bridge Surgery

Watling Medical Centre

Abbey View Medical Centre

Abbotsbury Road Surgery

Adam Practice (The)

Amherst Medical Practice

Carfax Medical Centre

Courtyard Surgery

Cricket Green Medical Centre

Hadleigh Practice (The)

Harvey Practice (The)

Hathaway Medical Centre

Market Lavington Surgery

Milton Abbas Surgery

Newland Medical Practice

Poole Town Surgery and Dr Newman's Surgery

Puddletown Surgery

Rosemary Medical Centre

Salisbury Walk In Health Centre

Sturminster Newton Medical Centre

Tolsey Surgery (The)

West Somerset Healthcare

Westbourne Medical Centre

Westbury Group Practice

Westlands Medical Centre

Wrythe Green Surgery