The state of care in independent online primary health services

Findings from CQC's programme of comprehensive inspections in England

STATE OF CARE

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 from the Chief Inspector

The healthcare landscape is constantly evolving, presenting new and innovative ways to deliver health care. New technology and change through innovation are core enablers to give people better care, and to make health and care services sustainable for the next few decades. Using online technology in primary health care has the potential to improve accessibility and convenience for patients, and may provide cost benefits to the wider health system. This applies both to independent non-NHS providers as well as NHS providers.

People have been able to get advice about health remotely for many years, particularly through telephone consultations, and in some areas healthcare has been delivered over the internet for some time. There has been a recent growth in independent sector providers offering online-only consultations with clinicians using video or questionnaire-based channels.

One of CQC's current strategic priorities is to encourage improvement, innovation and sustainability in care, and we support the development of new and innovative models of care delivery that improve the outcome and experience of people who use services. We therefore have a role in understanding innovation and change, but also to protect people, which means working with others to build our understanding of risks, and how to turn these into opportunities to improve.

To enable the public to make informed choices about providers, it is important that they feel protected by regulation and confident that they can receive safe, high-quality care as they should do when receiving care in other sectors that CQC regulates. CQC regulates the quality of services – not the channel through which they are delivered. Although there are contextual differences to consider between services delivered remotely and those delivered in person, the fundamentals of good clinical practice apply – regardless of how the care is provided.

Online delivery of primary health care is a rapidly expanding business model, but this must not be at the expense of safe and effective care. Providers have obligations to protect the people who use their services, and their individual doctors and clinicians need to be aware of their professional responsibilities.

This report relates to our first full programme of inspections of primary health care provided online in the independent sector, and subsequent re-inspections. This followed inspections of two independent providers in late 2016 that were in response to identified risks to patients, which required us to use our regulatory powers to protect them. The first programme highlighted variation and areas for improvement around the safety and effectiveness of care from some providers.

These included concerns about prescribing, not only inappropriate prescribing of medicines with the potential for misuse but also of antibiotics and medicines used to manage long-term conditions, including asthma. Safeguarding in an online context also presented a challenge for providers, as well as verifying patients' identity to provide safe care and treatment, obtaining proper consent, assessing capacity, and sharing information with patients' GPs.

We also saw some good examples in relation to the responsiveness of services, and how they adapted to meet the needs of people using them, as well as clinical oversight and quality improvement activity and how services followed up patients, both to check on their health and to gather feedback. After inspecting all independent online providers that were registered with CQC, our subsequent inspections have shown that most can and do improve, but some are not taking quality and safety seriously enough, which has resulted in us using enforcement powers. We are working with the sector to encourage this improvement and continue to keep people safe.

Going forward, the delivery of healthcare online has the potential to play a major part in how health care is provided in the future. The growing national demand for a GP appointment has been widely reported. NHS England acknowledges this and encourages greater use of technology and online consultations as a potential way to meet this growing demand and improve the patient experience. It is therefore important to develop evidence to enable us to understand how this method of consultation can be used most effectively for patients, and to ascertain its impact on the wider health and care system so that we can build on this.

The NHS is also developing access to online health care and some of the themes found in our inspection programme may apply to these services. For example, we know that integration between providers is key to a safe, smooth, and joined-up experience for patients, particularly where they receive care from a number of organisations within the NHS and independent sector. This applies both between NHS providers, and between the independent sector and the NHS. To support the safe and effective delivery of care, there needs to be a better flow of information between independent online healthcare providers and the patient's GP if they have one (and vice versa). We found this was particularly important to safe prescribing.

In the same vein, the flow of information between independent online providers and CQC needs to improve so that we know more about them, how they work and the scale of their operations. We know there are potential barriers that make it harder for some groups of people to access and receive good care from these providers. We need to work collaboratively with other regulators, people who use services, care providers in both the NHS and independent sector, and their commissioners, as well as organisations outside health, to learn how to overcome these.

There is now an opportunity – and a responsibility – for newly-emerging providers that are using technology to deliver care to put patients at the centre of any new developments, and to assure them that they are addressing risks and safety issues. It is also vital to have wider engagement between providers, regulators and people who use services around innovation and how it can be adopted. We both encourage this conversation and look forward to contributing to it.

We are aware of the regulatory challenges arising from the easier delivery of cross-border health care (both national and international) and the legal limits to our regulatory powers. We know there are challenges where organisations provide services online that are out of the scope of CQC's regulation. Together with our regulatory partners and the Department of Health and Social Care, we are acting in ways to mitigate these.

As technology as a whole continues to evolve, we welcome discussion on how it can improve people's care, while safety and quality of care is assured.

Professor Steve Field CBE FRCP FFPH FRCGP
Chief Inspector of Primary Medical Services and Integrated Care

Introduction

Delivering primary health care online is a growing business model. In England, the Care Quality Commission (CQC) has seen an increase in the number of independent healthcare providers that deliver remote consultations to patients over the internet.

The number of providers registered with CQC to deliver these services at any one time is likely to change as some organisations de-register (either voluntarily or through enforcement action) and new providers enter the market. When we started our programme of inspections in January 2017, 41 online-only providers were registered to provide services; at the time of publishing this report, there were 40. These providers vary, with some providing a questionnaire-based interaction with clinicians, usually for a fixed range of conditions and medicines, and some providing real-time interactive health care by video.

Background and context

NHS England's *General Practice Forward View* recognises that technology and online consultations can improve the patient experience and encourages them as a potential way to meet growing demand.[1] In 2013, NHS England set up the GP Access Fund to "improve access to general practice and stimulate innovative ways of providing primary care services".[2] NHS England also allocated specific budget to improve IT/technology services, including an additional £45 million available to the NHS over three years to support and encourage online consultations.[3]

Online-only primary health care services operated by independent (non-NHS) providers may either charge a monthly or annual subscription or a fee per consultation or prescription, or they may be part of an insurance arrangement. Some independent organisations that offer services direct to patients are commissioned to provide NHS services, and are working with the NHS to deliver online video consultations and questionnaire-based sexual health services to NHS patients. As patients can choose to access services across a variety of providers – both in the NHS and independent sector – high-quality care relies on having appropriate, effective communication between different healthcare providers.

Remote consultation is not a new phenomenon: a survey of NHS general practices in 2015 on the use of alternatives to face-to-face consultation showed that telephone consultation as a way of delivering clinical practice was widespread.[4] Online consultations using video or email had been tried. However, at the time of the survey, none of the 319 practices that participated offered online video consultation, and only 18 offered consultation by email.

In contrast, for providers in the independent sector delivering online-only primary health care, remote consultation is the core offer. There are two main types of consultation:

- **Real-time video consultation** where the patient and clinician consult using a video platform, for example, a custom app or Skype™. This may be delivered through a computer, smartphone or tablet device. Following consultation, the clinician may issue a prescription or statement of fitness to work, give advice, or refer the patient to other suitable services.

- **Questionnaire-based consultation** using a web form, which can be accessed through a web browser on a computer or portable device. The patient fills in a form that gathers a medical history. This may be checked by automated systems before being reviewed by a clinician. Using the information in this form, the clinician may issue advice, a prescription, or may contact the patient for additional information. Frequently, there is no real-time communication between the patient and the clinician.

Following a consultation where a prescription is issued, the medicines may be remotely dispensed by a registered pharmacy contractor (registered with and regulated by the General Pharmaceutical Council) that is often linked to the provider, and delivered directly to the patient. Alternatively, the prescription may be issued to a pharmacy near the patient so they can pick it up in person. There is not usually a capability to arrange physical examinations for patients through an online-only provider.

Providers vary in terms of their size and scale – including the number of employees, the number of consultations carried out and number of prescriptions issued.

The lack of a physical presence when delivering healthcare services online enables a much larger potential geographic coverage, including the capability to provide care across national and international borders. CQC only regulates health and care providers in England, and healthcare regulation in the UK is devolved (in contrast to medicines and professional regulation). We therefore work closely with regulatory partners in the other UK countries to collaborate where providers pass between our scopes of responsibility. We have articulated our commitment to collaborate and align our approaches in our letter of 24 August 2017.[5] This collaboration within the UK is vital to deliver effective regulation that works for people who use services, providers and the regulatory system.

However, there are concerns about the effectiveness of regulation of health care delivered from abroad to patients in the UK. We are working with the Department of Health and Social Care and partner regulators throughout the UK to consider approaches to assure patients of the quality of services they may choose to use.

There is a challenge that some organisations provide services online that are out of the scope of CQC's regulation and which, therefore, do not have to be registered with us. Where the quality of these providers has the potential to cause harm, we are working closely with partner regulators to ensure the safety of patients. If we believe that a provider should be registered with CQC, we will investigate and take the appropriate action.

CQC's role and regulatory approach

In England, CQC regulates health and care providers that come under the scope of our regulation. This means that the legal body that provides a regulated activity listed in the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 must be registered with CQC by law.

The regulated activities that providers of online primary health care are registered to provide include:

- treatment of disease, disorder or injury

- transport services, triage and medical advice provided remotely

- diagnostic and screening procedures.

It is the regulated activities that are subject to regulation by CQC – not the channel through which they are delivered, for example web-based consultations through real-time video or questionnaires.

CQC only regulates providers based in England, but some providers also fall under the regulatory responsibility of other regulators. In the online primary health care sector, the General Pharmaceutical Council regulates pharmacists, pharmacy technicians and pharmacy premises in England, Scotland and Wales; the General Medical Council regulates individual doctors on its register; the Nursing and Midwifery Council regulates nurses and midwives on its register; and the Medicines and Healthcare products Regulatory Agency regulates medicines, medical devices and blood components for transfusion in the UK. We also work with the quality regulators in Wales, Scotland and Northern Ireland.

The focus of our regulatory approach – across all types of providers that we regulate – is on the quality and safety of services, based on the things that matter to people. This enables us to get to the heart of people's experiences.

Before they can start to deliver services, organisations must apply to CQC to register the regulated activities they intend to deliver. They must satisfy CQC that the care and treatment provided will meet the requirements of the Health and Social Care Act 2008, and its associated regulations, which include the fundamental standards.

Once providers are registered with us, our regulatory approach involves ongoing monitoring, inspecting, and reporting on what we have found. We take action where care falls short of the required standards and where there is a breach of a regulation.

Following inspection, we publish a report of what we have found to help the public, providers, and people who use services make choices about their care. Our reports focus on what our findings for each of our five key questions mean for the people who use the service: are services safe, effective, caring, responsive and well-led?.

The report states whether, for each key question, the provider was delivering care in accordance with the relevant regulations. We describe any notable practice we find as well as any concerns we have.

Where we identify concerns, we decide on the appropriate action to take. This is proportionate to the impact of the concern on the people who use the service and how serious it is. Our enforcement policy sets out what action we take to require providers to improve and, where necessary, the action we take to make sure those responsible for poor care are held accountable for it.

In this programme of inspections, we did not provide ratings as we did not have the powers to rate all independent healthcare providers, including primary health care services provided online. However, the Department of Health and Social Care has since given CQC the power to rate providers in the independent health care sector that we had previously been unable to rate, and we have consulted on how we propose to do this, to align with other sectors, starting from 2018/19.

Refining CQC's regulation

We started to develop our regulatory approach to independent primary care provided online in 2015, in response to the increasing number of providers registering with CQC to deliver care in this way. This involved consulting with an external advisory group, testing and evaluation in two operating online providers of primary care, and gathering feedback from providers on draft guidance in March 2017. This engagement has helped us build on our existing approach to regulating general practice and capture where there are differences in online-only independent healthcare provision.

We also engaged with the public and worked closely with partner regulators throughout the UK. Working collaboratively with partners has been essential to share information where providers operate across the remit of different regulators. We established a provider forum in October 2017, to make sure that our approach remains relevant in the online sector going forward, and to provide consistent expectations of those we regulate.

Our inspectors use CQC's assessment framework for healthcare services with its key lines of enquiry (KLOEs), together with a tailored subset of prompts that apply to services delivered remotely over the internet.

We carried out inspections in late 2016 in response to intelligence received about risk to patients (this was separate from the piloting process). These inspections found significant concerns about the quality and safety of care, and led to us taking enforcement action, including moving to urgently cancel the registration of one provider.

Following these initial inspections, and given the level of enforcement action taken due to our concerns about the quality of clinical care delivered, we brought forward our first round of inspections of registered online providers of primary care in England. We prioritised inspections where there was potentially higher clinical risk, starting in January 2017, and we completed this in July 2017. We also coordinated inspection activity with the Medicines and Healthcare products Regulatory Agency and the General Pharmaceutical Council where services came within their regulatory responsibilities. Our inspection teams were led by specialist CQC inspectors, and included members of CQC's Medicines Optimisation team and GP specialist advisors trained in inspecting online providers.

Delivering services online has increased the complexity of where organisations may be based to deliver care to patients in England. CQC is the regulator for health and social care providers in England, but technological advancement has lowered barriers to enable services to be delivered across national and international borders. This has raised questions about the effective regulation of cross-border health care, particularly where it is delivered from outside the UK, and where organisational structures mix organisations based inside and outside UK regulation.

Access to care for different patient groups

Online consultations with a clinician have the potential to improve access and convenience for some patients, for example those with physical impairments for whom attending a face-to-face appointment is difficult, those with a sensory impairment, and those who live in rural areas and have poor transport links. They may also be more convenient for people with busy lives who may not have time to attend a surgery, and particularly younger people who are more computer-literate and used to organising their lives online.

But not everyone may have easy access to online services. Coverage of sufficient broadband connection speeds for average home use was available to 99% of premises in urban England compared with 85% of premises in rural England,[a] and access to the internet at home varies with age (more than 90% of people aged under 55 had internet access in 2017, compared with 53% of people aged over 74).[6, 7]

We engaged with some organisations representing patient groups to discuss the themes and challenges after this programme of inspections. Age UK responded that the take-up of such services by older people is likely to be very low and expressed concern about the scope of these services in the context of older people or patients with complex needs. Age UK did think that online providers could help to encourage people to self-manage their care, which could mean people having greater control of their conditions and helping to maintain independence for some older people. They told us that it is important that all those who use online primary health care are supported to understand whether an online consultation

a. Based on a download speed of at least 10Mbit/s; Ofcom's analysis shows that this speed is sufficient to meet the current needs of a typical household.

may be appropriate for them, including where services may be mis-sold or mis-represented, and to ensure patient safety.

The Men's Health Forum felt strongly that, as men often prioritise work over health and therefore do not always access the care they need in a timely way, primary care delivered online has the potential to give better access. Mental health care is another area that men may be reluctant to access. Providing care online may increase the likelihood of men seeking help as it is easier, quicker and more discreet to do so.

However, Mind highlighted the importance of having appropriate procedures to signpost patients to other sources of information and support, including to relevant mental health organisations. Mind believes that this needs to go beyond general national helplines, for example Samaritans, and should focus on what support is available in local areas, such as crisis cafes. Building contacts and relationships with other support organisations in local areas will help providers to achieve the knowledge needed to safeguard people appropriately, and Mind believed this ambition should be included in providers' safeguarding strategies wherever possible.

CQC has found there is a need to develop a clear understanding about the opportunities and effective delivery of primary care services online. It is important that the health and care system builds an understanding about the demographics of the people who use online channels for primary care the most, and the potential barriers for those who do not. The wider system needs to work together to overcome these barriers, not only with health and care providers, but also with organisations outside health that are essential to widespread uptake – for example, those responsible for communications infrastructure.

This report

In this report, we present what CQC found about the quality of care delivered by independent online-only primary health care providers in England.

The evidence collected through our inspections is beginning to give a detailed picture and provides a baseline against which we can continue to monitor and measure the quality of independent primary health care delivered online in England.

When we inspect a provider for the first time, we carry out a comprehensive inspection, where we look at all of our five key questions (is the service safe, effective, caring, responsive and well-led?). Re-inspections are usually focused. A focused inspection follows a similar process to a comprehensive inspection but is smaller in scale, and looks at areas where we have concerns, either following a comprehensive inspection or from information received through our monitoring activity.

We carried out qualitative analysis of a sample of 25 published reports (18 comprehensive inspections and seven focused follow-up inspections) and we also analysed findings from inspections through interviews with CQC's National Clinical Advisor for Independent Health and Digital Healthcare, and inspectors who have been involved with the programme.

This analysis focused on:

- issues identified on inspection
- the characteristics of good quality care and notable practice
- outcomes from re-inspecting where we had previously found poor quality care.

We are committed to engaging with the public and people who use services to understand their experiences of care. We therefore engaged with representative organisations to get an insight of particular groups of people in relation care provided in an online environment. We carried out telephone interviews with:

- Mind
- Age UK
- Carers UK
- Men's Health Forum
- Patient's Association
- Asthma UK

We include some of their views in this report as further evidence of people's perceptions about primary care provided online.

Findings from inspections

Between November 2016 and July 2017, CQC carried out 35 comprehensive inspections of online primary health care providers. This included the two initial inspections that were in response to risk and all others as part of the programme of first inspections. By the end of February 2018, we had re-inspected and reported our findings for 16 of the 35 providers at least once (five of the 35 providers inspected initially were no longer registered with CQC at 28 February 2018).

Although at the time of the inspections CQC did not have the legal powers to give a rating to these services, we always asked our five key questions: were services safe, effective, caring, responsive and well-led? We also judged whether providers were meeting the necessary regulations associated with each key question.

Findings by key question

Of the five key questions that we looked at, performance was the highest for the caring question, followed by the responsive question. As with most types of provider that CQC regulates, where we found concerns, these frequently related to the provider's approach to safety and how well it was led and managed. Particular issues and areas for improvement were mostly around providers' systems and processes to deliver safe and effective care and for leadership under the well-led question.

Safe

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

The first inspections in the programme started with those providers where we had identified the highest level of potential clinical risk. Of the 35 providers inspected, 30 did not fully meet all the associated regulations under the safe key question, as we identified a range of concerns. These issues ranged in seriousness from where we identified examples of unsafe practice, to where we identified a lack of processes that increased the risk of poor quality care.

In the first inspections, five providers were meeting the relevant regulations for the safe key question (these five providers also met the regulations across all five key questions).

Re-inspection has shown improvement: at the end of February 2018, 17 providers were meeting regulations for the safe key question.

Where providers were not delivering safe care, we identified that it was common for them to also not be providing effective or well-led care in accordance with the relevant regulations.

We found a range of issues under the safe key question, including concerns in relation to:

- ineffective systems for monitoring long-term conditions; the range of conditions treated and treatments offered varied significantly between providers, but the treatments offered were not always considered in light of the limitations of the this method of consultation

- systems to keep people safeguarded from abuse and a lack of safeguarding awareness specific to providing care in an online environment

- lack of clinical oversight and monitoring

- limited identity verification to underpin safe care and treatment

- ineffective systems to monitor, record and act on patient and medicines safety alerts

- limited information sharing with patients' GPs.

We include some examples from inspection reports and discuss these in further detail under the key issues section of this report.

Effective

To consider how providers performed for this key question, we looked at evidence-based practice, the way providers review patient outcomes, quality improvement activity (including audit), consent to care and treatment, access to treatment, training for staff, coordinating patient care and information sharing.

On first inspection, 10 providers were meeting the regulations associated with the effective key question. Of the 25 that were not fully meeting these regulations, we identified two main issues from our inspections:

- prescribing that was not in line with evidence-based guidance

- information not being shared with a patient's NHS GP in accordance with guidance from the General Medical Council (GMC).

We saw improvement on re-inspection, and at the end of February 2018, 19 providers were meeting regulations for the effective key question.

To provide effective care, training for staff is essential. There was a mixed picture in respect of training for both clinical and non-clinical staff. In some providers, we saw evidence that staff had undertaken training appropriate to their role and that it was being monitored. In these providers, clinicians could not start consulting with patients until they had provided evidence of their training, for example, training certificates.

In other providers, although staff had received training, providers were not able to show us evidence of this during the inspection itself, which highlighted weak governance and oversight arrangements. Some providers relied on a doctor's GMC registration as evidence of training being up to date.

We also found in some providers that not all staff had received appropriate training and there was a lack of oversight to ensure that training was up to date. In some cases, we identified that clinicians as well as non-clinical staff lacked awareness about safeguarding, capacity and consent. These are discussed in more detail under key issues section.

We also saw limited evidence of quality improvement activity, such as clinical audit or the peer review of clinical practice.

Caring

Under this key question, we reviewed providers' systems and arrangements for maintaining patient confidentiality, providing access to information about services, and gathering patient reviews. This enabled us to look specifically at the areas of compassion, dignity and respect, and involvement in decisions about care and treatment.

On first inspection, nearly all providers (31) were found to be delivering caring services in line with the regulations. Two were not fully meeting all the associated regulations and for two providers, we did not make a judgement on whether they were meeting the regulations.

Many providers had engaged with an online review website to gather feedback from patients and had scored over nine out of 10 based on these patient ratings. In addition, many providers directly sought feedback following patient consultations and were able to demonstrate a high level of patient satisfaction.

For sexual health services, we identified a caring approach when giving patients their test results, as providers telephoned them rather than just emailing their results. We also identified that providers offered partner notification services, where they could confidentially trace a person's contacts (with their consent) to flag to those who may have been at risk and encourage them to be tested.

Of the two providers that were not fully meeting the regulations relating to the caring key question, one provided a questionnaire-based service where, on the first inspection, we identified that the provider had not ensured that email accounts had sufficient protection for personally identifiable information. Therefore, the provider's information governance system was an area for improvement to ensure that patient information is stored and kept confidential. This provider was also not meeting the regulations against all five key questions, although we did find significant improvement on re-inspection.

For another provider offering a questionnaire-based service, we found no evidence of the provider making checks to govern when and where the clinician accessed patients' records or carried out consultations. We were also not assured that consultations were always carried out in an appropriate location.

Across all services, providers expected that clinicians would carry out consultations in private and maintain the patient's confidentiality. Clinicians often worked remotely and, although some providers checked to ensure they were complying with policies and guidance to meet these expected service standards, this was not always the case.

Our inspections found that information for patients was often available and there were dedicated staff to respond to queries. However, there was variation in the extent of information for patients to help them to be involved in their decisions about their care, with some providers only making limited details available and with limited accessibility (see responsive). We also saw an instance where, although there was information on medicines and pricing, some of the information could be misleading for patients.

Responsive

We looked at responding to and meeting people's needs, tackling inequality and promoting equality, access to services and listening and learning from concerns and complaints under this key question.

On first inspection, we found that the majority of providers (28) were delivering responsive care, and seven were not fully meeting the relevant regulations for the responsive key question. At the end of February 2018, after re-inspection we saw improvement, and only three providers were not meeting the associated regulations.

Online primary care providers were able to demonstrate that they provided convenient access to services, with patients able to book a video consultation or submit a consultation questionnaire through the providers' websites 24 hours a day, seven days a week. Some providers aimed to issue prescriptions within an hour for those requested on weekdays. One provider offered patients the ability to book and have a consultation 24 hours a day, seven days a week.

Examples of responsive care during the first round of inspections included providing health promotion information, making type talk available for patients with hearing loss, providing online information in a different language in response to an increased uptake of services from a particular population group, and designing websites with regard to web content accessibility guidelines.

On first inspection, in the seven providers that were not providing responsive care (all offering questionnaire-based services), we found issues including:

- limited systems to choose a clinician of a particular gender, who spoke a specific language or who held a specific qualification

- lack of translation services

- unclear information about the limitations of the service provided, and no information on websites to tell patients to contact the appropriate service in an emergency

- limited information to tell patients how to make a complaint

- lack of an effective and accessible system for identifying, receiving, recording, handling and responding to complaints, to enable learning and improvement.

Although our analysis of inspection reports did not demonstrate any discrimination against specific client groups, in a number of reports we identified that improving accessibility of services was an area for improvement. For example, some providers only had information on their website in English and many did not have translation services and had not fully considered the need for these. Several providers had not made any assessment of the needs of patients with sensory impairment.

Well-led

Our analysis looked at business strategy and governance arrangements, leadership values and culture, safety and security of patient information, seeking and acting on feedback and continuous improvement.

Leadership affects the whole organisation, and the effects of good or poor leadership are reflected in a provider's performance in the other key questions. The well-led key question reflects how a culture of monitoring and improving quality through effective clinical leadership is central to delivering safe and effective care. CQC has found this to be the case in all sectors that we regulate.

On first inspection, we identified good leadership in 12 providers. In well-led providers, all staff were able to access up-to-date policies, procedures and systems to ensure that all patient information was stored securely and kept confidential. There was a clear organisational structure, staff understood their responsibilities and were involved in

discussions about how to run and develop the services. These providers also had a clear vision. The quality of their services was monitored through regular programmes of checks, which were then discussed at clinical team meetings to ensure that they shared findings and made improvements. In addition, providers routinely asked patients for feedback following consultations; where it fell below expected standards, they carried out a review. As at 28 February 2018, 22 providers were meeting the regulations associated with the well-led key question.

However, on first inspection we found that 23 of the 35 providers were not well led.

Some of the issues reported for providers included:

- lack of clinical leadership

- a lack of effective quality monitoring systems and quality improvement activity

- policies and procedures that were not up-to-date, did not reflect the considerations of providing care in an online setting and did not reflect national guidance

- ineffective systems to disseminate information to ensure all staff were aware of and had access to policies, and that lessons were learned.

We discuss these under the key issues section.

Key characteristics of good care

On first inspection, five providers were delivering care that met regulations associated with all five key questions. Two of these providers used real-time video consultations and three offered questionnaire-based services. Despite the differences in the type of services provided, all these providers had similar characteristics. As previously mentioned, CQC has found that good leadership, management, and governance of policies and processes are essential in providing good quality care and positive outcomes for patients. Good performance for the well-led key question therefore affects the other four questions.

The following are some examples of the characteristics that we saw from these five providers.

Systems to verify patient identity

Although one of the providers offering questionnaire-based services carried out only limited identity checks, relying on checking patients' payment cards, it was commissioning an external organisation to verify patient details through national databases. It had also carried out an effective risk assessment, which concluded that the medicines prescribed were 'low risk'.

Another questionnaire-based provider had implemented further checks to confirm a patient's identity at the point of collecting a prescription. This provided a further opportunity to put safeguards in place for potentially vulnerable patients.

Clinical leadership and quality improvement activity

We saw that these providers carried out a range of consultation and prescribing audits to improve patient outcomes and to ensure prescribing was appropriate and evidence-based. The providers also monitored record-keeping and held regular clinical meetings. For example, one provider had a clinical oversight board that took an active role in approving any new services offered to patients.

Understanding safeguarding

Providers had an understanding of safeguarding and a willingness to improve awareness across their service to ensure that they protected patients from harm and abuse. For example, they extended safeguarding training to child protection Level 3 to all clinicians and raised awareness of the named safeguarding lead. A questionnaire-based provider had worked with the General Medical Council and the NHS England Safeguarding Lead to develop a policy that was specific to the online environment and this provider had been invited to share learning at the British Association for Sexual Health and HIV 2017 conference.

Sharing information appropriately with GPs

Providers routinely asked patients if details of their consultation could be shared with their own GP. One provider made this easier by having a 'look-up function' on its website to enable patients to identify the contact details for their GP practice. In another provider, sharing information with a patient's GP was a mandatory requirement, and if they did not receive consent the staff could not issue prescriptions. Where it was not mandatory to share information, providers encouraged patients to provide their GP's details to support safe and effective care. We saw examples of information being shared in line with guidance from the GMC and copied to the patient.

Understanding consent and capacity

All staff in these providers who had contact with patients had received training about the Mental Capacity Act 2005, and staff understood and asked for patients' consent to care and treatment in line with legislation and guidance. Where it was unclear whether the patient had the mental capacity to consent to treatment, the GP assessed the patient's capacity and recorded the outcome of the assessment. Two providers monitored the process for seeking consent through audits of patient records.

We also identified some other areas of notable practice across published inspection reports:

Building evidence for practice

One provider stood out as a research-led organisation. It was actively looking at ways to improve and offer an effective and convenient sexual health service based on its own research. The provider had carried out a randomised control trial, which showed that its online sexual health testing service increased access for all socio-demographic groups, which may increase diagnoses. The service was able to demonstrate evidence of its other research activities that were published or were pending publication in peer reviewed journals.[8]

Patient follow-up

We saw examples of established feedback systems to ascertain how effective treatments had been, or whether a patient had experienced side-effects or had concerns. One provider followed up patients after the consultation and again after seven days. We saw very positive feedback from patients regarding systems for follow-ups after all consultations.

Responding to patients' needs

The pharmacists at this provider gave feedback about their experience of delivering the meningitis B service to children, which prompted the provider to produce a video for parents to help them understand what to expect at their appointment and the role they had to play. This provider also became aware of a significant uptake in the number of Chinese students requesting services, which resulted in them producing an information leaflet in Mandarin.

Key issues from inspections

From the analysis of inspection reports, and the feedback from inspectors and our National Clinical Advisor, there were some common areas of concern from this inspection programme that enabled us to identify a number of themes where improvement was needed. These are relevant both to an online-only setting and also to the wider delivery of remote consultations. These themes are inter-linked, and we could identify a combination of these issues for a number of providers, which increased the risk of poor quality care.

During inspections we identified the following six common themes where poor performance risks providing poor quality care:

- safe prescribing

- safeguarding in the context of an online environment

- verifying patient identity to provide safe care and treatment

- assessing mental capacity

- obtaining consent

- communicating with patients' GPs (NHS or independent sector).

Safe prescribing

There were a number of concerns relating to safe prescribing, which were often exacerbated by a lack of clinical oversight and governance to ensure that clinicians were prescribing appropriately.

The O'Neill report on antimicrobial resistance clearly describes the challenges of prescribing antibiotics.[9] One of the report's key recommendations was the need to limit the overall prescribing of antibiotics. The UK Five Year Antimicrobial Resistance Strategy recommends "the right antibiotic at the right time and for the right duration" as well as the need for clinicians to remain up to date with emerging evidence on resistance and appropriate antibiotic usage.[10]

There is also concern that some clinicians are managing the challenge presented by the remote nature of care by lowering the threshold at which they prescribe antibiotics.[11] In our inspections, we saw that this was a particular challenge for video-based services. On inspection, we saw examples where, because the clinician was not able to effectively carry out the usual clinical assessment that would be normal practice in a face-to-face setting, such as examining a patient's chest, ears or throat, the threshold for prescribing antibiotics had been lowered.

Prescribing for long-term conditions

Patients with long-term conditions such as asthma or diabetes need to be monitored regularly. For asthma in particular there is strong evidence from The Royal College of Physicians and Asthma UK that over-prescription of reliever inhalers is a strong indicator of poor asthma control, which increases the risk of hospitalisation and death and should signal a need for urgent review of asthma control.[12, 13] Inspection identified this as an area of concern as providers did not always have systems to monitor these patients. Combined with a lack of formalised prescribing guidance and limited information sharing with patients' GPs, this presented significant risks to patients.

We did find some examples of good practice in this area, with providers incorporating alerts into clinical systems to identify where the number of prescriptions issued might exceed national guidance.

On re-inspection, we found some improvement where it was needed. Examples included providers requiring consent to share information with the patient's GP in order to agree to prescribe certain medicines; by developing specific prescribing policies for these conditions, and, in some providers, by carrying out a review of the range of treatments that they offered. In one questionnaire-based provider, we had identified that a patient had been prescribed 12 asthma reliever inhalers over four months. When we re-inspected, we saw that the provider had reviewed the treatments that were available and no longer offered medicines to treat long-term conditions that it considered to be higher risk.

The prescription of long-term opioid analgesics in isolation from the wider healthcare system presents a source of significant concern. While not widespread, this issue was compounded by the volume of opioid analgesics being prescribed, and a lack of information sharing with the patient's GP, both before and after prescribing.

Another area of concern was medicines not being prescribed in line with evidence-based guidance, for example from the National Institute for Health and Care Excellence (NICE). One provider had no evidence-based tools for clinicians; in other providers the medical questionnaires for patients to fill in did not align with evidence-based guidelines; and in others we saw examples of prescribing that was outside of national guidance. For example, we found a medicine used for excessive sleepiness, which requires specific investigations both before and during use, was being prescribed without this monitoring, which did not support safe prescribing.

Even where clinicians told inspection teams that they followed evidence-based guidance, some providers did not have any processes to monitor the quality of prescribing, for example, by auditing individual prescribing decisions or clinical peer review processes and regular review of consultation tools. This demonstrated a concerning lack of clinical oversight.

On re-inspection, there was some improvement, for example, through appointing a clinical lead to review clinical assessments, and re-designing patient questionnaires.

What patients and the public think

Groups representing the public felt that over-prescribing should flag up to providers that patients need to receive appropriate clinical review, particularly those suffering from asthma. This is because asthma attacks can occur suddenly and sometimes catastrophically, and they are often preceded by hours or days of high emergency (usually blue in colour) inhaler use. Asthma UK told us that identifying people with asthma who are high risk and have poor control is central to preventing poor health outcomes and deaths resulting from asthma. It is essential that prescribing medicine for asthma does not happen in isolation.[14]

Patient and medicines safety alerts

Not all providers had effective systems to monitor and act on alerts. In some services, providers relied on clinicians dealing with alerts themselves, and as a result the provider had no oversight as to whether any patients may have been affected by medicines that were the subject of safety alerts. In other providers, there was no evidence to demonstrate that alerts had been shared with relevant staff and the most recent alerts had not been recorded, which meant clinicians were unaware of potentially serious side-effects of medicines they were prescribing. When re-inspecting one provider, we saw that it had not taken action by amending its patient medical questionnaire in response to an alert regarding the risk of suicide associated with a medicine.

In addition, some IT systems did not have the functionality to easily identify patients who would be affected by specific alerts, and searching patient records was not a straightforward process.

Off-label medicines

There are clinical situations when the use of unlicensed medicines or use of medicines outside the terms of the licence ('off-label') may be judged by the prescriber to be in the best interest of the patient on the basis of available evidence. We found an issue around safe prescribing where providers did not seek specific consent from patients, and patients were not being adequately informed, that medicines were being prescribed outside of the terms of their UK licence or that they had no licence for use in the UK. Guidance from the General Medical Council states that prescribers must give patients (or their parents or carers) sufficient information about these medicines to allow them to make an informed decision.[15] A number of providers made no statement on their websites to inform patients if a medicine was being used for an unlicensed purpose and the only patient information provided was the manufacturer's leaflet, which only referred to the licensed use.

On re-inspection, some, but not all providers had made improvements in these areas.

Prescribing policies and guidance

We saw that these were not always up-to-date or didn't reflect what actually happened in practice. For example, some clinicians had prescribed medicines such as controlled drugs, sedatives and strong painkillers, which was not in line with their provider's consultation policy. At one provider, 137 prescriptions had been issued for medicines that its policy had specified should not be prescribed. Although the provider had systems to monitor the quality of prescribing, they had not identified all these cases.

Some providers did not have clinical or prescribing policies and when they were introduced, they were not in line with evidence-based guidance. In some providers, clinicians did not have access to a complete provider-held patient record. Clinicians in one provider relied on receiving information collated by non-clinical staff and there were cases where clinicians

always relied only on information given by patients themselves, rather than requesting and obtaining supplementary information, such as blood test results, to assure themselves that they were prescribing safely. For example, in one provider, female patients were not asked details to ascertain if they were pregnant, breastfeeding or planning to start a family, which posed a serious risk as it meant that contra-indicated medicines could be prescribed.

Ineffective or insufficient systems for monitoring prescribing in some services meant that there was limited evidence of quality improvement activity. In these services, arrangements were also minimal for identifying, recording and managing risks, and implementing mitigating actions.

Managing prescribing records

Another area that affected the safety of prescribing was in managing the quality and completeness of prescribing records. In the case of one provider, two GPs kept their own set of clinical records, which were not readily available to each other. Any email correspondence was only visible to the GP who sent it and although the GPs had access to the patient's previous orders with the provider, their full history was not visible to both GPs.

Patient records often lacked a record describing the clinical rationale, or even diagnosis, leading to the decision to prescribe, and did not always record the rationale for prescribing medicines outside of their licensed use. Notes and information gathered as part of a consultation were not always fully completed, in some cases even in the diagnosis field.

Further examples of poor and unsafe prescribing included:

- non-clinical staff receiving applications for medicines and making an assessment about the validity of the application

- a protocol for emergency contraception that could have resulted in unintended pregnancy

- a patient being prescribed non-recommended medicines for migraines and, despite this being acknowledged by the prescriber, there was no rationale recorded for this

- a patient being prescribed four courses of antibiotics for urinary tract infections, which was inappropriate as they should have been referred for further investigation, and the prescribing was not in accordance with national guidance

- a provider prescribing opioid analgesics for periods longer than two years without contacting the patient's GP or having access to their full medical record.

> **Example of poor prescribing practice**
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> We saw that prescriptions, including some from overseas, would be transcribed and signed by the doctor. These included medicines for diabetes, Parkinson's disease, heart disease and a treatment for mental ill health – in all cases, conditions or medicines that required regular monitoring. There was no provision within the provider for the doctor to undertake this monitoring, and no evidence that the provider had ascertained that it was being carried out elsewhere.

Safeguarding

Providers did not always have clear systems to keep people safeguarded from abuse. Many had not fully considered how they could take safeguarding into account when delivering online services nationally. There was insufficient understanding of safeguarding, with some providers not having a named safeguarding lead.

Although providers told CQC's inspection teams that their clinicians had undergone appropriate safeguarding training, we could not always see evidence of this, despite it often being a requirement for the clinician to provide training certification before consulting with patients. We also found a lack of awareness of the importance for not just clinicians but all staff who have contact with patients or access to patient records to have an understanding safeguarding, to have received training appropriate for their role and to have access to relevant policies.

Examples of poor practice included adult safeguarding training for clinicians that was not up-to-date, and on more than one inspection we saw that clinicians failed to respond appropriately to scenarios relating to potential safeguarding issues.

Where policies were in place, they were not always tailored to the service or specifically to safeguarding in an online environment, and did not include appropriate details of agencies to enable them to make referrals if required.

Staff working remotely did not always have access to policies. Even where all staff did have access to policies there was evidence that not all were aware of them because of ineffective arrangements to disseminate information. For example, although one provider had a safeguarding policy, it was only available in paper form or on the registered manager's computer.

> **What patients and the public think**
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> Age UK recognised the value of online consultations, specifically as they provide access to care for carers who may not easily be able to make appointments for their own needs. However, there is a concern that a carer may be able to have consultations on the patient's behalf and that a patient may be coerced, which would not be picked up through an online consultation. There is also a risk that abuse and/or living in unsafe conditions may go unnoticed if care is being accessed primarily online.
>
> In addition, Age UK also raised the concern that older people are particularly vulnerable to online scams and that accessing bogus online providers could risk stolen identity and fraud.

Safeguarding children

Where providers treated children, inspections found variable arrangements to ensure that they were protected. Some providers needed to review their arrangements to improve in this area, including implementing appropriate checks to verify the identity of the patient or systems to ascertain the relationship between the child and any accompanying adult, and ensuring that safeguarding policies considered these issues.

Following re-inspection, we identified that some providers had made improvements in this area to mitigate risk, for example, either by introducing checks to verify the parental responsibility before a child could be registered with the provider, or by reviewing the age limit of patients that they could treat. This improvement was in response to our enforcement action in one case.

There has been a lack of understanding about responsibilities to safeguard children by those providers who state they provide only to adults. The competencies are set out in *Safeguarding children and young people: roles and competences for health care staff – Intercollegiate Document* (2014).[16] CQC has clarified our position in relation to 'adult' services and expectations around safeguarding children in the Inspector's Handbook – Safeguarding.[17]

Verifying patient identity

In August 2017, CQC and partner regulators published a letter to providers about the key themes we found, which stated: "Identity plays an important role in ensuring that patients are who they say they are for the purposes of safe care and treatment. Prescribing for potentially unknown patients makes the identification or escalation of safeguarding concerns unreliable – as well as creating issues around correct or appropriate prescribing, accurate communication with other healthcare professionals and safe sharing of clinical information between providers and professionals involved in a patient's care."

Across both questionnaire-based providers and those offering and real-time video consultations, identity checking was reported as an area for improvement. Inspectors also acknowledged that there has been a lack of clear guidance for online providers on the issue of identity checking and that, even with checks in place, it is difficult to eliminate the associated risks entirely.

Some providers had no systems to verify identity and would only ask for verification if patients gave contradictory responses. Others relied on credit card checks as the primary method of verifying, and their systems had not been risk-assessed to ensure they were appropriate. Where procedures were in place, they were not always followed and there were examples of prescriptions being issued without proof of an identity check. Furthermore, some providers also allowed members of a patient's family to access their services, but not all these providers checked the identity of relatives.

The absence of adequate identity checks in providers that only treat adults, particularly for questionnaire-based providers, meant that they could not assure CQC that they did not offer treatment to children. This issue is inter-linked with the issue of safeguarding children. For providers that did treat children, there were not always appropriate checks to verify the identity of the child and ascertain the relationship between the child and an accompanying adult.

What patients and the public think

Some representative groups viewed confirming identity online as a 'two-way situation' as patients procuring online services also need to know that the doctors are who they say they are, and that their qualifications and expertise is genuine. This was particularly important for patients with a mental health condition: confiding in an online GP requires a certain level of trust for full disclosure and there is no rapport established with an online doctor as they remain essentially anonymous.

Our engagement with Men's Health Forum also raised the issue that some people may use online services specifically for 'embarrassing problems' and that requiring proof of identity when registering might prevent some people from seeking help.

Overall, the patient representative groups thought that verifying identity is important to mitigate risk and provide safe care, particularly when prescribing.

We found some improvements on re-inspection. For example, when re-inspecting a real-time video-based provider, we found stronger identity checks of the children and relatives of corporate customers. This provider had amended its policy to require relatives to provide evidence of their identity before using the service by photographic identification and a contemporaneous photograph and also evidence of parental responsibility for children. Patient accounts were only activated once these checks had been completed. We also found that providers had moved from minimal identity checking to using the services of an identity checking agency.

Consent and capacity

A number of providers had no procedure for assessing a patient's mental capacity during a consultation. Some providers assumed that adults had capacity if they were able to complete the processes to register and order a prescription, or if they agreed to the terms and conditions of use on the website. However, particularly in an online environment with no face-to-face contact, this in itself it is not evidence that someone has mental capacity to determine their care or treatment. There should be a robust system to identify where there might be concerns about mental capacity and to perform appropriate confirmation. Coupled with limited access to a patient's medical history and subsequent sharing of information with GPs, this increased the risk of inappropriate prescribing.

Inspections identified a lack of understanding of the Mental Capacity Act 2005 (MCA) across a number of online primary care providers and inspectors were not always assured that staff asked for patients' consent to care and treatment in line with legislation and guidance. For some providers, even where clinical staff did understand the need for consent, their policies were not always up-to-date, with no guidance on when consent was needed and no information on the requirements of the MCA.

On more than one inspection, clinicians failed to respond appropriately to scenarios relating to a patient's capacity to make decisions. In some providers offering questionnaire-based services, it was very uncommon for the prescribing doctor ever to speak to a patient, which made the assessment of capacity difficult.

Although some providers had ensured that GPs and staff were aware of the MCA, not all of them had received specific training about the MCA or they could not provide evidence of this training. On re-inspection we saw improvement, as staff had either completed training or were due to receive it, and providers had amended patient questionnaires to help identify patients for whom they would need to complete additional mental capacity documentation, and who should receive assistance.

Providers that were delivering safe, effective, caring, responsive and well-led care had trained all their staff who had contact with patients in the MCA, and the staff understood and asked for patients' consent to care and treatment in line with legislation and guidance. In these providers, where a patient's mental capacity to consent to treatment was unclear, the GP assessed this and recorded the outcome of the assessment. Two providers monitored the process for seeking consent through audits of patient records.

> **What patients and the public think**
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> Groups representing patients highlighted that some people with mental health conditions may require more specialist help than a GP would be able to identify over a questionnaire-based consultation.
>
> They fully supported standardised questions and exercises to help to ascertain mental capacity and to identify patients who may need more help.

Another issue identified through inspection was providers not seeking specific patient consent in relation to the use of medicines outside of their licensed indications. In providers that met regulations associated with the safe and effective key questions there was limited prescribing of medicines in this way and they were only issued after patients gave informed consent to receive the medicine outside of its licensed indication. These providers recorded clear information on the consultation form and gave additional written guidance to patients on how to use the medicines safely. However, in other providers there was variability in what information was available to patients and whether they sought consent.

However, in some cases patients were not being informed that the medicine requested was being used outside of its licensed indication and the implications of this, and there was no evidence of consent. On re-inspection, we saw evidence of providers producing tailored information leaflets explaining how to use the off-label medicine in the context that it was being prescribed.

Sharing information appropriately

Patients can access care from a range from primary, secondary and tertiary care providers in the NHS, and also from the independent sector (for example, clinics, hospitals, or from an online GP). Appropriate sharing of information between providers involved in a patient's care is an important part of good practice (as outlined in guidance from the General Medical Council on remote prescribing).[18] This is particularly (though not exclusively) important when managing long-term conditions, or prescribing medicines that require ongoing monitoring, or medicines with the potential for misuse.

Inspections found considerable variation in both the level of information sharing that took place with patients' own GPs and the awareness of why this was important to ensure safe prescribing.

Good practice included arrangements to ensure that if a decision was taken to prescribe without sharing information with the patient's GP, this had to be justified and would automatically be flagged to the clinical lead.

The General Medical Council's *Good Medical Practice* emphasises the importance of continuity of care, and sets out the responsibility of doctors to contribute to the safe transfer of patients between healthcare providers. The explanatory guidance states that doctors must share all relevant information with colleagues involved in their patient's care, including all relevant information about their current and recent use of other medicines, other conditions, allergies and previous adverse reactions to medicines. It also states that when providing care, doctors who are not the patient's GP must tell their GP about changes to the patient's medicines including existing medicines changed or stopped and any new medicines started. Doctors must also include information about the reasons for the changes, the intended length of treatment, and the monitoring requirements.

The guidance also explains the importance of doctors asking for the patient's consent to contact their GP, and that if the patient objects, doctors should explore their reasons and explain the potential impact of their decision on their continuing care. If the patient still objects, doctors should consider whether the information they have is sufficient and reliable enough to enable them to prescribe safely. If they do prescribe, there should be a clear record of the decision and the reasons for it. If they decide that they do not have enough information, they should explain to the patient that they cannot prescribe for them and what their options are.

General Medical Council

Many providers routinely asked patients whether the details of their consultation could be shared with their GP, although this was not always recorded. However, some providers only collected details of a patient's GP if the patient gave consent to share the information, and GP details were not required to be recorded irrespective of whether information would be shared. In these providers, for patients that did not provide consent, there were no details to fall back on in case of an emergency.

We identified some improvements through follow-up inspections, with examples of providers making it mandatory to provide GP details as an additional safeguard in an emergency. Where patients did not give their consent to share information, clinicians discussed this with them to ensure that they understood why they were asking for consent. However, this was not the case for all providers.

Even when patients gave consent to share information, we found examples where information had not been shared with their GP. In one case, a provider had not shared over 400 patient contacts with GPs, when they had the consent to do so and should have done.

This was even the case for long-term conditions, where a consistent approach to care is important. We also saw a lack of sharing in relation to the prescription of medicines that have a potential for misuse.

Examples of poor prescribing practice

In one particular provider that prescribed a high volume of opioid medicines, a clinician told the inspection team that they had never asked for information from a patient's GP and the provider could not show evidence of any information-sharing at all. A review of patient records found cases where opioid analgesics and other analgesics subject to misuse had been prescribed for up to two years without contacting the patient's GP and with no access to the patient's full medical records. Some of these medicines had been unsafely prescribed and included a case where an opioid medicine was prescribed despite the patient confirming that their GP would not prescribe it. Although on re-inspection the provider had increased the amount of information it shared, we still had concerns about the prescribing of opioid medicines.

In another provider, although it had implemented limits to restrict some prescriptions (opioid medicines and asthma inhalers) that patients could receive before they had to consent to their GP being informed, they were still able to receive medicines without information being shared with the GP. However, on a further inspection, we saw that the provider had taken action so that it was now mandatory to share information with the GP if opioid medicines or inhalers were being prescribed. In addition, the provider also implemented restrictions in the clinical system where an opioid prescription triggered an automatic letter to the patient's GP where there was consent. If the GP declared that the patient was not actually registered at that practice or that the treatment was inappropriate, the patient's account was frozen so that further prescriptions could no longer be issued.

What patients and the public think

Groups told us that sharing information with a patient's GP is essential to identify those at risk. They identified a need to look at the system as a whole and have one method of sharing information at the system level, with access to details of patients' conditions and summary care records. As such, there is a need to establish the identity of the patient and to establish a way of sharing data between providers – both independent and NHS providers.

Sharing information between healthcare providers is especially an issue for people experiencing more than one long-term physical health condition and/or mental health condition. When prescribing medicines for a patient it is essential to have the full information about all the medicines that the patient is taking to avoid prescribing a medicine that may interact with, or adversely affect, a medicine the patient is already taking and to avoid the possibility of restarting a treatment that has been tried previously and found to be ineffective.

For people with asthma, there is a crucial need to share information with GPs, to enable patients to receive a personal asthma action plan that details their own triggers and current treatment, and specifies how to prevent relapse and when and how to seek help in an emergency.

Asthma UK told us that from a safety perspective, if an online provider prescribes asthma medication this information must be shared with a person's GP as a default. They stated that joined-up communication between online providers and a GP involved in managing someone's asthma is critical to ensure that the GP has the full picture and can identify patients with poor control and who may be at risk of an asthma attack. Without this link, there is a risk of more high-risk prescribing. As the National Review of Asthma Deaths advised, asthma deaths can be prevented when system-wide measures are put in place to prevent unsafe prescribing.

Groups felt that it is essential for people's care to be coordinated as much as possible to ensure patients get the right treatment and consistent information, rather than conflicting advice that many receive when seeing multiple practitioners.

There are many nuances with safeguarding and sharing information, but patient groups felt it was important to pass on information to patients' GPs. At the same time, they felt it was also vitally important to encrypt information and for providers to have the necessary processes to meet confidentiality criteria.

Improvement – evidence from follow-up inspections

We are pleased that many organisations are taking on board feedback from our initial inspections and implementing changes to improve their services.

By the end of February 2018, we had re-inspected and reported our findings for 16 online primary care providers at least once, and many have demonstrated improvements. Fourteen of the 16 providers with follow-up inspections have demonstrated improvement against some of the key questions, and the remaining two providers were no longer registered as at 28 February 2018.

Safeguarding

Where we had previously found concerns around safeguarding, our follow-up inspections found evidence that providers had improved by updating their policies and by training staff in safeguarding appropriate to their role. One follow-up inspection found that the provider had introduced a safeguarding emergency alert button for staff, which would send an alert to the clinical lead to investigate further.

Quality assurance and improvement

Following initial inspection we saw that many providers had introduced systems to monitor the effectiveness of their services. We saw examples of introducing clinical audit and adopting systems of peer reviewing clinical activity.

Consent and capacity

We had initially identified concerns in a questionnaire-based provider in relation to assessing capacity. On re-inspection, the provider had introduced a new policy to guide clinicians, which highlighted the need for vigilance when assessing written information from patients in order to consider potential concerns about capacity. The provider then also provided links to consent and capacity assessment support tools for its clinicians.

Sharing information with GPs

Many providers responded to concerns about lack of information with patients' GPs. Some changed the range of clinical conditions that they were prepared to manage in an online environment, for example, no longer treating long-term conditions online, including asthma. When we first inspected one provider, it responded extremely quickly to our concerns in relation to the treatment of asthma. On the day of our inspection, it changed its policy so that it would no longer provide treatment for asthma by prescribing reliever medicines without having permission to share information with the patient's GP.

Conclusion and next steps

Next steps for online care

In CQC's strategy for 2016 to 2021, we outlined our priority to encourage improvement, innovation and sustainability in care by focusing on areas where there may be emerging risks, for example providers of online health. We are also committed to learning alongside providers who offer new care models or use new technology to encourage innovation. We encourage innovation that will improve access to and quality of care, and change that can help manage the pressure in the wider health and care system and improve sustainability for the future.

Delivering primary health care online is a growing and evolving area, and our first round of inspections was prioritised in response to intelligence about significant risk to patients. Inspections highlighted variation in quality, with the most important areas for improvement around the safety and effectiveness of care and treatment, in particular relating to:

- safe prescribing
- safeguarding in the context of an online environment
- verifying patient identity to provide safe care and treatment
- assessing mental capacity
- obtaining consent
- communicating with patients' GPs (NHS or independent sector).

These echo the themes found from our work with our partner regulators, which we jointly highlighted in 2017.

Where we initially found concerns, our re-inspections have shown a willingness among providers to improve and adapt. We have found examples of good care, for example responding and adapting to meet patients' needs, carrying out clinical oversight and quality improvement activity, and following up patients, both to check on their health and to gather feedback to improve.

We have learned a great deal about the strengths and limitations of primary health care provided online. One of the main barriers we found to providing safe, high-quality care is a lack of coordinated two-way sharing of information between providers – particularly in the safe management of long-term conditions, including asthma. As patients receive care from a number of organisations both within the NHS and independent sector, access to their NHS records, underpinned by appropriate safeguards, has the potential to improve the

information available to clinicians that work outside the NHS, and ease the sharing of information back into the wider healthcare system.

Professionals who deliver care through digital channels need to be personally vigilant and act responsibly to balance the benefits of innovation with their professional responsibility to ensure safe care for patients. They need to take due account of guidance, such as from the General Medical Council, the Royal College of General Practitioners and from organisations that represent them, including the British Medical Association. We have worked closely with partner regulators and national bodies to clarify or update guidance to take into account, where relevant, the growth of care delivered through digital channels.

We are aware that delivering primary health care online has the potential to enable access to suit people's personal circumstances. It allows care across geographic borders – both national and international. However, the pace of advancement in technology has outpaced the evolution of the regulations, laid out in the Health and Social Care Act 2008 and the regulations, and this has left gaps in the regulatory landscape.

These gaps can represent risks to patients, care providers and regulators.

For patients, this means services that are available in England, but based outside England, may be unregulated, in contrast to their England-based counterparts. Regulators have limited opportunities to take action in response to harm by providers that are outside the scope of their legal powers. We are working closely with partner regulators to share information and collaborate to minimise gaps, but this does not completely resolve these issues.

For providers, the UK represents a single market for services. The disparity in regulatory frameworks between the four UK nations, and between UK and non-UK based providers means that services may be either unregulated, regulated by one, or by more than one regulator. This increases the regulatory impact on providers, and creates a potentially uneven market between the regulated and the unregulated. We have committed to aligning approaches for remotely delivered services with regulatory partners in the UK, in our joint letter to providers.

For regulators, this poses a considerable challenge in delivering their part in ensuring that patients receive safe, high-quality care, and that providers improve where our legal powers to support this role are limited. Together with our regulatory partners, we are engaging with the Department of Health and Social Care to look at ways to better deliver regulation for patients, providers and the wider regulatory landscape.

CQC has previously had powers to rate only certain types of independent healthcare providers. As a result, we have inspected and reported on providers that deliver primary care online, but not rated them. In 2017, the Department of Health and Social Care consulted on amending the performance assessment regulations to enable CQC to rate most

independent healthcare providers. In January 2018, we received confirmation that we will have powers to rate the providers in this sector, and we published a formal consultation on our plans for introducing ratings more widely in the independent healthcare sector on 26 January. We are now developing our approach in consultation with the public, providers and other stakeholders and will confirm the timescale for introducing ratings when we publish our response to the consultation.

We propose to rate online providers of primary care in the same way that we rate other providers. This includes awarding a rating for each of the five key questions and then aggregating these into an overall provider rating on our four-point scale: outstanding, good, requires improvement or inadequate.

It is important for a consistent approach across the sectors we regulate. We have committed to adopting our approach to online providers as appropriate when inspecting providers that offer online consultation in more traditional healthcare environments.

Through our engagement with the public and providers, we will continue open and active dialogue to gain a better understanding of innovation in the health and care sector, encourage improvement and continue to refine our regulatory approach as online delivery of services grows. This involves working and learning alongside those that are within our regulatory scope – as well as outside it – to identify risks and develop solutions to barriers.

Regulating innovation and new technology

Innovation is a key enabler of improvements in health and social care. Many of the things we now think of as essential to high-quality care were once considered new and innovative, and today's innovations will be tomorrow's best practice. Technological innovation in particular is likely to be crucial to ensuring that health and social care services are sustainable in the future.

The ability of health and social care providers to innovate depends on the context in which they operate, and regulation is an important part of this. When we regulate providers we must allow them to develop and implement innovative ways of improving care, but we also need to make sure that this is done in the right way. Good leadership is crucial to maximising the benefits of innovation and new technology and minimising the associated risks to people using health and care services. It is important that health and care services work together with the people who use them, as well as with commissioners, professionals and others, to develop an understanding of quality, as this is not just for the regulator.

Our strategy for 2016 to 2021 identifies encouraging innovation as a priority. We are continuing to work closely with innovators, providers and the public to understand what good innovation looks like and how our regulatory activity can help to drive it.

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