

The state of care in independent doctor and clinic services providing primary medical care

Findings from CQC's programme of
comprehensive inspections in England

The Care Quality Commission

Our purpose

The Care Quality Commission is the independent regulator of health and adult social care in England. We make sure that health and social care services provide people with safe, effective, compassionate, high-quality care and we encourage care services to improve.

Our role

- We register health and adult social care providers.
- We monitor and inspect services to see whether they are safe, effective, caring, responsive and well-led, and we publish what we find, including quality ratings.
- We use our legal powers to take action where we identify poor care.
- We speak independently, publishing regional and national views of the major quality issues in health and social care, and encouraging improvement by highlighting good practice.

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

Since I came to CQC nearly four years ago I have been privileged to experience the huge variety of health and social care that is being developed by a whole range of different models of provider from huge NHS trusts to small charities and private providers. Although CQC regulates all healthcare services under the same overall operating model and under the same regulations, we have always recognised that it is important to understand the context and challenges that each sector faces. We therefore worked with colleagues and providers to develop a methodology that could accurately reflect the sector for patients and providers when we began our first inspection programme for independent doctors and clinics providing primary medical care.

This report summarises the key messages of that first programme of comprehensive inspection. Irrespective of the source of funding or the sector, healthcare professionals want to provide good quality experiences and patient-centred care, and we found that many providers were delivering good quality services. However, we found that a number of services were not meeting the regulations and not delivering the standard of care that we expect to see. There are some particular challenges for providers in this sector, particularly the smaller providers, including:

- what it means for clinical decision making when patients are commissioning their own care
- the potential for professional isolation and difficulties in accessing support and training
- the lack of support to ensure that the sector can access ‘modern’ IT – a number of the systems we saw lacked functionality and made it difficult to keep good quality patient records or use these for audit or quality improvement; in fact, we saw a lot of paper-only records.

We were pleased to see that on re-inspection there was improvement in a number of areas and a better awareness among providers of their responsibilities – not just to their patients but to the wider healthcare system. However, there remain areas where further progress needs to be made and I hope this report will help providers and others to identify what they need to do and where they might focus their efforts.

For this programme services were not rated, but from April 2019, CQC will start to introduce ratings for independent doctors and clinics. This will help the public to make more informed decisions when choosing their care and treatment as our ratings will enable them to compare our judgements about quality. Where we have rated other types of services, it has encouraged improvement as the service strives for a better rating.

I would like to personally thank the many people who have given generously of their time and expertise to make this programme, and the learning we can draw from it, so positive and ultimately helpful for the patients we all serve.

U. Gallagher.

Ursula Gallagher

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Care Quality Commission

Summary

This report presents key findings from the Care Quality Commission's inspections of independent doctors (private GMC-registered GPs and clinicians) and clinics that provide primary medical services in the independent or private sector, carried out between January 2017 and October 2018.

We found that many services were meeting the necessary regulations by responding well to the needs of their patients, as they deliver a caring service that is tailored to people's specific requirements and needs. However, a number of services were not meeting the regulations and not delivering safe and effective care.

Many key themes from these inspections are similar with what we have found in other services, particularly primary medical services provided online, and with NHS services. For example, the caring key question is the area with the most positive feedback and fewest concerns, whereas most concerns fall under the safe key question. Common issues here include concerns that are interlinked with the well-led key question, such as poor processes for record keeping, governance and information sharing.

We found that some issues are specific to private doctors and clinics. The nature of consultations can be different from NHS services as they do not necessarily work with a registered list and many patients may be accessing care from a variety of non-NHS and NHS sources at the same time. Private consultations can be episodic: many people visit for a one-off consultation or second opinion rather than for continuing care linked with other local health services, with little relationship-building. Some people may not want their own NHS GP to know about certain conditions. For some, their culture or religion may dictate their decision visit a private doctor rather than their family GP. In some areas, such as travel clinics, the NHS may not routinely provide the services.

We found some common key issues from inspection.

Safe and effective prescribing: Good clinical oversight and governance ensures that clinicians are prescribing appropriately. However, we found this was not always happening. Episodic care means that some people may not divulge important information with a private practitioner, such as an underlying physical or mental health condition or current prescriptions. This has implications for the safety of prescribing, specifically of high-risk medicines including opioid painkillers and antibiotics. For example, some patients may choose to use a private service after already having been refused a prescription from an NHS GP as it was considered inappropriate or unsafe. Inappropriate antibiotic prescribing and administration can lead to antibiotic resistance, and poorer outcomes for patients. Over-prescribing opioid analgesics has also become a concern, where a patient may not disclose information to a private doctor that they already have a prescription from their own GP.

We had concerns regarding prescribing medicines without a strong evidence base and prescribing unlicensed medicines. At a number of the services inspected, the prescriber had failed to inform patients that the medicine was unlicensed, or there was no clear documentation to support their decision to prescribe an unlicensed medicine. Some people may choose a private consultation where an aspect of treatment is not available on the NHS. For example, we found that some slimming clinics were prescribing and supplying medicines that were neither clinically or cost effective.

Medicines management: Linked to concerns around prescribing, we also identified improvements that were needed in relation to how medicines were stored, packed and supplied to patients.

Clinical records: Our inspection teams have found that the infrastructure of some independent doctor services can have an impact on the effectiveness of care and treatment. With no common or shared IT systems between different types of services, there is limited opportunity to be connected to other services in the local health economy, or with other agencies for example if a safeguarding risk was identified. We saw variation in the quality, management and security of patient records: some lacked sufficient detail to provide an adequate and accurate record of consultations. We had concerns about the basic functionality of some IT systems, which did not enable services to perform a search of records to identify patients who require a review for long-term conditions or who may be at risk following a patient safety alert. This also limits the ability to improve care through quality improvement activity. We found a number of patient records were not kept in English and, more worryingly, some providers were still working with paper records.

Consent: Many services obtained patients' consent appropriately and recorded this in their records before delivering any care or treatment, and they assessed and recorded a patient's mental capacity where appropriate. Some audited patient records to monitor the process for seeking consent. However, even though some services asked for consent verbally, they did not always record it. Other services either relied on implied consent or their process did not comply with the Mental Capacity Act 2005.

Sharing information: All doctors have a duty to share information with others providing care and treatment for their patients; this is a two-way requirement between NHS and private practitioners. We found variation in both the level of information sharing between services and patients' registered GPs, and providers' awareness of why this was important to ensure safe and effective care and treatment, and to alert both parties to any safeguarding concerns.

Safeguarding: This was a particular theme where we found areas for improvement. It may be more difficult for private services to properly safeguard all patients when they do not disclose all their personal information. This applies to protecting more vulnerable people from exploitation, for example, as a result of people trafficking and modern slavery. However, practitioners still have a professional responsibility for safeguarding.

We found that some providers did not fully understand the wide-ranging nature of safeguarding or accept that the professional guidance and regulations apply to them in the same way as all other health and care providers.

Referrals: Referrals were not always made or recorded. We found that some services provided an 'open' referral letter and relied on patients to give this to any consultant with a particular speciality for treatment, rather than taking responsibility to hand over their care by explicitly naming a specific consultant.

Governance: We found a need to improve roles, responsibilities and systems to support good governance. There was limited evidence of effective systems for quality assurance and improvement such as clinical audit, as well as limited recognition of the need to improve quality of care. Policies and procedures for key areas such as safeguarding, infection control or business continuity are central to this.

CQC's operating model and the way we assess services against our key lines of enquiry is the same for all providers. Our regulation can play an important part in influencing people's decision whether to have care and treatment from NHS services or to pay for private care, as our judgements about the quality and safety of services and our inspection reports help them to compare and choose a provider.

From April 2019, we will start to introduce ratings for independent doctors and clinics to align with our approach to regulating other services.

Awarding and publishing quality ratings means that people can be empowered to make informed choices about their care in a sector where there is currently limited comparative information on the quality of services.

Introduction

This report presents key findings from the Care Quality Commission's inspections of independent doctors (private GMC-registered GPs and clinicians) and clinics that provide primary medical services in the independent or private sector – that is those not provided by NHS organisations. It does not include independent consultants in hospitals, independent hospital services, or providers of online consultations over the internet or by other remote means, as we have already reported on these.^{1,2}

Inspections of independent doctors and clinics have highlighted some common themes, which enable us to understand more about the way they provide services to patients and how they contribute to primary health care in England.

The types of service that we cover in this report range from individual single-handed practitioners to private organisations that may operate for one or more days a week in private practice. This is a diverse sector, with providers delivering a wide range of services in many different settings, including:

- private GP services
- travel clinics
- slimming clinics
- circumcision clinics
- allergy clinics
- clinicians registered with the General Medical Council who provide consultations and/or treatments.

Independent doctor services operate under different contractual arrangements from NHS services, for example through insurance companies and direct arrangements with business (which are often exempt from CQC registration) and individual clients. Unless independent doctors provide any element of NHS-funded care, there is no contractual obligation on them to provide care and treatment in the same way that NHS providers may offer, although they must provide evidence-based care and they must meet the relevant regulations (if they are within the scope of CQC registration).

CQC's role and regulatory approach

Although CQC regulates the services that independent doctors and clinics provide, and the General Medical Council is the professional and primary regulator of individual doctors, we have a mutual interest to ensure that patients receive safe, effective, high-quality and evidence-based care and treatment.

Our regulatory approach involves registering, ongoing monitoring, inspecting, and reporting on what we have found, and taking action where care does not meet the required standards and a regulation has been breached. The same regulations and operating model apply to all registered services and feedback from formal public consultations has shown strong support for CQC to use the same regulatory approach for both independent and NHS services, irrespective of the type of organisation or how they are funded.^{3 4}

Our [approach to inspection](#) involves judging whether a provider is meeting regulations based on our assessment of the evidence gathered against key lines of enquiry in the [assessment framework for healthcare services](#).

Independent doctors and clinics have not previously received a quality rating, as we have not had the powers to rate all types of provider in the independent healthcare sector. For these services, our inspection teams have made a judgement on whether they were meeting the regulations and necessary legal requirements. From April 2019 we will start to rate these services to help drive up quality in the sector and provide patients with a more accurate picture of the quality of care from a provider.

This report

We analysed a sample of 85 inspection reports for independent doctor services (20% of all published inspection reports for inspections carried out between 1 January 2017 and 5 October 2018). These include both first inspections (66 reports) and follow-up inspections (19 reports). As well as this, we include themes from a review of inspection reports for 38 independent slimming clinics for inspections carried out between January 2017 and March 2018, and re-inspections of eight services.

The analysis enabled us to understand the common issues that we found on inspection, identify good practice in this setting, and the improvements we found on follow-up inspections. This learning informs how we develop our regulatory approach to these providers.

We also gathered the views of CQC's senior inspection staff, who provided expert opinion and are involved in inspecting these providers. To find out what the public think about using services in the independent sector, we carried out a short survey of people through our Public Online Community. It is important that CQC considers the views and experiences of people who use services in our regulation, and we include some of their views in this report as further background of people's perceptions.

Analysis of findings by key question

Between 1 January 2017 and 5 October 2018, CQC carried out 454 inspections of independent doctor services and 59 inspections of slimming clinics and published reports for these. This included 34 re-inspections of private doctors and 12 of slimming clinics.

Although we did not have the legal powers to rate these services at that time, we asked our five key questions: were services safe, effective, caring, responsive and well-led, and we judged whether providers were meeting the necessary regulations associated with each key question.

Our analysis of the sample of inspection reports showed that many independent doctor services and slimming clinics were found to be providing safe, effective, caring, responsive and well-led care on their first inspection. However, inspections often identified areas that needed to improve, particularly in delivering safe, effective and well-led care.

From the analysis and discussion with experts from CQC's senior inspection staff, we identified some common themes from inspections. In all our inspections, we find that many common issues are interlinked and, where they are combined, this increases the risk of poor quality care for patients.

Safe

Under this key question our inspection teams considered: the safety of prescribing, managing and learning from safety incidents and alerts, safeguarding, staffing and recruitment, monitoring health and safety, and responding to risks.

In the sample of inspection reports, just under half of independent doctor services and slimming clinics were not providing safe care in accordance with the relevant regulations on their first inspection. However, of those that we re-inspected, most had improved.

The analysis identified a range of issues affecting how the providers delivered safe care across both types of service, including concerns in relation to:

- not sharing information with a patient's NHS GP or other health professionals in accordance with guidance from the General Medical Council (GMC)
- awareness of safeguarding and establishing patients' identity, particularly for children and their parents or legal guardians
- limited clinical oversight and monitoring

- prescribing medicines outside of evidence-based guidance and licensed use
- recording details and managing patients' care records
- monitoring, recording and acting on safety alerts for patients and medicines
- managing infection prevention and control and maintaining equipment
- recruitment, including checking identity, Disclosure and Barring Service (DBS), references and qualifications.

We discuss some of the common issues in further detail below.

Sharing information

Guidance from the General Medical Council states, "Appropriate information sharing is an essential part of the provision of safe and effective care. Patients may be put at risk if those who provide their care do not have access to relevant, accurate and up-to-date information about them."⁵

Not all services had a clear policy or protocol for sharing information or routinely asked patients for the contact details of their NHS GP. This is good practice clinically and from a safety point of view. Seeing patients and determining treatment based on an incomplete medical history, and without access to test results and two-way information sharing with a patient's NHS GP, presents risks to patients. Sharing important information between a private practitioner and a patient's NHS GP ensures better continuity of care, reduces risks from interactions between treatments given, and makes both parties aware of any safeguarding concerns. Prescribing guidance from GMC recognises that there may also be circumstances in which privacy concerns override a duty to share information.

Inspections also found variation in the level of awareness of why this was important to ensure safe prescribing. In one example, a slimming clinic supplied a patient with medication without informing their GP, even though they had a complex long-term medical condition that required regular monitoring. In some services, patient notes did not include all the necessary information, such as details of consultations, examination and test outcomes, to enable effective information sharing. This is key when prescribing for patients with long-term conditions such as asthma or diabetes, which require regular monitoring.

CQC expects to see that providers ask all patients for consent to share details of their consultation with their NHS GP each time they use a private service, and that there is informed consent to receive any medicines prescribed. We also expect providers to risk-assess the treatments they offer to identify medicines that are not suitable for prescribing if the patient does not consent to share information with their GP, or they are not registered with a GP. Examples are medicines liable to misuse and those used to treat long-term conditions such as asthma. If patients agree to share their information, we expect to see evidence of communication sent to their GP in line with GMC guidance.

In the analysis, some services relied on patients to pass on information, giving them a letter to give to their NHS GP or simply encouraging the patient to let their GP know about treatment, rather than doing so directly. Although one service did ask patients for the details of their NHS GP, it did not then ask them for consent to share the details of consultations.

Where patients did consent to share information, there were cases where details were not shared with the patient's GP in accordance with either the patient's request or the service's own policy. However, on follow-up inspections, we saw that these services had reviewed their processes, and records showed that information was shared appropriately unless the patient had specifically asked for it not to be.

Example of safe practice in information sharing

The provider of a private GP service told our inspection teams that if patients did not give consent to share their information with their NHS GP, they would not register the person as a patient. The terms and conditions given to the patient when registering also stated that by registering, they gave their consent to sharing information with their NHS GP.

Safeguarding

Safeguarding is a legal responsibility under Regulation 13, but we found it was an area for improvement. The analysis showed that services did not always have clear systems to keep people safeguarded from abuse, and some had no formalised safeguarding policy or no named safeguarding lead.

Discussion with our senior inspection staff has highlighted that not all providers recognised their wider responsibility for safeguarding, or they had not fully considered or understood

what was expected of them in relation to children's and adults' safeguarding. For example, even if they were not specifically seeing and treating children, some practitioners did not associate the fact that they would still be seeing adults who have responsibilities for children as part of their families, and therefore they needed to have risk-assessed the level of training needed for themselves and their staff.

Safeguarding may be more challenging for private services when patients do not disclose all their personal information. This applies both to protecting children and more vulnerable people from exploitation, for example as a result of people trafficking and modern slavery. However, practitioners still have a professional responsibility for safeguarding.

In this respect, it is imperative that staff are aware of the competencies in the intercollegiate guidance, *Safeguarding Children and Young People: Roles and competencies for healthcare staff*⁶ as well as guidance from GMC on protecting children and young people.⁷ CQC has clarified our position in relation to services for adults and expectations around safeguarding children in the Inspector's Handbook – Safeguarding.⁸

The analysis also highlighted that safeguarding policies were not always easy for staff to access. In some services, policies and procedures were not always adequate as they did not tell staff what to do or who to contact if they had a safeguarding concern. Inspection reports also identified policies that were:

- limited in scope as they only considered suspected abuse of a patient by a member of staff and not the possibility of any suspected abuse of a patient by another person
- not tailored to the specific nature of the service and the population groups served.

Inspection reports indicated that some staff had not received any safeguarding training and that not all staff had received safeguarding training to an appropriate level and were unable to demonstrate a good understanding of safeguarding. This included safeguarding leads, registered managers, clinicians and non-clinical staff. Where providers told inspection teams that staff had received appropriate safeguarding training, they could not always provide evidence of this during the inspection.

On follow-up inspections we found improvements, with better availability of policies, and evidence of staff having appropriate safeguarding training and, importantly, being able to demonstrate that they understood their responsibilities and how to identify and report concerns.

Several services did not collect the details of patients' NHS GPs as a matter of routine and their identity checks were ineffective. Therefore, if these services were to identify safeguarding concerns, this risks staff being unable to raise them with the patient's own NHS GP.

For services such as slimming clinics that only provide treatment to adults, the absence of identity checks meant that some services could not be assured that the patient was over 18 years old. However, there were examples of effective safeguards to ensure that children were unable to access a service, for example through requesting proof of identification.

Where services treated children, inspections found variable arrangements to ensure that they were protected. The better arrangements included safeguards to prevent anyone under 18 from accessing the services unless accompanied by someone with parental responsibility, and photographic identification for both the child and the consenting adult or adults being shown. However, some arrangements needed further review: although clinicians in some services would ask the child to verbally confirm their relationship with the adult during the consultation, inspection teams found no formal checks to formally verify the identity of the patient and confirm the identity of the consenting adult to ensure that they had parental responsibility.

In circumcision clinics, inspections identified appropriate systems to obtain consent from both adults with parental responsibility, unless they could demonstrate that one parent had sole responsibility for the child. However, some services had not always obtained written consent from both parents where they were both responsible for a child before a procedure, or they only asked for consent from both parents when they suspected a possible dispute.

There are geographic challenges to safeguarding for independent doctors and clinics. For example, one service in our analysis sample had contact details to enable them to report any safeguarding concerns for patients who lived locally. However, as the service was located in the City of London, most patients lived elsewhere. Following the inspection, the service updated its safeguarding policies with details of safeguarding teams throughout England. The lack of safeguarding contact details was a concern for specialised services that patients are more likely to travel to, such as circumcision clinics.

Other concerns included inadequate systems to ensure appropriate checks on staff, such as identity and disclosure and barring service (DBS) checks.

Clinical records

[Guidance from the General Medical Council](#) states that when clinicians use documents to formally record their work (including clinical records), these must be clear, accurate, legible and usable in a UK context, and record the details of decisions made.⁹ However, our inspections identified a number of problems relating to the quality and management of patient records. This is a risk to both the safety and the effectiveness of people's treatment.

Because some IT systems do not have the reliability offered by NHS systems, the security of records could potentially be at risk, and could also affect continuity of care for patients as well as business continuity. Our senior inspection staff also reported a lack of awareness that record holders are under a legal and ethical obligation to maintain records safely and securely.

Patients' records were still held on paper in a number of services and, even when they were held electronically, the records systems did not always enable the service to search patients' records. This meant services were unable to audit or follow up safety or medicine alerts for patients, or build disease registers to identify patients with a specific diagnosis, condition or procedure.

At some services, we found that records were incomplete, did not include a detailed medical history and lacked sufficient detail to provide an adequate and accurate record of the consultation. On occasions, records were not kept in English, which can potentially compromise safe and effective care for patients, and the continuity of care if staff cannot understand the contents of clinical records.

Specific examples of inadequate record-keeping included:

- Patients' medical records that were handwritten in another language, often illegible (translators could not decipher them), and of a variable standard as information, including rationale for diagnosis and treatment, was frequently absent.
- Records of examinations and mammograms with limited or no detail, for example clinical consultation notes with a doctor, evidence of clinical justification for a mammogram, and record of the date of the patient's last mammogram. There was also limited evidence of any active monitoring of low risk people presenting with symptoms ('safety-netting'), or evidence of any follow-up with patients.
- Records in slimming clinics that showed no target weights set at the initial appointment or no targets set at all, as well as records without any rationale for continuing to prescribe below the national guidance thresholds of body mass index (BMI).
- Records at an independent doctor service showing a prescription for a medicine that was not licensed for the treatment of Lyme disease. Although the manufacturer recommends extra monitoring and blood tests before and during treatment with this medicine, there was no record in the medical notes that these tests had been carried out. The clinician had not recorded their rationale for prescribing the medicine outside of its licensed indication, and there was no record that they had discussed this with the patient.

Example of safe practice through auditing patient records

A programme of audits at a specialist clinic ensured regular monitoring of the quality of its care and treatment, and the service made any necessary changes as a result. For example, patients' records were audited for the quality of content and completeness. In the most recent audit of 100 patient notes from each clinic, 10% of the notes did not contain answers to set questions asked. Lessons were learned and actions were documented, which included looking into an electronic notes system that requires the user to complete all required fields.

Safe and effective prescribing

Good clinical oversight and governance ensures that clinicians are prescribing appropriately. However, we found this was not always happening.

One area of concern was prescribing medicines without a strong evidence base – for example, medicines that are not considered to be in line with evidence-based guidance such as from the National Institute for Health and Care Excellence (NICE). If providers do not follow best practice guidance, we expect the clinician to provide and document a clear rationale.

This included the use of **unlicensed medicines** in slimming clinics. Guidance from the Medicines and Healthcare products Regulatory Agency states that unlicensed medicines may only be supplied against valid special clinical needs of an individual patient.¹⁰ The General Medical Council's prescribing guidance specifies that unlicensed medicines may be necessary where there is no suitable licensed medicine to meet the specific needs of the patient.

In several of the slimming clinic services inspected, we found that patients were treated with unlicensed medicines, which are not currently recommended by NICE or the Royal College of Physicians as there is not enough clinical evidence to advise using these treatments to aid weight reduction. GMC guidance states that doctors need to be able to adequately justify and explain their decision to prescribe an unlicensed medicine and record this in patient records.¹¹ Inspection reports stated that providers needed to make improvements in line with national guidance.

Legislation requires that when medicines are used outside of their licensed use or they are unlicensed, people must be given information that clearly states the licence status and the side-effects of the medicine, with a record of this retained in patient notes. At a number of the services inspected, the prescriber failed to inform patients that the medicine was unlicensed, or there was no clear documentation to support their decision to prescribe an unlicensed medicine.

Not all services had **prescribing policies**. We found evidence that prescribing in some services was not in accordance with their own policies and did not reflect evidence-based guidance. For example, inspections of slimming clinics identified cases where appetite suppressants were prescribed to patients with a BMI lower than that recommended, or to patients who had high blood pressure above the safe thresholds set out in both the clinic's policy and in national guidance.

Some services prescribed antibiotics without any evidence to support effective **antimicrobial stewardship**, and one circumcision clinic prescribed prophylactic antibiotics after every procedure as a failsafe, as the service was only open one day a week. It is not in the best interest of patients to receive medicines that they do not need and to be exposed to unnecessary side-effects. In January 2019, the [Government announced](#) its five-year action plan for antimicrobial resistance 2019-2024 and its 20-year vision, which emphasises the need for clinicians to remain up to date with emerging evidence on resistance and appropriate antibiotic use. Inappropriate prescribing and administration can lead to antibiotic resistance, and poorer outcomes for patients.

Inspection teams identified that not all services were signed up to receive **patient and medicines safety alerts**. In services that did receive alerts, systems did not always monitor and act on safety alerts effectively. As a result, clinicians were unaware of potentially serious side effects of the medicines they were prescribing and providers were not doing everything practicable to mitigate risks to patients. In some services we found no evidence to demonstrate that alerts had been shared with relevant staff and a lack of documentary evidence of how they had responded to alerts. In other services, the providers relied on clinicians to deal with alerts themselves. With no monitoring system to ensure that they had appropriately considered and responded to alerts, these providers had no oversight as to whether any patients may have been affected by medicines that were the subject of safety alerts.

As mentioned earlier, the limited functionality of the IT systems of some services meant they were unable to easily identify patients affected by specific medicines alerts, or the process to recall patient notes was complicated. Where services recorded patient records on paper, this was made even more difficult.

We note that when we re-inspected, some services had taken immediate action to improve, as they had signed up to receive alerts and implemented systems to share, record and act on them.

Inspectors raised concerns over the lack of a structured approach to **clinical audit and oversight for prescribing**. Across different types of services, we found a lack of prescribing audits to monitor the quality of prescribing, and that prescribing decisions were not subject to regular review. Where services did monitor prescribing, inspections identified clinical concerns that the provider's clinical audits had not picked up. This demonstrates a concerning lack of clinical oversight.

The safety of prescribing was also affected by variation in the quality of records management. As outlined above, not all clinicians recorded a detailed medical history from patients and patient records did not always record the rationale for prescribing decisions, whether in relation to unlicensed medicines, treatment breaks or treatment outside of national guidance.

Examples of poor and unsafe prescribing in slimming clinics included:

- patients prescribed medicines outside the provider's policy and doctor's manual, which were higher than the recommended starting dose and prescribed before information was received from their NHS GP
- prescribing an appetite suppressant for more than a year without a treatment break and without any improvement in weight loss: a treatment break is recommended after 12 weeks of consecutive treatment
- not documenting patients' BMI in their notes on every appointment but supplying medicines on all occasions
- supplying medicines to patients for extended periods, with no clinical rationale recorded for this in their medical notes.

The analysis of inspection reports also included examples of poor and unsafe prescribing in other types of independent services:

- prescribing Isotretinoin (a medicine used in the treatment of acne) when MHRA guidance states that this should be prescribed only in a consultant-led team
- prescriptions for very young or small children not based on weight or age when appropriate
- prescribing antibiotics with no prescribing protocol, for example prescribing antibiotics as first-line treatment with no documented risk assessment or rationale for their use.

Medicines management

Linked to the concerns around prescribing, inspections also identified improvements that were needed in relation to how medicines were stored, packed and supplied to patients.

Inspection teams identified medicines requiring refrigeration that were not stored appropriately in line with national requirements. For example, at one service, vaccines were kept in an ordinary domestic fridge for which the temperature could not be monitored. In other services, fridge temperatures were not monitored effectively, which meant the effectiveness of those medicines and vaccines could not be guaranteed.

Inspections also found instances where prescription stationery was not stored securely or monitored, which increases the risk of forms being removed and misused to obtain medicines illegally.

In other services, there were issues with medication dispensing labels. For example, at one service the inspection found that some labels stated the wrong quantity or there was no information to help patients to take their medicines safely. The clinic had not recognised these as incidents and told the inspection team that there had been no significant patient safety events in the last year.

Two inspection reports highlighted concerns with medicines or vaccines to be administered through a patient specific direction (PSD).^{*} These were being supplied before the PSD was signed by a doctor and therefore there was no assurance that staff had the appropriate authorisation to administer medicines safely.

During inspections of slimming clinics, there were instances where waste medicines were not destroyed in line with controlled drugs regulations and some services did not have the appropriate exemption certificate to enable them to carry out this activity.

Effective

Inspection teams looked at how providers assess patients, gain consent, deliver and monitor people's care and treatment, coordinate care and share information, and the effectiveness of the staffing arrangements.

From reviewing the sample of inspection reports, we found that a quarter of independent doctor services and around a quarter of slimming clinics on the first inspection were not providing effective care in accordance with the relevant regulations.

Across both types of service, we identified concerns relating to the effective key question in relation to:

- not keeping up-to-date with, and following, current evidence-based practice and guidance
- inappropriate prescribing
- gaining appropriate consent
- limited quality improvement activity
- making referrals
- limited formal clinical leadership, supervision and support.

We discuss some common issues in further detail below.

^{*} A Patient Specific Direction (PSD) is a written instruction, signed by a prescriber for medicines to be supplied and/or administered to a named patient after the prescriber has assessed the patient individually. In practice, a PSD is may be referred to as a 'prescription' by those who write and follow them because this indicates that it is written by a prescriber. This should not be confused with an FP10 or other written prescription given to the patient for supply from a pharmacy or dispensary.

Gaining consent

Consent is an important aspect of providing care and treatment ([Regulation 11](#), Health and Social Care Act). When gaining informed consent for treatment, we expect practitioners to make every effort to be sure that patients understand the purpose, benefits, risks, and other options available, and then to get their consent before starting. However, providers must not deliver unsafe or inappropriate care just because someone has consented to care or treatment that would be unsafe.

Many services obtained and recorded patients' consent appropriately and recorded a patient's mental capacity where appropriate. Some services audited patient records to monitor the process for seeking consent. However, this was not the case in all services. For example, even though services asked for consent verbally, they did not always record it. Other services either relied on implied consent, or their process did not comply with the Mental Capacity Act 2005.

Example of effective practice in gaining consent to share information

A provider of private GP services, health assessments and travel health consultations carried out a three-cycle audit to review eligible patients' documented consent to Human Papilloma Virus (HPV) testing as part of cervical screening. The audit was carried out in October 2017 and in May and July 2018. It showed that, following the introduction of new health assessment recording software, the documenting of consent had improved from 36% to 100%.

Referrals

Making appropriate referrals was another concern, as these were not always made or recorded. For example, an inspection report of a slimming clinic noted that a patient had breathlessness but the clinic did not make a referral to another service, despite this being a recorded side-effect of the medicine prescribed. In some services, where referrals were made, this was sometimes through an 'open' referral letter. This is where the practitioner refers patients to any consultant with a particular speciality for treatment, rather than the service itself taking responsibility to hand over that care by explicitly naming a specific consultant.

Effectiveness of care: What the public think

We asked members of our Public Online Community about using independent doctors and clinics. Of the respondents who had seen a private doctor, 22% said they still needed to visit an NHS doctor afterwards. This was mostly for follow-up treatment, as either the cost of private treatment was prohibitive or their health insurance did not cover the type of treatment they needed.

Some respondents felt that the care they received was no better than care offered on the NHS, the main difference being the availability of appointments.

Around 9% of respondents said they would use a private doctor if they wanted a second opinion or had concerns about the quality of care in an NHS setting. Conversely, of the people who had not used a private doctor, 47% said that if they did, they would still want to see an NHS service afterwards for a second opinion and to ensure that they're being offered the right treatment.

Caring

Under this key question, inspection teams looked at how providers maintained patients' privacy and dignity, how they delivered care with kindness, respect and compassion, and how they involved patients in decisions about care and treatment.

We identified very few concerns under the caring key question, as the analysis of inspection reports for all the independent doctor services and slimming clinics in the sample found they were providing caring services in accordance with the relevant regulations.

Overall, analysis showed that privacy and dignity were respected, services could demonstrate high levels of patient satisfaction, and CQC's comment cards that patients filled in were positive about their experience of services. Some services asked for feedback following each consultation, which was reviewed against target scores. These services could demonstrate good practice in using this information proactively to make improvements. One service had adapted and translated its patient satisfaction surveys into the most common first languages of patients and developed a child-friendly version.

However, inspections did identify a small number of services that needed to improve how they promoted privacy – for example, by ensuring that consultations with patients could not be overheard, and visibly warning colleagues not to enter rooms when a consultation was taking place.

Confidentiality can be compromised if patient records are not stored securely or in a fireproof area. For example, at one slimming clinic we saw that patients' medical records were stored in open boxes in the corridor next to the waiting room and near the entrance door. This is a potential risk to patients' confidentiality.

Responsive

We looked at timely access to the service, how services responded to and met people's needs, and how they listened to and learned from concerns under this key question.

Responsiveness is generally a strong area of performance in independent services. Patients and insurers are paying for services, and so they expect prompt, convenient access to consultations and treatment. In this sense, services perform well against the responsive key question.

However, being responsive is not just about access to services. Some services may not be set up to empower patients to have a say in the direction of the services, with patient engagement taking more of a customer satisfaction approach than asking for suggestions to improve.

In the sample of inspection reports, we identified that a small number of services were not fully meeting the regulations under the responsive key question on their first inspection. Even in services that were providing responsive care in accordance with the relevant regulations, there were areas for improvement, including:

- providing adequate information for patients about how to make a complaint and what to do if they were unhappy with how their complaint was handled, and having arrangements to manage and learn from complaints
- relying on informal translations by family or friends, and having limited arrangements to provide translation services and written information in other languages
- providing adequate accessibility for patients with protected equality characteristics, such as information in large print and induction loops for patients with hearing difficulties
- making patients aware that the premises may not be fully accessible to all people; although some services directed patients to alternative services or told them about limited access, it was not clear that they were fully considering their responsibilities under the Equality Act for patients with a disability.

The analysis of inspection reports showed that in a small number of services there was no evidence that they formally collected feedback from patients. In some cases, although people were encouraged to give feedback, it was not collected proactively, or people were only asked for feedback about issues other than the quality of care and treatment.

There were also concerns about ineffective systems and processes to analyse and act on feedback to drive improvement and share learning.

There were examples of more responsive care, including providing reasonable adjustments for people with a disability, and providing extensive information to help worried patients, as the following examples show.

Examples of responsive practice in circumcision clinics

A circumcision clinic made sure that it responded to any lessons to be learned from treating patients, and shared these with staff to make sure that they took the necessary action to improve procedures or safety in the clinic. For example, the clinic noticed that they were always being asked the same type of questions from anxious parents after a procedure on a child. They therefore produced an aftercare leaflet that answered these, and they set aside time the day after a procedure to respond to any calls and answer queries.

Our analysis of inspection reports identified two circumcision clinics that were providing post-operative support 24 hours a day. One of the clinics sent daily text alerts for two weeks following a procedure to give prompts and advice; the other clinic reviewed patients after their procedure. This gave an added opportunity for parents to discuss any concerns about their child's treatment.

Another two circumcision clinics had produced and published a number of medical papers, and had produced guidance about circumcision, which other health institutions had adopted. One clinic was considering arranging seminars for primary and secondary care colleagues to improve their knowledge of circumcision, particularly around aftercare.

Example of responsive practice: supporting patients to live healthier lives

The provider of a private medical service for patients who were primarily from the Somali community had a clear vision to proactively improve health outcomes. They saw this as part of their duty to the wider community that they served, as well as reducing unnecessary interactions with NHS emergency services. They provided services free of charge to promote education and healthier lifestyles among the Somali community. This included work in local mosques, schools and community organisations to improve awareness of the importance of good diet and exercise to prevent long-term health conditions, providing free health checks to the public during Ramadan, and internet-based video clips with advice about healthier lifestyles and preventing ill-health. Some of these videos had been viewed more than 1,000 times.

The provider's knowledge of the Somali community was recognised by two local authorities, who had asked them for advice on providing care to that community. For example, in 2016, one local authority consulted the provider about how to improve the low uptake rate for certain childhood immunisations among the Somali community, while another local authority had discussed female genital mutilation, as the provider had particular insight. This provider was also a frequent contributor on health-related matters to a UK-based cable channel broadcasting in the Somali language.

Responsiveness of care: What the public thinks

We asked respondents in our Public Online Community survey if they had used an independent doctor or clinic and why.

Choice: Many respondents felt that having a choice between private and NHS services was a positive thing. The most common way to choose care among respondents was by word of mouth (32%), but 24% of respondents said that the clinic or doctor was chosen by insurers and not themselves.

Access: It was clear that people had higher expectations from private providers than they did of NHS services. For example, unsurprisingly one of the main benefits to people was access, as waiting times for consultations may be reduced considerably compared with an NHS service.

People said they used private services because the service they needed was not available on the NHS. This could be for routine procedures that have a long NHS waiting list. Others said they used a private doctor because they had medical insurance, most often through their employer.

Of those respondents who had not used a private service, 68% said they would visit a private service if they had an urgent medical need and there were long waiting lists on the NHS. The types of medical need that people said would persuade them to seek private treatment tended to be for serious and/or acute illnesses, such as cancer.

However, in the NHS the maximum waiting time for suspected cancer is two weeks from the day an appointment is booked through the NHS e-Referral Service, or when the hospital or service receives a referral letter. People's perception of long waiting times may be influenced by poor performance against other targets reported in the media.

Well-led

We looked at governance arrangements, culture, leadership capacity, vision and strategy, managing risks, issues and performance and continuous improvement under this key question.

As we find in all types of health and care services, poor performance under the well-led key question affects all areas, including the safety and effectiveness of care and treatment. From the review of inspection reports, we found that some services were not well-led in accordance with the relevant regulations on their first inspection, although we found some improvements on re-inspection.

The issues that we found included:

- ineffective overall governance frameworks and quality monitoring systems, which led to a lack of quality improvement programmes
- out of date policies and procedures that were not service-specific or fully risk assessed, or were not formally recorded and easy for staff to access
- ineffective arrangements to identify, record and manage risks
- ineffective systems to share information with staff to learn lessons.

We discuss some of the common issues in further detail below.

Governance arrangements

Good governance involves having systems to assess and monitor the quality of services. When assessing the well-led key question, inspection teams need to be assured that a provider is aware of their responsibility to improve care and treatment, but across all types of service there was limited evidence of effective systems for quality assurance, such as clinical audit.

We found there was a need to improve roles, responsibilities and systems to support good governance. Arrangements for identifying, recording and managing risks and issues, and implementing mitigating actions, were minimal. As a result, there was limited evidence of quality improvement activity in services.

The analysis of inspection reports showed a need to improve policies and procedures for key areas such as safeguarding, infection control and business continuity. In some services, policies and procedures were not always up-to-date, had not been reviewed, or were generic in nature and not designed to reflect the specific service provided. Not all staff were aware of the policies and they were not operating as intended. For example, some slimming clinics had not recorded patients' health details in line with their policies, had not instigated treatment breaks for all patients as recommended in their policy, and were not sharing information in accordance with their protocol.

Where services did carry out audits, inspections identified that some had failed to identify risks, and clinicians were not sufficiently involved in the audit process to drive improvement. In other services, there was no clear record of the actions taken following audits, or the findings from clinical effectiveness audits had not always been shared with clinicians so did not support review and learning. Inspections also found little evidence of governance meetings that were attended by clinicians. We also saw limited evidence of the peer review of clinical practice.

For example, in one slimming clinic there was no evidence of quality improvement activity such as audits of clinical care, prescribing, infection prevention and risks, and incidents and near misses. There was also no system to assess compliance with policies, most of which had not been reviewed for more than 10 years. The inspection of the clinic found evidence of prescribing that was not in line with the provider's policy, and written information given to patients did not make it clear that the medicines prescribed were unlicensed or being used outside of their product licence.

Not all services had carried out appropriate risk assessments such as those relating to registering children or risks associated with circumcision procedures.

The systems and processes in relation to maintaining equipment also required improvement. For example, the analysis of inspection reports found that weighing scales, medicine fridges and other clinical equipment had not been calibrated, which compromises the safety and effectiveness of treatment for patients.

In some services there were also limited processes to gather feedback from staff, which is vital to create a good working environment and culture.

Examples of improved care for patients through audit and quality improvement activity

The doctor in a slimming clinic service took every opportunity to access learning relevant to their role, and the provider supported them to do this. The doctor had regularly analysed data on weight loss, which enabled them to tailor treatments to better meet patients' needs. This included offering free of charge weight checks and advice outside of the schedule for providing medicines.

Analysis of referral data demonstrated the value of carrying out physical monitoring. The doctor adapted their approach to checking patients' blood sugar levels by making sure they had fasted beforehand, which reduced the need for inconvenient re-testing if they had not fasted. They offered follow-up appointments for testing if an initial risk assessment had indicated a high risk of diabetes.

The doctor at another slimming clinic carried out clinical audits to determine whether the treatments were successful. The outcomes for nine of the 11 patients audited had reached their target weights. The doctor also carried out an audit to determine whether the frequency of appointments had any bearing on the outcomes, and found that treatment was more successful with a shorter interval between appointments. The doctor now encouraged more frequent visits at no extra cost to the patient.

There was a mixed picture in respect of training for both clinical and non-clinical staff. In some services, inspection teams saw evidence that staff were trained appropriately for their role and that training was being monitored. In other services, although staff had received training, providers had no evidence of this during the inspection, which highlights weak governance and oversight arrangements. In other services, not all staff had been trained appropriately, there was minimal clinical supervision and a lack of oversight to ensure that training was up-to-date. In some cases, inspection teams did not see evidence of sufficient medical indemnity insurance for all relevant staff and revalidation for clinical staff was not managed effectively.

These issues highlight how a culture of quality monitoring and improvement through effective clinical leadership is central to delivering safe and effective care.

Under the well-led key question, we also look at how services form partnerships to improve their services. There were some examples of good practice in the analysis of inspection reports that show how some independent providers are looking beyond their immediate business model to improve care and treatment for patients in their local community.

For example, one provider of private GP services had good links with the local clinical commissioning group and local medical committee. This has allowed an open dialogue to discuss problems and overcome barriers such as the interface between private and NHS care, and how the two systems can work cohesively to benefit patients.

Improvement on re-inspection

Between January 2017 and October 2018, we re-inspected 34 independent doctor services and 12 slimming clinics at least once.

As part of the analysis of inspection reports, we looked at 19 re-inspection reports for independent doctor services, which were to follow up on concerns identified and focus on the areas that needed to improve.

Although all demonstrated some improvement on re-inspection, this was not always sufficient across all the re-inspected key questions, as some services still needed further improvement to meet the relevant regulations. The re-inspections found breaches against Regulation 12 (safe care and treatment), Regulation 17 (good governance) and Regulation 18 (staffing). If a service has still not shown enough improvement to meet a regulation we will carry out a further inspection.

Eleven of the 19 re-inspected services demonstrated sufficient improvement on the next inspection to confirm that they were providing care in accordance with the relevant regulations for all re-inspected key questions. Many services responded well to inspection findings and engaged with CQC to understand what they could do to improve.

As a result, they are now providing safer, more effective care.

Similarly, as part of the inspection report analysis, we looked at re-inspections of eight slimming clinics. Reports showed evidence of improvement over the course of the inspection programme, with action to address concerns and how services had applied learning both from inspections of their own services and those of other providers.

However, not all services improved sufficiently. For example, on a second inspection, one slimming clinic was still not meeting the relevant regulations for re-inspected key questions and is no longer registered with CQC, as we took enforcement action to remove its registration to operate.

Conclusion and next steps

Our inspections of independent doctors and clinics have shown that many services are meeting the necessary regulations by responding well to the needs of their patients and delivering a caring service that is tailored to people's specific requirements and needs.

However, a number of services were not meeting the regulations and not delivering the standard of care that we expect to see. Where services were not meeting regulations, we found limited awareness of the regulatory requirements that apply to all health and care services in all regulated sectors as well as limited appreciation of the wider professional responsibilities of practitioners, for example safeguarding. Our main concerns were around the ability to provide safe and effective care, which relies to a great extent on sharing information appropriately with other providers to ensure safe prescribing and safeguarding patients, as well as good practice in areas that support this such as record keeping. Where we saw poor governance processes, there was also limited quality assurance and improvement activity, for example through clinical audit and acting on patient feedback.

All providers have a professional responsibility and duty to act in their patients' best interests. But the nature of self-funded care can be episodic, which can influence clinical decision-making and present a challenge for practitioners to provide ongoing care and to work in their patient's long-term best interests.

We found that an underpinning reason for poor information sharing and record keeping was a lack of support for the sector to access more up-to-date IT systems with greater functionality. This makes it difficult for providers to keep good quality patient records and to use these to audit activity and improve quality.

Next steps

CQC's operating model and the way we assess services against our key lines of enquiry is the same for all providers. Our regulation can play an important part in influencing people's decision whether to have care and treatment from NHS services or to pay for private care, as our judgements about the quality and safety of services and our inspection reports help them to compare and choose a provider.

From April 2019, we will start to introduce ratings for independent doctors and clinics to align with our approach to regulating other services.

Awarding and publishing quality ratings means that people can be empowered to make informed choices about their care in a sector where there is currently limited comparative information on the quality of services.

References

1. Care Quality Commission, [*The state of care in independent online primary health services*](#), March 2018
2. Care Quality Commission, [*The state of care in independent acute hospitals*](#), April 2018
3. Care Quality Commission, [*Response to our consultation on our proposed approach to how we regulate independent doctor services*](#), December 2016
4. Care Quality Commission, [*Response to consultation 3, our next phase of regulation: Independent healthcare services*](#), June 2018
5. General Medical Council, [*Using and disclosing patient information for direct care*](#)
6. Royal College of Nursing, [*Safeguarding Children and Young People: Roles and Competencies for Healthcare Staff*](#), January 2019
7. General Medical Council, [*Protecting children and young people: The responsibilities of all doctors*](#), July 2012
8. Care Quality Commission, [*Inspector's Handbook, Safeguarding*](#), February 2018
9. General Medical Council, [*Good Medical Practice*](#), paragraphs 20 and 21
10. Medicines and Healthcare products Regulatory Agency, [*Off-label or unlicensed use of medicines: prescribers' responsibilities*](#), December 2014
11. General Medical Council, [*Prescribing and managing medicines and devices*](#), paragraph 70

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