Bodyvie Medi-Clinic

Inspection report

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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?	Requires Improvement
Are services well-led?	Inadequate

Overall summary

This service is rated as Inadequate overall. This service was registered in August 2019. This was 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? – Requires improvement

Are services well-led? – Inadequate

We carried out an announced comprehensive inspection at Bodyvie Medi-Clinic under Section 60 of the Health and Social Care Act 2008 as part our inspection programme.

At this inspection we took a primary care team to check whether the service was meeting the legal requirements and regulations associated with the Health and Social Care Act 2008. This report includes evidence gathered by our team.

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

- We urgently suspended some of the provider's activity using our powers under section 31 of the Health and Social Care Act 2008 which the provider met.

Bodyvie Limited is an independent provider of medical services and offers a full range of private general practice services to self-funding and insured patients.

There is a 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.

This service is registered with CQC under the Health and Social Care Act 2008 in respect of some, but not all, of the services it provides. There are some exemptions from regulation by CQC which relate to particular types of regulated activities and services and these are set out in Schedule 1 of The Health and Social Care Act 2008 (Regulated Activities) Regulations 2014. Bodyvie Medi-Clinic provides a range of non-surgical cosmetic interventions, for example non-surgical facelift and thread lift treatments, which are not within CQC scope of registration. Therefore, we did not inspect or report on these services

Our key findings were:

- The provider did not have an auditable 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.

Overall summary

- 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 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 no evidence of a system and processes in place regarding safeguarding children and vulnerable adults.
- 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 patient complaints.
- The provider did not have a system in place to drive quality improvement, including clinical audit.
- The provider was unable to demonstrate that all staff had 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.
- There should be regular health and safety risk assessments of the premises and equipment. The findings of the assessments must be acted on without delay if improvements are required.

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

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

- Review the flooring in the premises area, which is used to provide regulated services, to make improvements and reduce the risk of healthcare acquired infection.

I am placing this service in special measures. Services placed in special measures will be inspected again within six months. If insufficient improvements have been made such that there remains a rating of inadequate for any key question or overall, we will take action in line with our enforcement procedures to begin the process of preventing the provider from operating the service. This will lead to cancelling their registration or to varying the terms of their registration within six months if they do not improve.

The service will be kept under review and if needed could be escalated to urgent enforcement action. Where necessary, another inspection will be conducted within a further six months, and if there is not enough improvement we will move to close the service by adopting our proposal to remove this location or cancel the provider's registration.

Special measures will give people who use the service the reassurance that the care they get should improve.

Dr Sean O'Kelly BSc MB ChB MSc DCH FRCA

Chief Inspector of Health Care

Our inspection team

Our inspection team was led by a CQC lead inspector and included a GP specialist adviser.

Background to Bodyvie Medi-Clinic

The Bodyvie Medi-Clinic is located at 133-135 Kew Rd, Richmond, Surrey, TW9 2PN in the London borough of Richmond Upon Thames.

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 surgical procedures.

Services provided included general practitioner services; paediatrics; dermatology and minor surgery; women's health and gynaecology consultation services; antenatal ultrasound scans; family planning and contraceptive services; blood and other laboratory tests. Patients can be referred to other services for diagnostic imaging and specialist care.

The service is open Monday to Thursday 10am to 6pm; Friday 9am to 4pm and Saturday 9am to 4.30pm. The service does not offer out of hours care. The provider's website can be accessed at www.bodyvie.com

How we inspected this service

To get to the heart of patients' experiences of care and treatment, we always ask the following five 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 effective 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 provider's patient records system being combined with its aesthetic service records and they had not implemented a reference system to enable searches and audits to be completed.
- Safeguarding systems were not fully developed, and we identified several gaps in the provider's system.
- The provider could not demonstrate that 6 clinical and 4 non-clinical members of staff had completed safeguarding training for vulnerable adults and children, in line with national intercollegiate guidance. Following the inspection the provider submitted evidence all staff complete safeguarding training.
- The provider did not place alerts on patients' records, for whom there may be safeguarding concerns. This meant staff would not have been alerted to concerns that the individual was at risk of abuse or neglect, or that they pose a risk to others.
- The provider did not maintain registers of patients for whom there may be safeguarding concerns. A safeguarding register is used to inform staff of vulnerable patients who are at risk and the severity of the risk for each individual patient.
- Staff told us there had not been any incidences of patient safeguarding concerns since 16 August 2019.
- 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 however the policy did not contain explicit relevant information regarding female genital mutilation (FGM). 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.
- We reviewed recruitment records, including DBS checks, for 6 clinical and 4 non-clinical members of staff and found:
- That 2 out 4 clinical staff had DBS checks from different employers dated August and November 2022 and this had not been risk assessed by the service. The provider submitted evidence of DBS checks underway following the inspection.
- No information was submitted in any staff records regarding a signed written employment contract or other form of employment 'terms of engagement' agreement.
- 5 out 6 clinical staff had one reference in place and we found some references contained lack of sufficient detail, including start and finish dates. We saw that one referee stated they were a current colleague although we reviewed evidence that this doctor was de-registered. No reference evidence was provided for the sixth clinician.
- The provider did not submit evidence of a CV or work and education history for 2 out of 6 clinical staff and the evidence submitted for a further 2 clinical staff contained insufficient information and unexplained gaps.
- The provider could not demonstrate that reception staff who acted as chaperones were trained for the role.

Risks to patients

There were insufficient systems to assess, monitor and manage risks to patient safety.

Inadequate

Are services safe?

- The provider could not provide evidence that appropriate medical indemnity insurance was in place for 4 medical staff and 2 sonographers who worked at the service. Following the inspection we recevied evidence of vaild medical indemnity insurance.
- There were arrangements for planning and monitoring the number and mix of staff needed.
- The provider could not demonstrate they had an effective induction system in place for staff tailored to their role.
- The provider could not demonstrate they operated a failsafe system regarding urgent referrals including for patients who did not have access to NHS care. We reviewed evidence where 3 patients, who had been diagnosed with a malignancy or pre-cancer lesion, who had not been followed up appropriately and were only followed up when we requested copies of patients records.
- Due to the limitations of the provider's paper-based patient records system, as this was not referenced or searchable, they could not demonstrate they had safety-netted urgent referrals for patients, with red flag signs, to secondary care. We found their referral policy was contradictory, and stated that referrals would be monitored monthly, however they could not provide evidence they had completed monitoring of failsafe systems on a regular basis in line with their service policy.
- The provider could not demonstrate that they had a system in place to safely manage patient safety alerts, including historical alerts that remained clinically relevant. There was no evidence that searches had been conducted and saved on the clinical system to identify patients who may be affected. In addition, the provider could not demonstrate they had a mechanism in place to disseminate relevant patient safety alerts to all clinicians who worked at the service.
- The provider could not demonstrate complete oversight of the patients on their list. For example, the provider did not know how many patients were on their patient list, who attended for services that come under the scope of regulation. Patients' medical records were stored jointly with the records for people who were attending the aesthetics service. This meant it was not possible to undertake searches and audits of patients' medical records.
- The provider could not demonstrate that non-clinical staff, who worked on the reception desk, had received training regarding 'red flag' signs and symptoms for patients.
- We reviewed records for staff immunisations and certified immunity for 6 clinical and 4 non-clinical staff. The provider could not demonstrate they held a complete record for any member of staff. 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 had not demonstrated they operated a safe system regarding infection prevention and control to mitigate the risk of healthcare acquired infection. For example, they had not completed hand hygiene and cleaning audits for the previous 12 months.
- In addition, the provider could not demonstrate they had completed audits of post-minor-surgery outcomes. They told us that post-surgery infections are so rare they were unable to recall any incidents. However, we reviewed evidence that a patient who had undergone a minor surgical procedure at the service, had developed a significant infection following the surgery.
- The provider could not demonstrate they had an appropriate risk assessment and procedures in place to reduce the risk of Legionella, or other bacteria, developing in water systems, in line with national guidance.
- The provider could not demonstrate they had a safe system in place to effectively manage fire safety. They submitted their previous fire safety risk assessment, which was dated 2021 and this should have been completed every two-years as stated in the risk assessment. In addition, they submitted an overarching fire safety document, which included several relevant templates, however, when we reviewed this we found the document to be blank. During our onsite inspection visit on 02 August 2023, we saw that 3 fire extinguishers were last serviced in 2018. The provider told us the servicing contract for fire extinguishers was in the process of being set up. However, they have not submitted evidence of this to CQC.
- Patient medical records were not maintained in line with the general data protection regulation.

Inadequate

Are services safe?

- The provider could not demonstrate that 4 non-clinical staff, who had undertaken chaperone duties, had been appropriately trained. They submitted evidence of a service policy regarding chaperone duties, however, this did not contain relevant information. For example, the chaperone's role and responsibilities and the necessity for training staff and what this should include.

Information to deliver safe care and treatment

Staff had limited information systems in place to deliver safe care and treatment to patients.

- As part of our review of the delivery of safe care and treatment we reviewed 8 patient records. We found 4 of the 8 patient records had not been managed in line with national guidance regarding the removal of suspicious skin lesions.
- Following the inspection the provider reviewed the 4 patients records and submitted a detailed account for each patient. This new information provided us with assurance. However, the 4 patient records highlighted a lack of failsafe for the referral process.
- 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 reviewed the records for 2 patients who had attended for minor surgery and found these patients had not been followed up in a timely way. Following the inspection the provider submitted evidence to confirm referrals were produced for both patients. However, this information was not available on the day of inspection due to incomplete medical records and a lack of failsafe system.
- The service had a system in place to retain medical records in line with Department of Health and Social Care (DHSC) guidance in the event that they cease trading.

Safe and appropriate use of medicines

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

- The provider could not demonstrate they had a safe system in place regarding prescribing and prescriptions. We found they had not completed audits of prescribing in the service and did not keep records regarding prescriptions issued to patients, in line with best practice guidelines for safe prescribing.
- The provider did not have an overarching system to manage emergency medicines and equipment for children and adults. We found some medicines and equipment were missing, for example, paediatric oxygen masks, oxygen for administration and glucagon used to treat patients with diabetes who had low blood glucose levels. The provider was unable to demonstrate they had risk assessed the emergency medicines and equipment and could not provide evidence demonstrating these emergency items should not be stocked as part of their emergency kit. Following the inspection, the provider submitted evidence of appropriate emergency medicines and equipment on site for both children and adults.
- We found the provider could not demonstrate all staff had completed basic life support training and had the skills and knowledge to effectively handle a medical emergency. Following the inspection the provider submitted evidence of all staff completing basic life support training.
- The provider did not have a policy in place for deteriorating patients and did not hold an anaphylaxis kit on the service premises.

Track record on safety and incidents

The service did not have a good safety record.

Inadequate

Are services safe?

- The provider could not demonstrate that some comprehensive risk assessments had been conducted to assess and manage risks appropriately, for example, fire safety.
- The provider could not demonstrate they monitored and reviewed activity to safely manage their service premises, for example, regarding the management of Legionella.
- The provider told us that fixed electrical wiring testing had been arranged for after our on-site inspection visit. To date, this has not been submitted.

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. Initially, staff told us there had not been any significant events, since the service opened for providing regulated activities on 16 August 2019. However, we reviewed evidence of two significant events that had been included in a medical indemnity insurance document, however these had not been recorded as significant incidents.
- The provider had a policy to manage significant events, however this referred only to significant events which were of a medical nature. The policy did not set out what the complete SEA process is including recognition of events and incidents, including non-clinical and positive, the requirement for information gathering and a facilitated team-based meeting should take place to discuss, investigate and analyse events.
- The provider subsequently submitted evidence of one significant event that had been recorded by the service. However, when we reviewed this information we saw that this particular significant event did not come under the scope of CQC regulation.
- For these reasons, 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.

- The provider could not demonstrate that care and treatment was consistently delivered in line with national guidance due to the limitations of the provider's paper-based patient records system. For example, the paper-based system was not referenced or searchable and they could not demonstrate they had safety-netted urgent referrals for patients to secondary care. When we spoke with the provider, they told us they were aware of national guidance regarding patient care and treatment.
- Following the inspection, we subsequently reviewed 4 of the 8 patient records and found they had not been managed in line with national guidance, regarding the removal of skin lesions which may be suspicious or in a high-risk area.
- We saw no evidence of discrimination when making care and treatment decisions.
- Staff assessed and managed patients' pain where appropriate.

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, treatment and improvement 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 2 doctors undertook surgical procedures and removal of suspicious skin lesions at the service. They submitted evidence of Royal College of General Practitioners (RCGP) minor surgery training level 2 for 1 clinician, which had been completed in 2014. This training should have been completed at level 3. The evidence submitted did not detail what the training included or excluded, and no evidence was submitted of regular updating training, which should have been completed on at least a 3-yearly basis. The provider did not submit evidence of relevant training to enable the delivery of safe care and treatment for patients who presented with potentially serious skin lesions.
- During our inspection on 02 August 2023, the provider told us they offered antenatal and nuchal translucency ultrasound scanning at the service. The provider had not assured themselves that staff had met the requirements regarding training, evaluation of a portfolio of scan images and consistent practical experience to enable them to safely carry out this activity, in line with national guidance.
- The provider could not demonstrate that a safe effective system was in place to manage staff training. We requested to see evidence of regular training for 6 clinical and 4 non-clinical staff regarding:

1. IPC.
2. Sepsis.
3. Fire safety.
4. Information governance.

Inadequate

Are services effective?

5. Basic life support (BLS).
6. Mental capacity Act (MCA).

- The provider told us their staff training matrix they had was unreadable, and although this would take time to put together, they would send us copies of training certificates. The provider submitted evidence of training following the inspection.

Coordinating patient care and information sharing

Staff did not work together or with other organisations, to deliver effective care and treatment.

- Staff told us they would share information with patients' GPs regarding care and treatment that patients had received at the service, including prescribed medicines. The provider was unable to demonstrate this took place. For example, when we reviewed patient records we found the provider was unable to demonstrate they had informed patients GPs of treatment received or the need for secondary care referrals.
- The provider could not demonstrate that care and treatment for patients in vulnerable circumstances was coordinated with other services.

Supporting patients to live healthier lives

- Due to the limitations we found regarding the provider's medical records system and other patient-focused concerns found during our inspection on 02 August 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.

- The provider was unable to demonstrate staff had completed mental capacity act training.
- Due to the limitations, we found regarding the provider's clinical system during our inspection on 02 August 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. We reviewed 4 patient records who had undergone minor surgery at the service and saw that patients had signed a consent form prior to completing minor surgery. However, we found there was a lack of detail in terms of what was discussed with patients. This included what working diagnosis had been identified, what side effects or symptoms may be experienced post-surgery, including 'red flag' signs and symptoms and when to seek further medical review.

Requires Improvement

Are services caring?

We rated caring as Requires improvement because:

Kindness, respect and compassion

- The service could not demonstrate that feedback was sought from patients on the quality of clinical care they 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.

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. We did not find evidence of this taking place during our patient records review.
- The provider could not demonstrate they had undertaken patient feedback surveys.

Privacy and Dignity

The service respected patients' privacy and dignity.

- Staff recognised the importance of treating people with 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.

Requires Improvement

Are services responsive to people's needs?

We rated responsive as Requires improvement 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.

- There was no evidence there were systems in place to alert staff that they were interacting with vulnerable patients.
- There was no evidence the provider had a failsafe in place for patients who may require follow up with secondary care.
- There was no evidence of record reviews taking place to ensure care and treatment was in line with national guidance.
- There was no evidence that risk assessments of medicines or facilities management had taken place. This meant potential risks has not been mitigated which may posed a risk to patients and staff.
- Staff were committed to providing a good service to all patients.

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, 02 August 2023, therefore we could not assess whether the appointments system was easy to use. We asked the provider how they assessed patient feedback in relation to access, they told us they did not currently have a system in place to request and monitor patient feedback.
- Due to the 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. Staff we spoke to were unable to demonstrate how they would identify vulnerable patients or patients with urgent needs. The provider was unable to provide evidence of an embedded triage system.
- 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, as part of our patient records review, we asked for evidence of the patients the GPs had made referrals to secondary care referrals for and the treatment they had received. The provider was unable to provide this evidence.

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 not readily available in the service premises or on the website.
- The 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 relevant information for patients who may be dissatisfied with the response to a complaint. For example, 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.

Requires Improvement

Are services responsive to people's needs?

- The provider could not provide assurance they had a system in place to recognise, acknowledge and investigate patient complaints. 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 complaint and the investigation that had taken place, therefore 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 prescribing; failsafe systems for urgent 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.
- We asked the provider for evidence of a business continuity plan; the provider was unable to provide evidence of a plan to prevent interruptions to the service. After the inspection took place the provider submitted a business continuity plan.
- 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.
- 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 how many patients were included on their list and they could not provide us with accurate information regarding this request. This difficulty had arisen, in part, by the provider's medical records system.
- Following conditions being placed on the location's registration, the provider has pro-actively submitted evidence to demonstrate the action taken. The impact of this action will be assessed at our next inspection.

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

- The provider was unable to demonstrate there was a strategy in place to identify and address risk. We found there was a lack of oversight in key areas of safety systems. For example, lack of oversight of staff training, an ineffective referral process which had no failsafe and the inability to audit prescribing practices.
- 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. For example, the provider did record or investigate patient complaints and therefore did not learn from feedback to improve services provided.
- Staff were aware of the vision and values for the service. However, 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.

- The provider did not always focus on the needs of patients. The paper-based records system meant there was an un-auditable medical record system to facilitate searches and audits of clinical records. No mitigation had been implemented to ensure patient records were audited to assess the quality of care and treatment.

Inadequate

Are services well-led?

- The provider could not demonstrate they had completed prescribing audits 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 suspicious skin lesions from clinicians 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 started providing regulated activities on 16 August 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 service users. For example, the provider did not systematically plan for patients who had undergone minor surgery and it was not possible to complete histology audits and searches regarding this, given the limitations of their medical records system.
- The provider had not undertaken checks regarding clinicians' training; that clinicians' had completed appropriate updating training to ensure the delivery of safe and effective care and relied on checking an individual's registration with the General Medical Council (GMC).

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, 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, we were not provided with evidence that regular governance meeting took place or that there was a lead member of staff who had 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 were in place to regularly review and manage risk and manage performance? 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 who used the service. This was managed when patients attended the service for medical consultation, for example when they attended offering health checks or screening such cervical screening.
- The provider used a paper-based medical records system which was difficult to navigate and did not facilitate searches and audits of prescribing and any medicines monitoring that may be required. The provider could not give us any details regarding their medicines formulary.
- 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. For example, there was no evidence of a clinical triage system and no system in place to check the identity children or parental authority.
- The provider could not demonstrate they had appropriate risk assessments and systems in place regarding fire safety and the management of Legionella.

Inadequate

Are services well-led?

Appropriate and accurate information

The service did not have appropriate and accurate information.

- It was unclear what evidence the provider used to make improvements to the quality of care. The provider was unable to demonstrate there was a system for identifying risks and making improvements. For example, the clinical system did not facilitate audit of patient care and there was no evidence of a failsafe in place for urgent referrals to secondary care.
- There was no system in place for pro-actively identifying and recording risks or concerns in the service. There were no action plans in place to response to known risks or concerns.
- The provider could not demonstrate that clinical staff had been appropriately trained and were competent for the roles they were undertaking. For example, there was no or limited evidence of staff completing specific surgical training or surgical update training, completing basic life support training or mental capacity act training.
- 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 that regular audits had undertaken regarding prescribing 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 urgent 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 provider 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

Requirement notices

Action we have told the provider to take

The table below shows the legal requirements that were not being met. The provider must send CQC a report that says what action they are going to take to meet these requirements.

Regulated activity	Regulation
Diagnostic and screening procedures Surgical procedures Treatment of disease, disorder or injury	Regulation 12 CQC (Registration) Regulations 2009 Statement of purpose **Regulation 12 HSCA (RA) Regulations 2014 Safe Care and Treatment** **How the regulation was not being met:** • 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 staff safeguarding training for vulnerable adults. • The provider failed to have a safe system in place to safely manage prescribing and prescriptions. • 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. • The provider failed to have a safe and effective system in place to monitor and manage patients who had been referred via the urgent referral system and for cervical screening. • The provider failed to operate a safe system in place to effectively manage infectious diseases and staff immunisations. • The provider failed to have a system in place to safely manage chaperone training for non-clinical staff. • The provider failed to have an effective system in place to safely manage staff training, specific to their role. • The provider failed to have an effective system in place to safely manage regular staff training. **This was in breach of Regulation 12 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014.**

Regulated activity	Regulation

This section is primarily information for the provider

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Regulated activity	Regulation
Diagnostic and screening procedures Surgical procedures Treatment of disease, disorder or injury	Regulation 15 CQC (Registration) Regulations 2009 Notifications – notice of changes **Regulation 15 1(d) HSCA (RA) Regulations 2014 Premises and equipment** **How the regulation was not being met:** • The provider failed to have a system in place to safely manage the service premises, including Legionella, fire safety and fixed electrical wiring testing. **This was in breach of Regulation 15(1) of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014.**
Diagnostic and screening procedures Surgical procedures Treatment of disease, disorder or injury	Regulation 17 CQC (Registration) Regulations 2009 Notification of death or unauthorised absence of a person who is detained or liable to be detained under the Mental Health Act 1983 **Regulation 17 HSCA (RA) Regulations 2014 Good governance** **How the regulation was not being met:** • There was a lack of systems and processes established and operated effectively to ensure compliance with requirements to demonstrate good governance. • The provider failed to have an effective patient record system in place to safely manage searches and recall of patients. • The provider failed to have a safe system in place to safely manage patient safety alerts, including those which remain clinically relevant. • The provider failed to operate a safe and effective recruitment system. • The provider failed to operate a safe system in place to effectively manage infectious diseases and staff immunisations. • The provider failed to have a system in place to manage patients paper records in a safe way.

This section is primarily information for the provider

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- The provider failed to have a system in place to effectively manage audit activity across the service, including clinical audit and quality improvement.
- 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 significant events.
- The provider failed to have an effective system in place to manage patient feedback exercises.

This was in breach of Regulation 17(1) of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014.