BG Medical Clinic

Inspection report

48 North Street
Romford
RM1 1BH
Tel:

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This report describes our judgement of the quality of care at this service. It is based on a combination of what we found when we inspected, information from our ongoing monitoring of data about services and information given to us from the provider, patients, the public and other organisations.

Ratings

Overall rating for this location	Inadequate
Are services safe?	Inadequate
Are services effective?	Inadequate
Are services caring?	Requires Improvement
Are services responsive to people's needs?	Inadequate
Are services well-led?	Inadequate

Overall summary

This service is rated as Inadequate overall. This is the first inspection of this service.

The key questions are rated as:

Are services safe? – Inadequate

Are services effective? – Inadequate

Are services caring? – Requires improvement

Are services responsive? – Inadequate

Are services well-led? – Inadequate

We carried out an unannounced inspection at BG Medical Clinic under Section 60 of the

Health and Social Care Act 2008 due to concerns that dental services were being carried out at the service location without being appropriately registered.

At this inspection we took a primary medical services (PMS) and dental team to check whether the service was meeting the legal requirements and regulations associated with the Health and Social Care Act 2008. This combined report includes evidence gathered by the PMS and dental teams.

Following the inspection, we undertook civil enforcement action, under the Health and Social Care Act 2008, by:

- **Imposing an urgent suspension, of six-weeks duration, by issuing a s.31 notice under the Health and Social Care Act 2008.**
- **Issuing warning notices regarding Regulations 12 (Safe care and treatment) and 17 (Good governance).**

BG Medical Clinic Limited is an independent provider of medical services and offers a full range of private general practice services predominantly to the Bulgarian community. This is the first inspection of the service.

Dr Andrean Damyanov is the registered manager. A registered manager is a person who is registered with the Care Quality Commission to manage the service. Like registered providers, they are 'registered persons'. Registered persons have legal responsibility for meeting the requirements in the Health and Social Care Act 2008 and associated Regulations about how the service is run.

Our key findings were:

- The provider did not have an adequate clinical system in place to enable safe prescribing and patient reviews.
- The provider did not submit evidence of appropriate medical indemnity insurance for all clinical staff who worked at the service.
- The provider did not have a system or policy in place to safely manage patient safety alerts and follow-up patients who may be affected by them.
- The provider did not have a system in place to safely manage patients who had been prescribed medicines.

Overall summary

- The provider did not have a system or policy in place to safely manage patients who had a long term condition.
- The provider did not have a system in place to safely manage laboratory test results for patients who attended the service.
- The provider told us that a dentistry, including surgical procedures, was not provided, at the location. However, we reviewed evidence to demonstrate that dentistry, including evidence of surgical procedures, had been carried out at this service.
- The provider did not have a system or policy in place to safely manage recruitment, including disclosure and barring service (DBS) checks.
- The provider could not demonstrate there was oversight of their patient list and relative risk regarding their patient population group.
- The provider did not have a system or policy in place to safely manage emergency medicines and equipment.
- There was limited evidence of a system and processes in place regarding safeguarding children and vulnerable adults.
- Clinical records and ultrasound images were not maintained appropriately from a legal-medical perspective.
- There was an overall lack of clinical governance and oversight for patient care.
- The provider did not have a system in place to safely manage significant events.
- The provider did not have a system in place to safely manage patients complaints.
- The provider did not have a system in place to drive quality improvement, including clinical audit.
- Some staff did not have the required training, knowledge and experience to carry out the roles that were undertaken.

We identified regulations that were not being met and the provider **must** make improvements regarding:

- Care and treatment must be provided in a safe way for service users.
- Establish effective systems and processes to ensure good governance in accordance with the fundamental standards of care.

(Please see the specific details on action required at the end of this report).

The areas where the provider **should** make improvements are:

- Continue to review and update service policies regularly, in line with relevant national guidance.
- Actively seek patient engagement and feedback from those who attend the service.

Dr Sean O'Kelly BSc MB ChB MSc DCH FRCA

Chief Inspector of Hospitals and Interim Chief Inspector of Primary Medical Services

Our inspection team

Our inspection team was led by a CQC lead PMS inspector and a Dental Inspector**.** The team included GP, dental and practice nurse specialist advisers.

Background to BG Medical Clinic

The BG Medical Clinic is located at 48 North Street, Romford, London, RM1 1BH, in the London Borough of Havering.

The provider is registered with the Care Quality Commission (CQC) to deliver the regulated activities: treatment of disease, disorder or injury, diagnostic and screening procedures and family planning

Services provided include: general practitioner services; cardiology; orthopaedic; ENT (ear, nose and throat); paediatric; endocrinology; general surgery and gynaecology consultation services; ultrasound scans; dressings; blood and other laboratory tests. Patients can be referred to other services for diagnostic imaging and specialist care.

The service is open Monday to Friday from 9am to 6pm; Saturday 9am to 4pm and Sunday 10am to 2pm and does not offer out of hours care. The provider's website can be accessed at www.bgmedicalclinic.com

How we inspected this service

To get to the heart of patients' experiences of care and treatment, we always ask the following 5 questions:

- Is it safe?
- Is it effective?
- Is it caring?
- Is it responsive to people's needs?
- Is it well-led?

These questions therefore formed the framework for the areas we looked at during the inspection.

Inadequate

Are services safe?

We rated safe as Inadequate because:

Safety systems and processes

The service did not have clear systems to keep people safe and safeguarded from abuse.

- The provider could not demonstrate they had systems and processes in place to safely manage patients care and treatment. For example, it was not possible to undertake searches and recall of patients due to the severe limitation of the provider's clinical system.
- Safeguarding systems were not fully developed, and we identified several gaps in the provider's system.
- We found training for staff had not been completed at the appropriate level, in line with intercollegiate guidance.
- The provider did not place alerts on patients' records, for whom there may be safeguarding concerns.
- The provider did not maintain registers of patients for whom there may be safeguarding concerns.
- Staff told us there had not been any incidences of patient safeguarding concerns in the past three years.
- We saw that safeguarding was not a standing agenda item in the minutes of practice meetings.
- The provider did not have a system to highlight children and vulnerable patients on their records and did not provide evidence of a system to safety net and protect children for whom there were safeguarding concerns, to ensure these are reviewed.
- There was a safeguarding policy in place for children and vulnerable adults which contained hyperlinks to national guidance and applicable legislation. However, neither policy contained explicit guidance for staff regarding female genital mutilation (FGM). For example, the service made no reference to the legal requirement to report FGM and of the necessity to complete a safeguarding assessment for children whose mothers may have been subjected to FGM.
- The provider could not demonstrate that it had systems in place to check a person's identity, age and, where appropriate, parental authority.
- The provider could not demonstrate that 9 members of clinical staff and 1 non-clinical member of staff had completed safeguarding training for vulnerable adults, in line with national intercollegiate guidance.
- The provider could not demonstrate that 9 members of clinical staff and 2 non-clinical members of staff had completed safeguarding training for children, in line with national intercollegiate guidance.
- We reviewed 11 staff records and found the provider had completed DBS checks for 7 out of 9 medical staff, 1 phlebotomist and 1 receptionist/administrator. However, for 2 doctors the DBS checks were from different employers. Following our inspection on-site visit on 19 January 2023, the provider submitted evidence that enhanced DBS checks that had been initiated for a further 2 doctors. The provider did not submit evidence for 1 newly recruited receptionist/administrator.
- We reviewed 11 staff recruitment records for 9 medical staff, 1 phlebotomist and 1 receptionist/administrator and found:

1. No information was submitted in any staff records regarding a signed written employment contract or other form of employment 'terms of engagement' agreement.
2. 8 out of 10 staff records did not contain appropriate references evidence to demonstrate satisfactory conduct in previous employment, and 1 record contained references from 2007 and 2009.
3. 9 out of 10 staff records did not contain an application form or CV. One staff record contained an unexplained gap of 3.5 years.
4. No staff records contained a signed confidentiality agreement.
5. No information was submitted for a recently employed receptionist.

- The provider could not demonstrate that reception staff who acted as chaperones were trained for the role.

Risks to patients

Inadequate

Are services safe?

There were no systems to assess, monitor and manage risks to patient safety, including radiography (X-rays)

- The provider could not demonstrate evidence that medical indemnity insurance was in place for four medical staff; one dentist and two dental nurses. A dental team of 1 dentist and 2 dental nurses was included in the current staff list provided to us during our inspection on 19 January 2023. The provider had offered to arrange interviews with dental staff during our on-site visit, however this did not materialise.
- The provider could not demonstrate that a failsafe system was in place to ensure patients test results had been reviewed and actioned appropriately.
- The provider could not produce evidence or otherwise demonstrate that a failsafe system was in place regarding urgent cancer referrals and cervical smears. Staff told us letters are given to patients following a consultation and the service does not follow-up after this. The provider does not hold details for patients' NHS GPs and rely on patients relaying any information to their GP themselves.
- The provider could not demonstrate that a system was in place to safely manage patient safety alerts, including historical alerts that remained clinically relevant. The provider could not demonstrate that searches had been conducted and saved on the clinical system to identify patients who may be affected. In addition, the provider had a limited mechanism in place to disseminate relevant patient safety alerts to all clinicians who worked at the service.
- The provider could not demonstrate oversight of the patients on their list. For example, the provider did not know how many patients were on their patient list. The service operated a dual system regarding patient record-keeping: a paper and clinical IT system. Staff told us that both systems hold identical information. However, we reviewed two random samples from patient records and could not find one patient at all on the clinical IT system. This patient's medical record information could potentially be lost to follow-up if the paper records were lost.
- We reviewed records for staff immunisations and certified immunity for 8 doctors; 1 dentist; 2 dental nurses; 1 phlebotomist and 2 receptionist/administrators. The provider could not demonstrate they held a complete record for any member of staff. They have not submitted any evidence for 1 dentist and 2 dental nurses. This was not in line with UK Health Security Agency guidance.
- The provider could not demonstrate that any staff had undertaken appropriate training to identify patients who may be developing signs and symptoms of sepsis.
- The provider could not demonstrate they operated a safe system regarding medical equipment and stores and we found multiple examples of expired equipment and stores. For example, blood glucose testing strips, pregnancy testing strips and blood bottles.
- The provider could not demonstrate they operated a safe system regarding infection prevention and control. For example, the cleaning systems, equipment and processes did not mitigate the risk of healthcare acquired infection. It did not comply with the national colour-coding scheme for all cleaning materials and equipment which is widely applied throughout healthcare organisations to reduce cross-contamination risk between different types of area, for example, bathrooms and kitchens. The provider did not maintain appropriate sharps bins in rooms where phlebotomy and injectable medicines are undertaken. In addition, 6 sharps bins we reviewed were not dated as to when they were opened.
- The provider had limited systems in place to safely manage facilities and equipment. For example, there were some systems in place to safely manage healthcare waste, however, audits in relation to this had not been undertaken.
- We did not see infection prevention and control procedures specifically for dental practices. We asked the provider for infection prevention and control audits, however, staff told us that dentistry was not undertaken at the location. Dentistry appeared to have been provided at some point given the use of dental materials, missing burs and endodontic files from their original packaging. On the day of the inspection, the dental chair looked ready for use in that the high-speed and low-speed (air-turbine) handpieces were both connected to the dental unit with burs in place. Furthermore, we found suction/aspirator tubes and 650ml of distilled water in the bottle which was attached to the dental chair. This raised additional infection prevention control concerns as these items were not cleaned and sterilised.

Inadequate

Are services safe?

- The practice had procedures to reduce the risk of Legionella, or other bacteria, developing in water systems, in line with a risk assessment.
- The practice had policies and procedures in place to ensure clinical waste was segregated and stored appropriately in line with guidance. We reviewed consignment notices, specifically those for collection made in December 2022 and found that a waste amalgam pot was collected and charged to provider's account. The provider told us that dentistry was not undertaken at the location.
- The practice had a recruitment policy; however, we were unable to review recruitment records for dental staff. This was because the provider told us at the time of inspection there, were no dental staff employed. This was not reflective of the staffing information provided to us by the practice which included a dentist and a dental nurse as part of the staff working at the practice.
- We were unable to confirm if clinical dental staff were qualified, registered with the General Dental Council and had professional indemnity cover.
- One of the rooms had a dental chair which appeared to be in good working order on the day of inspection. However, the provider was unable to provide us evidence that the equipment was safe to use, maintained and serviced according to manufacturers' instructions. There were 2 other pieces of equipment which were pertinent to the function of any dental practice; autoclave which was used to sterilise dental instruments and a compressor which was used to generate high quality air for the dental handpieces to work. The provider had these on the premises on the day, however, we saw no service records, nor did they have a written scheme of examination as per the legal requirements of the Pressure Systems Safety Regulations 2000 and the Health and Safety at Work Act 1974.
- A fire safety risk assessment was carried out in line with the legal requirements. We saw there were fire extinguishers and fire detection systems throughout the building and fire exits were kept clear. In addition, portable appliance testing was completed on all electrical appliances in the last 12 months to ensure appliances were in good working condition. Records confirmed staff had received training in fire safety.
- The provider could not demonstrate an effective induction system was in place for staff tailored to their role.

Information to deliver safe care and treatment

Staff did not have the information needed to deliver safe care and treatment to patients.

PMS service

- Due to the limitations of the clinical IT system, we could not be assured that all care records for patients were appropriately managed. We reviewed 17 randomly chosen individual care records and saw that care for 11 patients had been managed in a way that kept patients safe. For example, a patient who had metabolic disorder and a patient who had attended with an ear problem.
- However, the provider could not demonstrate that care records for patients who did not have access to NHS care, were managed in a safe and effective way.
- We saw that ultrasound scanning was carried out at the service. However, the images produced from the ultrasound examinations were not always saved into patients (paper) records and retained for the statutory length of time. If the image print-outs are lost, the information is lost to follow-up. This is significant regarding the clinical management of patients and for medical-legal reasons.
- The service did not have a system in place to retain medical records in line with Department of Health and Social Care (DHSC) guidance in the event that the provider ceased trading.
- The provider could not demonstrate that appropriate and timely referrals had been made for patients in line with up to date evidence-based guidance.
- We were unable to confirm that patient care records were complete, legible, kept securely and complied with General Data Protection Regulation requirements.

Inadequate

Are services safe?

Safe and appropriate use of medicines

PMS and dental services

The service did not have reliable systems for appropriate and safe handling of medicines.

- The provider did not have a system or process in place to safely manage patients who were prescribed high risk medicines, to ensure patients receive appropriate blood monitoring and were regularly reviewed.
- The provider could not demonstrate that regular medicines audits had been carried out to ensure prescribing was in line with best practice guidelines for safe prescribing.
- The provider did not have an overarching system to manage emergency medicines and equipment. For example, we found some medicines and equipment had expired for example, a medicine used to treat croup in young children which expired on 30/04/2022. In addition, there were some items of emergency equipment which were missing, for example airways. We saw paediatric and adult masks were absent from the resuscitation kit.
- We saw that some emergency medicines stored in the vaccine fridge had expired, for example, glucagon as used in a diabetic emergency.
- There were 2 syringes filled (1.5mls in each syringe) with a clear fluid. These were not labelled as to the name of the medicine or contents of the syringes; when these were drawn up and when these would expire. The syringes were not labelled with any patient-identifiable information.
- We saw the cold chain fridge did not have a data logger in place and the temperature probe was faulty. The temperature range for a cold chain fridge is between 2 and 8 celcius. We saw that the temperature of the cold chain fridge had remained between 14-16 celsius during our visit. Temperature records had been completed for several days, although staff confirmed the practice was closed during those dates. We could not be sure that records were reliable and therefore that medicines stored in the fridge were safe to use.
- Emergency equipment and medicines were not available and checked in accordance with national guidance. The provider did not have oropharyngeal airways or a portable suction. We also found the provider did not have Buccal Midazolam (Oromucosal Midazolam) as part of their standard emergency drugs instead the provider held a supply of rectal diazepam. (Buccal midazolam has been tested and approved for seizure management and is now the NICE recommended drug of choice for emergency treatment for prolonged convulsive seizures). The provider told us this would be replaced.
- The provider could not demonstrate that primary medical service (PMS) and dental staff knew how to respond to a medical emergency and had completed training in emergency resuscitation and basic life support every year.

Track record on safety and incidents

Risks to patients

The service had a limited safety record.

- Some comprehensive risk assessments had been conducted to assess and manage risks appropriately, for example, fire safety and the management of Legionella.
- The practice did not have a COSHH policy. In addition copies of safety data sheets were unavailable and risk assessments had not been carried out to assess the risks associated with substances, stored on the service premises, that were hazardous to health, for example, phosphoric acid etchant which was used for enamel preparation before filling the tooth with a resin material. In addition, we saw potentially dangerous chemicals (hydrogen peroxide) left on the sides of consultation rooms and within reach of children. This was not in line with the control of substances hazardous to Health Regulations (COSHH) 2002.

Inadequate

Are services safe?

Lessons learned and improvements made

The service did not have systems in place to enable learning and improvements when things went wrong and there were unexpected or unintended safety incidents.

- The provider could not demonstrate that a safe effective system was in operation regarding significant events (SEAs). For example, staff told us there had not been any significant events, since the service opened in July 2019. However, we did review evidence of a significant event that had been documented but not recorded as a significant event. In addition, staff told us about a flooding in one of the clinical rooms, which had not been captured, reviewed and any learning discussed at a service meeting.
- Staff told us the service did not have a system in place for capturing and sharing learning from significant events. For this reason, it was not possible to assess whether the service gave affected people reasonable support, truthful information and a verbal and written apology.

Inadequate

Are services effective?

We rated effective as Inadequate because:

Effective needs assessment, care and treatment

Care and treatment was not consistently delivered in line with current legislation, standards and evidence-based guidance supported by clear pathways and tools.

- Due to the limitations we found regarding the provider's clinical system and other concerns found during our inspection on 19 January 2023, the provider could not demonstrate that care and treatment was consistently delivered in line with national guidance. When we spoke with the provider, they told us they were aware of national guidance regarding patient care and treatment. However, we reviewed evidence from eleven patient records that national guidance had not been followed; an appropriate plan of care had been documented or contained appropriate information, for example ultrasound scan images.
- The provider could not demonstrate evidence of equality and fairness of decision-making when making care and treatment decisions.

Monitoring care and treatment

The provider was not actively involved in quality improvement activity.

- The provider could not demonstrate that any quality improvement and clinical audit activity had been completed, to drive good quality care and treatment for patients.

Effective staffing

The provider could not demonstrate that staff had the skills, knowledge and experience to carry out their roles

The provider told us that two doctors undertook ultrasound scanning at the service. However, the training records provided to us were for different clinicians. Training for different clinicians was completed in 1993; 2006; 2012; 2016 and 2017. The evidence submitted did not detail what this training included or excluded and no evidence was submitted of updating training.

The provider told us during our inspection visit on 19 January 2023 and we reviewed evidence that ultrasound scanning for obstetrics and fetal abnormality was carried out at the service. This is a specialised training programme and the provider has not submitted evidence that they meet the requirements regarding training and consistent practical experience to enable them to safely carry out this activity, in line with national guidance.

The provider told us the phlebotomist undertook healthcare assistant activities. For example, blood pressure checks, pregnancy testing, blood glucose monitoring and urine testing. The provider have not submitted evidence that this person has been appropriately trained and competency checked. The information submitted demonstrated that their phlebotomist had last completed phlebotomy update training in 2016.

The provider could not demonstrate that a safe effective system was in place to manage staff training and we found:

1. Six out of eleven staff do not have fire safety training in place.
2. Six out of eleven staff do not have information governance training in place.
3. Six out of eleven staff do not have infection prevention and control (IPC) training in place.

Inadequate

Are services effective?

4. Evidence was not submitted to demonstrate regular training/updating for one dentist and two dental nurses.

Supporting patients to live healthier lives

- Due to the limitations we found regarding the provider's clinical system and other concerns found during our inspection on 19 January 2023, the provider could not demonstrate whether staff were consistent and proactive in providing support for patients, to enable them to manage their own health.

Consent to care and treatment

It was not possible to confirm if the provider obtained consent to care and treatment in line with legislation and guidance.

- It was not possible to assess whether staff understood the requirements of legislation and guidance when considering consent and decision making.
- Due to the limitations we found regarding the provider's clinical system during our inspection on 19 January 2023, the provider could not demonstrate that staff supported patients to make decisions and recorded a patient's mental capacity to make a decision.
- The provider could not demonstrate they monitored the process for seeking consent appropriately.

Requires Improvement

Are services caring?

We rated caring as Requires improvement because:

Kindness, respect and compassion

Staff treated patients with kindness, respect and compassion

- The service could not demonstrate that feedback was sought from patients on the quality of clinical care patients received.
- The provider did not submit evidence that they requested regular feedback from patients who attended the service, regarding kindness and compassion they experienced from staff.
- Staff understood patients' personal, cultural, social and religious needs. The provider displayed an understanding and non-judgmental attitude to all patients.
- The provider could not demonstrate they had maintained registers of patients living in vulnerable circumstances including homeless people, and those with a learning disability.

Involvement in decisions about care and treatment

There was limited information to demonstrate that patients were involved in decisions about care and treatment.

- Clinicians told us they included patients in decisions about their care and treatment but did not provide evidence to support this.
- Staff told us that patients were provided with information regarding their care and treatment, including its risks and benefits, however, it was not possible to evidence this.
- The provider could not demonstrate they had undertaken patient feedback surveys.
- The provider could not demonstrate they had a register of carers in place, and that for patients with additional needs, that family and carers were appropriately involved.

Privacy and Dignity

The service respected patients' privacy and dignity.

- Staff recognised the importance of people's dignity and respect.
- Staff knew that if patients wanted to discuss sensitive issues or appeared distressed they could offer them a private room to discuss their needs.

Inadequate

Are services responsive to people's needs?

We rated responsive as Inadequate because:

Responding to and meeting people's needs

It was not possible to confirm if the service organised and delivered services to meet patients' needs, based on the evidence found and provided.

- It was not possible to assess if the provider understood the needs of their patients and improved services in response to those needs.
- We found the facilities and premises were appropriate for the services delivered.
- The service premises and facilities were not appropriate to enable people in vulnerable circumstances to access and use services on an equal basis to others.

Timely access to the service

Patients were not able to access care and treatment from the service within an appropriate timescale for their needs.

- It was not possible to assess if patients had timely access to initial assessment, test results, diagnosis and treatment, as the provider did not maintain a failsafe system
- We were unable to speak with patients on the day of our on-site inspection visit, 19 January 2023, therefore we could not assess whether the appointments system was easy to use.
- Due to the severe limitations of the provider's clinical system, it was not possible to determine if patients with the most urgent needs had their care and treatment prioritised.
- It was not possible to assess if referrals and transfers to other services were undertaken in a timely way, as the provider did not maintain failsafe systems regarding this. For example, urgent referrals to secondary care.

Listening and learning from concerns and complaints

There was a limited system in place to appropriately manage patient complaints and improve the quality of care.

- Information about how to make a complaint or raise concerns was available.
- The clinical lead and Registered Manager was the designated responsible person for handling complaints in the clinic.
- The complaints policy and procedures contained information relating to the NHS Complaints Process. It did not contain information as recommended by the Independent Doctors Federation (IDF), regarding an external complaints process for patients'. The service did not subscribe to the Patients' Independent Sector Complaints Advisory Service (ISCAS), an independent body, that patients may access to make a complaint regarding an independent health organisation member.
- Staff told us they had not received a patient complaint since the service opened in July 2019. Therefore, the provider did not hold a summary of complaints or have a proforma regarding this. However, when reviewing other information during the inspection, we did see a patient complaint that had been documented but not recorded as such. The provider submitted limited information regarding this and as a result we could not review this fully.

Inadequate

Are services well-led?

We rated well-led as Inadequate because:

Leadership capacity and capability:

Leaders did not have the capacity and skills to deliver high-quality, sustainable care.

- Leaders could not demonstrate the capacity to prioritise safety and quality improvement. Several systems and processes had been found to be unsafe. For example, the management of high-risk medicines; failsafe systems for two-week wait referrals and cervical screening; and patient safety alerts, including historical alerts that remain clinically relevant.
- The management team could not demonstrate they had a comprehensive oversight of all the challenges to delivering care within a primary care setting or that they had an effective action plan to address those challenges.
- The provider could not demonstrate they had oversight of their patient list and relative risk regarding their patient population group. During our inspection, we asked the provider management team several times how many patients were included on their list and they told us they did not hold this information.
- The provider did not submit evidence of a business development plan. Therefore, we were unable to review information regarding a succession plan for retirement.
- The practice did not have clear systems in place to assess, monitor and improve the quality and safety of the service or to mitigate the risks associated with safe care and treatment**.**
- We found evidence of a lack of clinical governance and the practice was driven by reactive approaches as opposed to adopting a proactive systematic approach to risk.

Vision and strategy

The service did not have a clear vision and credible strategy to deliver high quality care and promote good outcomes for patients.

- The provider could not demonstrate they had a mission statement, vision and set of values in place. Due to the severe limitations of the provider's clinical IT system, it was not possible to review and assess patient clinical achievement data and governance arrangements did not contain fail-safe systems.
- The provider could not demonstrate they had a credible strategy in place to address any challenges they had identified and concerns we found on inspection. We found that there was a lack of oversight in key areas relating to the safety systems in place, staff provision, and governance structures all of which had the ability to compromise the quality of care provided by the practice and impact on its vision, aims and objectives.
- We were not assured that staff knew and understood the vision, values and strategy and their role in achieving them. It was not possible to determine if staff we spoke with were aware of the practice vision and values.
- The provider could not demonstrate they had a vision and set of values.
- The provider could not assure us they had a strategy to drive improvements.
- Staff could not demonstrate they were aware of and understood the vision for the service and their role in achieving this. There was no evidence of quality improvement and monitoring of clinical outcomes and we saw the provider did not always act on the latest information. For example, completing appropriate actions regarding patient safety alerts.

Culture

The service did not have a culture of high-quality sustainable care.

Inadequate

Are services well-led?

- The provider did not always focus on the needs of patients. For example, the provider had installed a clinical IT system which did not facilitate searches and audits of clinical records.
- They could not demonstrate they had completed prescribing audits; long term conditions reviews for patients and taken action to identify patients who may be affected by patient safety alerts, so they may be appropriately followed-up. We found there was a lack of knowledge regarding patients with long term conditions from a clinician who had clinical oversight for these patients.
- The provider could not demonstrate they operated a safe effective system regarding incidents and complaints. For example, staff told us they had not received any patient complaints or had any significant events, since the service opened in July 2019.
- We found that staff were committed to providing a good service to all patients. However, the provider had not actively considered how it would meet the needs of different population groups. For example the provider did not systematically plan for patients with long term conditions and it was not possible to run searches regarding this, given the limitations of their clinical IT system.
- The provider had not undertaken checks regarding clinicians' training; that clinicians' had completed updating to ensure the delivery of safe and effective care and relied on checking an individual's registration with the General Medical Council (GMC).
- The service actively promoted equality and diversity. Staff had received equality and diversity training.
- There were good relationships between staff and managers.

Governance arrangements

There were limited systems of accountability to support good governance and management.

- We found that structures, processes and systems to support good governance were not effective. In particular, we found concerns around the management and monitoring of safeguarding, DBS checks, prescribing and medicines management, recruitment, some premises risk assessments and failsafe systems for urgent referrals and cervical screening.
- Although all staff had specific roles and responsibilities the practice could not demonstrate who had oversight of all systems and processes to ensure effective care and to drive quality improvement. For example, effective staffing in relation to role-specific training and an overall lack of oversight to ensure safe and effective care.

Managing risks, issues and performance

Processes for managing risks, issues and performance lacked clarity.

- We were not assured that comprehensive and effective systems and process had been identified, were in place and regularly reviewed to manage risk and some performance data. For example, during our inspection we found the provider had not undertaken regular searches and audits to assure themselves that all female patients who had undertaken cervical screening had been followed up. We found the provider did not have complete oversight of safeguarding systems. Therefore, the provider could not demonstrate patients were safely reviewed. The provider could not demonstrate that it proactively identified and responded to all risks and assessed the impact on safety and quality.
- The practice did not have systems and processes in place to effectively risk manage and monitor all patients across the population groups. This was managed by medical consultations by opportunistic review.

Inadequate

Are services well-led?

- The provider had installed its own clinical IT system which was difficult to navigate and did not facilitate audits of prescribing and any medicines monitoring that may be required. The provider could not give us any details regarding their medicines formulary. In addition, the provider could not appropriately review patients records due to the limitations of the clinical IT system.
- We reviewed evidence that the provider had not ensured there was an effective, process to identify, understand, monitor and address current and future risks including risks to patient safety.
- The provider could not demonstrate they had a failsafe system in place regarding test results for patients to ensure that when tests were requested that had been completed.
- We reviewed evidence that the provider had appropriate risk assessments and systems in place regarding fire safety and the management of Legionella.

Appropriate and accurate information

The service did not have appropriate and accurate information.

- We were unable to review evidence that the provider used to make improvements to the quality of care. The clinical system did not facilitate audit of patient care.
- The provider could not demonstrate they had pro-actively identified any concerns in the service and any action plans in response.
- There were ineffective arrangements in line with data security standards for the availability, integrity and confidentiality of patient identifiable data, records and data management systems.
- The provider could not demonstrate that clinical staff had been appropriately trained, competency checked.
- We could not be assured that information held by the provider was accurate, valid, reliable and timely as we had found gaps in their systems. For example, the provider could not demonstrate they had assured themselves that all patients who had been prescribed medicines that required additional monitoring had been followed up. The provider could not demonstrate that regular audits had undertaken of those medicines and patient safety alerts, including historical alerts that remained clinically relevant, to evidence this, in line with national guidance.
- The provider could not demonstrate there were effective arrangements for identifying, managing and mitigating risks. For example, having failsafe systems in place to manage two-week wait referrals and cervical screening.

Engagement with patients, the public, staff and external partners

The service had limited systems to involve patients, the public, staff and external partners to support high-quality sustainable services.

- The practice could not demonstrate that they had a culture of high-quality sustainable care and acknowledged that work needed to be done to improve their systems and processes to achieve this.
- Staff could describe to us the systems in place to give feedback, for example, patients were encouraged to use comments forms in reception but could not provide evidence of this.

This section is primarily information for the provider

Enforcement actions

Action we have told the provider to take

The table below shows the legal requirements that were not being met.

Regulated activity	Regulation
Diagnostic and screening procedures Family planning services Treatment of disease, disorder or injury	Regulation 12 HSCA (RA) Regulations 2014 Safe care and treatment The provider failed to ensure that safeguarding systems and practices were fully developed and implemented in a way that kept people safe. The provider failed to have an effective system in place to safely manage ultrasound scan images and patient records. The provider failed to operate a safe cold chain in line with national guidance. The provider failed to have a safe and effective system in place to monitor and manage patients who had been referred via the two-week wait urgent referral system and for cervical screening. The provider failed to have a safe and effective system in place regarding staff immunisations and certified immunity. The provider failed to have an effective system in place to manage sepsis training for staff. The provider failed to have a safe and effective system in place regarding medicines management. The provider failed to consistently follow national guidance regarding care and treatment for patients. The provider failed to have an effective system in place to safely manage the control of substances hazardous to health (COSHH). The provider failed to operate safe infection prevention and control practices, in line with national guidance. The provider failed to have an effective system in place to safely manage clinical equipment and resources.

This section is primarily information for the provider

Enforcement actions

This was in breach of Regulation 12 (1) of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014.

Regulated activity	Regulation
Diagnostic and screening procedures Family planning services Treatment of disease, disorder or injury	Regulation 17 HSCA (RA) Regulations 2014 Good governance **We issued a warning notice.** **There was a lack of systems and processes established and operated effectively to ensure compliance with requirements to demonstrate good governance.** In particular we found: • The provider failed to have an effective system in place to safely manage staff training, specific to their role, including ultrasound and fetal ultrasound. • The provider failed to have a system in place regarding clinical audit and quality improvement. • The provider failed to have an effective system in place to safely manage regular staff training. • The provider failed to have an effective system in place to safely manage significant events. • The provider failed to have an effective system in place to safely manage patient complaints. • The provider failed to have an effective system in place to safely manage clinical supervision for non-medical staff. • The provider failed to have a system in place to the requirements of Duty of Candour. **This was in breach of Regulation 17(1) of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014.**

This section is primarily information for the provider

Enforcement actions

Regulated activity

Diagnostic and screening procedures

Family planning services

Treatment of disease, disorder or injury

Regulation

Regulation 12 HSCA (RA) Regulations 2014 Safe care and treatment

We imposed an urgent suspension under s.31 of the HSCA 2008.

Care and treatment must be provided in a safe way for service users

How the regulation was not being met:

- The provider failed to have an effective clinical IT system in place to safely manage searches and recall of patients.
- The provider failed to have a safe system in place to manage medical indemnity insurance.
- The provider failed to have a safe and effective system to monitor and manage patient safety alerts.
- The provider failed to have an effective system to place to safely manage prescribing and medicines management.
- The provider failed to have an effective system in place to safely manage patients who may have a long term health condition.
- The provider failed to operate a recall system for patients who may require blood and other monitoring related to medicines that are prescribed, including a failsafe system.
- The provider failed to operate a safe and effective recruitment system.
- The provider failed to monitor and manage a safe system to their patient list and records.
- The provider failed to have a safe and effective system to monitor and manage emergency medicines and equipment, in line with UK national resuscitation guidance.

This section is primarily information for the provider

Enforcement actions

This was in breach of Regulation 12 (1) of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014.