The Bio-Rejuvenation Clinic Limited

23MD

Inspection report

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Overall summary

We carried out an announced comprehensive inspection on 4 February 2019 to ask the service the following key questions; Are services safe, effective, caring, responsive and well-led?

Our findings were:

Are services safe?

We found that this service was not providing safe care in accordance with the relevant regulations.

Are services effective?

We found that this service was providing effective care in accordance with the relevant regulations.

Are services caring?

We found that this service was providing caring services in accordance with the relevant regulations.

Are services responsive?

We found that this service was providing responsive care in accordance with the relevant regulations.

Are services well-led?

We found that this service was providing well-led care in accordance with the relevant regulations.

We carried out this inspection under Section 60 of the Health and Social Care Act 2008 as part of our regulatory functions. This inspection was planned to check whether the service was meeting the legal requirements and regulations associated with the Health and Social Care Act 2008.

The Bio-Rejuvenation Clinic Limited, trading as 23MD, provides a comprehensive range of medical, dermatological and aesthetic treatments to their patients.

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 and Schedule 2 of The Health and Social Care Act 2008 (Regulated Activities) Regulations 2014. 23MD provides a range of non-surgical cosmetic interventions, for example fat reduction therapy and non-surgical face lift which are not within CQC scope of registration. Therefore, we did not inspect or report on these services.

There are two lead clinicians, who are clinic directors, at 23MD. One of the lead clinicians 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.

Summary of findings

As part of our inspection, we asked for CQC comment cards to be completed by patients prior to our inspection. We received eight completed comment cards and patients said they were satisfied with the standard of care received and thought the doctors were approachable, committed and caring. We did not speak with patients directly at the inspection.

Our key findings were:

- The provider had specialised in individualised bioidentical hormone replacement therapy for women and men. Patients were treated with unlicensed medicines which followed evidence-based guidelines and systems were in place to ensure this was carried out safely.
- Some systems and processes were in place to keep people safe. However, some aspects were not operated effectively.
- Staff had the skills, knowledge and experience to deliver effective care and treatment, in most respects. However, some core training for staff had not been completed on a regular basis. Following the inspection, the provider has arranged for staff to undertake specific training and we will review at the next inspection.
- Not all staff in direct clinical contact had undertaken the requisite blood tests and vaccinations to keep staff and patients safe; and there was cross contamination in relation to cleaning equipment. Following the inspection, the provider has initiated measures to mitigate the risk of infection in relation to staff immunity and immunisations and we will review this at the next inspection.
- The clinicians reviewed the effectiveness and appropriateness of the care provided to ensure it was in line with current research and national guidance. Quality improvement and monitoring was achieved through engaging with local and international networks of physicians, clinical audit and patient feedback. However, it would be considered good practice to demonstrate quality assurance and improvement in relation to the regulated activity.
- Staff we spoke with were aware of their responsibility to respect people's diversity and human rights.
- Patients were treated with compassion, kindness, dignity and respect and they were involved in their care and decisions about their treatment.
- Structures, processes and systems to support good governance and management were clearly set out, understood and effective.
- Some practice policies did not contain sufficient information.
- There were limited facilities and arrangements for those patients who are hard of hearing and whose first language is not English.
- There were systems to support improvement and innovation work.

We identified a regulation that was not being met and the provider must:

- Ensure care and treatment is provided in a safe way to patients.

You can see full details of the regulation not being met at the end of this report.

In addition, there were areas where the provider could make improvements and should:

- Consider implementing further clinical audit to measure and demonstrate improved health outcomes for patients receiving bio-identical hormone therapy.
- Review and update practice policies at an appropriate frequency and ensure they contain sufficient information.
- Review the safeguarding policy and consider broadening the definition of safeguarding and at-risk groups within it.
- Review employment processes to ensure appropriate information regarding references is documented during the staff recruitment process.
- Review processes to encourage quality improvement in clinical outcomes.
- Review the facilities and arrangements for those patients who are hard of hearing and whose first language is not English.

Dr Rosie Benneyworth BM BS BMedSci MRCGP

Chief Inspector of Primary Medical Services and Integrated Care

23MD

Detailed findings

Background to this inspection

We carried out this inspection under Section 60 of the Health and Social Care Act 2008 as part of our regulatory functions. This was the first inspection undertaken at this service, which was planned to check whether the service meeting the legal requirements and regulations associated with the Health and Social Care Act 2008.

23MD is in Elystan Street, Chelsea, London, and provides a range of bespoke healthcare service to adults, specialising in individualised bioidentical hormone replacement therapy and aesthetic treatments for men and women. The Bio-Rejuvenation Clinic, trading as 23MD, is a private limited company and the provider of this independent healthcare service. The clinic offers elective appointment based consultations and aesthetic, dermatological and medical treatments. Appointments for new patients last approximately an hour to allow for a detailed assessment. Timings of and frequency of subsequent appointments are agreed with each patient depending on their needs and treatment plan.

The clinic is open Monday to Friday, from 9.30am-5.30pm except for Thursday when clinic hours are 11am-7pm. Their website can be accessed via https://23md.co.uk

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

We gathered and reviewed information prior to the inspection. We interviewed two clinicians, a lead physician specialising in bio-identical hormone treatments (BHRT), and a specialist in cosmetic medicine and the operations manager. We reviewed the provision of care and treatment, patients' records, governance arrangements and patient feedback received by the clinic.

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.

Are services safe?

Our findings

We found that this service was not providing safe care in accordance with the relevant regulations.

Systems were in place to keep people safe. However, we found areas where improvements were necessary relating to the safety of patients. The impact of our concerns is minor for patients using the service, in terms of the quality and safety of clinical care. The likelihood of the issues identified occurring in the future is low once it has been put right. We have told the provider to take action (see full details of this action in the Requirement Notices at the end of this report).

Safety systems and processes

The service had some systems to keep people safe and safeguarded from abuse.

- Arrangements for safeguarding reflected relevant legislation and local requirements. Policies were accessible to all staff. There was information available to staff about who to contact for further guidance if staff had concerns about a patient's welfare and there was a lead member of staff for safeguarding. The clinic did not treat patients under 18 years of age. However, the safeguarding policy covered circumstances of children who were visiting the clinic who had contact with a client of the clinic. Whilst the policy met the needs of the service provided, best practice guidance would include broadening the definition of safeguarding and at-risk groups within it. Following the inspection, the provider has reviewed and updated their policy and we will review at the next inspection.
- Staff interviewed demonstrated they understood their responsibilities regarding safeguarding. The two clinicians currently providing services at the clinic had received training on safeguarding children. The lead clinician had received safeguarding training on vulnerable adults. The clinicians were trained to level two for child safeguarding, and level one for adults. The clinic did not see any children or young people under the 18 years old, however as matter of best practice, should consider child safeguarding training to level three. Non-clinical staff had been trained to level one child and adult safeguarding. Following the inspection, the provider has arranged for clinical staff to undertake level three safeguarding training and we will review at the next inspection.
- One of the lead clinicians specialised in individualised bioidentical hormone replacement therapy for men and women, and for antibiotic prescribing for simple dermatological conditions, on an infrequent basis. Patients were treated with unlicensed bio-identical hormones and systems were in place to ensure this was carried out safely.
- The lead clinicians had a system and process in place by which they managed patient and medicine safety alerts from the Independent Doctors Federation (IDF). They provided examples of alerts they had received but there were no examples of alerts being acted on as none had been relevant.
- All clinicians were registered with the General Medical Council (GMC) the medical professionals' regulatory bodies, with a licence to practice. All the clinicians had professional indemnity insurance that covered the scope of their practice.
- The lead clinicians had current responsible officers. They followed the required appraisal and revalidation processes. All doctors working in the United Kingdom are required to follow a process of appraisal and revalidation to ensure their fitness to practice.
- We reviewed the personnel files of one doctor, and two non-clinical staff currently providing services at the clinic. Appropriate checks had been undertaken in relation to their employment. For example, proof of identification, qualifications and appropriate checks through the DBS.
- Not all staff in direct clinical contact had undertaken the requisite blood tests and vaccinations to keep staff and patients safe; and there was cross contamination in relation to cleaning equipment. Following the inspection, the provider has initiated measures to mitigate the risk of infection in relation to staff immunity and immunisations and we will review this at the next inspection.
- The clinic had a formal written chaperone policy in place. However, patients were advised they could bring a family member with them to the consultation if they wished, despite the risk attached to this, there had been no reference to the Care Act 2014 or to Disclosure and

Are services safe?

Barring Service (DBS) checks. Following the inspection the provider has reviewed and amended its policy regarding this and we will review this at the next inspection.

- The clinic had engaged external advice on infection prevention and control (IPC), but this did not ensure effective IPC processes. We saw cross contamination in relation to cleaning equipment, staff had not undertaken IPC training and the lead clinician for IPC had not undertaken enhanced training. Following the inspection, the provider has arranged for staff to undertake specific training and we will review at the next inspection.
- We observed the premises to be clean and tidy and the clinic was cleaned three times per week. Clinical equipment was cleaned after each patient and clinical waste was disposed of appropriately.
- Comprehensive risk assessments had been completed. For example, health and safety, fixed electrical wire testing, PAT testing and calibration of medical equipment. We noted an outstanding action point from the Fire Safety risk assessment that had been identified as being medium risk and should have been completed within one month. This related to the installation of self-closing fire doors in the basement of the building. Following the inspection, the provider has made arrangements to have the fire doors installed and we will review this at the next inspection.
- The lead clinicians demonstrated an understanding of which incidents were notifiable under the duty of candour. The duty of candour is a set of specific legal requirements that providers of services must follow when things go wrong with care and treatment.
- There was limited disabled access to the premises. However, the clinic provided access to a ground floor consultation room and staff assisted patients and carers as necessary.

Risks to patients

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

- The clinic had an automatic external defibrillator (AED) on the premises and kept a supply of some emergency medicines in line with national guidance. Following the inspection the provider has added emergency medicines which would be used in the instance of an allergic reaction.
- The clinic had a written business continuity plan in place for major incidents such as power failure or building damage, which was accessible, stored electronically and as a hard copy.
- The practice provided evidence that Fire Marshals were in place and trained, and there were documented plans in place for when members of staff are absent from the premises
- There were arrangements for planning and monitoring the number and mix of staff needed, and the provider was in the process of recruiting more staff.
- Staff understood their responsibilities to manage emergencies and to recognise those in need of urgent medical attention.
- When there were changes to services or staff the lead clinicians assessed and monitored the impact on safety.

Information to deliver safe care and treatment

Staff had the information they needed to deliver safe care and treatment to patients.

- The clinicians had the information they needed to deliver safe care and treatment to patients. Clinical files containing patients' notes were stored securely on a secure server. Access to patient records was restricted and password protected, so only staff who needed to access patient information would be able to do so.
- The clinic's network and broadband were firewall protected and kept up to date with automatic updating and regular security upgrades.
- We saw individual patients' records were written and managed in a way that kept patients safe.
- The clinic had a system in place to retain medical records in line with DHSC guidance if they cease trading.
- When necessary, clinicians made appropriate and timely referrals in line with protocols and up to date evidence-based guidance.

Safe and appropriate use of medicines

The service had reliable systems for appropriate and safe handling of medicines.

- The systems and arrangements for managing medicines, including vaccines, controlled drugs, emergency medicines and equipment minimised risks. There was a medicines management policy in place.

Are services safe?

- All prescriptions were issued electronically on a private basis by the lead clinicians. Prescriptions were signed by the lead clinicians, printed and saved onto an electronic file.
- The clinic recommended that all patients shared their consultation and treatment with their usual GP. However, this was only done with the patient's consent. Consent and non-consent was recorded in the patient's record.
- The clinic did not hold stocks of any controlled drugs and did not prescribe any controlled drugs.
- The clinic kept prescription stationery securely and monitored its use.
- The clinic carried out informal medicines audits to ensure prescribing was in line with national guidelines for safe prescribing. They did not engage in formal audit of anti-microbial stewardship as patients were prescribed antibiotics on an infrequent basis only.
- Clinical staff prescribed, administered or supplied medicines to patients and gave advice on medicines in line with legal requirements and current national guidance. Where there is a different approach taken from national guidance there is a clear rationale for this that protects patient safety.
- Processes were in place for checking emergency medicines and equipment and staff kept accurate records of this.

Track record on safety

The service had a good safety record.

- Comprehensive risk assessments had been conducted to assess and manage risks appropriately, however, some aspects were not operated effectively.
- The clinic monitored and reviewed activity. This helped it to understand risks and gave a clear, accurate and current picture that led to safety improvements.
- The service had an up to date fire risk assessment in place and the contractor was carrying out regular fire safety checks, but an action point from the risk assessment had not been completed.
- The service had up to date legionella risk assessment in place and the contractor was carrying out regular water temperature checks. (Legionella is a term for a particular bacterium which can contaminate water systems in buildings).

Lessons learned and improvements made

The service learned and made improvements when things went wrong.

- There was a system for recording and acting on significant events. Staff understood their duty to raise concerns and report incidents and near misses. Under the system lead clinicians would support them when they did so.
- There were adequate systems for reviewing and investigating when things went wrong. The clinic had an incident reporting policy for staff to follow and there were procedures in place for the reporting of incidents and significant events. However, there had been no incidents or significant events since the clinic had opened in 2018.
- The lead clinicians demonstrated an understanding of the requirements of the Duty of Candour. The duty of candour is a set of specific legal requirements that providers of services must follow when things go wrong with care and treatment. The clinic was a policy of being open and transparent which included processes for communicating notifiable safety incidents to external organisations, including the Care Quality Commission.

Are services effective?

(for example, treatment is effective)

Our findings

We found that this service was providing effective care in accordance with the relevant regulations.

Effective needs assessment, care and treatment

The provider had systems to keep clinicians up to date with current evidence based practice. We saw evidence that clinicians assessed needs and delivered care and treatment in line with current legislation, standards and guidance (relevant to their service.)

- The service ensured that all patients must be seen face to face for their initial consultation and in person regularly thereafter.
- We reviewed patients' records and saw the clinicians had assessed needs and delivered care in line with relevant national guidance and standards such as the National Institute for Health and Care Excellence (NICE), the Menopause Society and the British Association of Sexual Health (BASSH).
- The service used a comprehensive assessment process including a full life history account and necessary examinations such as blood tests or scans to ensure greater accuracy in the diagnosis process. The assessments were tailored according to information on each patient and included their clinical needs and their mental and physical wellbeing.
- Clinicians had enough information to make or confirm a diagnosis, and referred patients to other specialist services if required.
- We saw no evidence of discrimination when making care and treatment decisions.

Monitoring care and treatment

The clinic was involved in some quality improvement activity. For example, following a clinical audit related to complications following procedures, the clinic have introduced a 24-hour callback system to ensure patients' wellbeing. In addition we have reviewed audits regarding record keeping and repeat prescribing.

- Clinicians participated in peer review monthly and had a network of colleagues, locally and internationally, they could contact for professional and clinical discussion, and participated in peer review
- The service used information about care and treatment to make improvements. There was clear evidence of one cycle audit to resolve concerns and improve quality. For example, record keeping and repeat prescribing and complications following procedures. The latter audit was completed to identify any themes, regarding concerns or problems patients had experienced following treatment, and for this audit cycle, no patients had reported any issues that had followed a procedure.
- Patients' health was monitored to ensure medicines were being used safely and followed up on appropriately and patients were required to attend a periodic check with the service.
- We found the service was following up on pathology results and had an effective monitoring system in place to ensure that all abnormal results were managed in a timely manner and saved in the patient's records.
- The clinic involved patients in regular reviews of their treatment according to their symptoms and need.
- The practice monitored its performance by feedback from patient satisfaction surveys, utilising a 24-hour call back tool and maintaining up-to date evidence-based clinical practice.

Effective staffing

- All staff were appropriately qualified. The provider had an induction programme for all newly appointed staff. There was limited evidence that staff had undertaken regular training in relation to fire safety, infection prevention and control, and information governance. Following the inspection, the provider has arranged for staff to undertake specific training and we will review at the next inspection.
- Relevant professionals were registered with the General Medical Council (GMC) and were up to date with revalidation.
- The clinic could demonstrate internal appraisal, and role-specific training for all staff.
- The lead clinicians were registered with the Independent Doctors Federation (IDF) the independent medical practitioner organisation in Great Britain. (IDF is recognised as the nationwide voice of independent doctors in all matters relating to private medicine, their education and revalidation).
- The provider understood the learning needs of staff and provided protected time and training to meet them. Up to-date records of skills, qualifications and training that had been undertaken were maintained.
- Staff were encouraged and given opportunities to develop.

Are services effective?

(for example, treatment is effective)

- The lead clinicians had arrangements in place for supporting and managing staff when performance was poor or variable. For example, performance was assessed and extra training was provided when necessary.

Coordinating patient care and information sharing

Staff worked together, and worked well with other organisations, to deliver effective care and treatment.

- Patients received coordinated and person-centred care. Staff referred to, and communicated effectively with, other services when appropriate.
- Before providing treatment, doctors at the service ensured they had adequate knowledge of the patient's health, any relevant test results and their medicines history.
- Upon initial attendance at the clinic all patients were asked for consent to share details of their consultation and any medicines prescribed with their registered GP and other health professionals as required.
- Patient information was shared appropriately (this included when patients moved to other professional services), and the information needed to plan and deliver care and treatment was available to relevant staff in a timely and accessible way. Referral letters contained appropriate information and the provider had a system in place to safety net those referrals.
- Pathology results were directed to patients' GPs when necessary, for example, when the doctors were on annual leave.

Supporting patients to live healthier lives.

Staff were consistent and proactive in empowering patients, and supporting them to manage their own health and maximise their independence.

- The clinic aimed to provide patients, and their carers/ families as appropriate, with personal treatment plans. The aim was to support people in understanding the treatment options available so that they could make informed choices about their care. The clinical team drew on the best practice advice from its peer group and specialist groups to provide on-going support and information to patients.
- Risk factors were identified, highlighted to patients and where appropriate notified to their GP for additional support. For example, patients were given full information prior to and when they had been prescribed unlicensed medicines.
- Where patients' needs could not be met by the clinic, staff referred them to the appropriate service for their needs.
- The service had a range of information available on their website, including a blog discussing women's and men's health issues.

Consent to care and treatment

The service obtained consent to care and treatment in line with legislation and guidance.

- Clinical staff we spoke with understood the relevant consent and decision-making requirements of legislation and guidance, including the Mental Capacity Act 2005.
- Staff supported patients to make decisions. Where appropriate, they assessed and recorded a patient's mental capacity to decide.
- The lead clinician we spoke with informed us that information regarding the use of medicine outside of its licence was provided, the risks explained to the patient and documented during the consultations. Patients signed consent forms prior to treatment which stated they were receiving a medicine for use outside of its licence. However, there was no statement on the clinic's website which informed people about the risks associated with the use of an unlicensed medicine.
- The clinic monitored the process for seeking consent appropriately.

Are services caring?

Our findings

We found that this service was providing caring care in accordance with the relevant regulations.

Kindness, respect and compassion

Staff treated patients with kindness, respect and compassion.

- Clinicians we spoke with were aware of their responsibility to respect people's diversity and human rights.
- We received eight completed Care Quality Commission comment cards which were all very positive about care they had received and staff at the clinic.
- Feedback from patients was very positive about the way staff treat people.
- Patients said they felt the provider offered an excellent service and the doctors were helpful, caring and treated them with dignity and respect. They told us they were satisfied with the care provided by the provider and said their dignity and privacy was respected.
- Staff understood patients' personal, cultural, social and religious needs. They displayed an understanding and non-judgmental attitude to all patients.
- Clinical staff gave patients timely support and information.

Involvement in decisions about care and treatment

Staff helped patients to be involved in decisions about care and treatment.

- Clinicians involved patients in decisions about their care and treatment.
- Patients were provided with information regarding their care and treatment, including risk and benefits, to help patients be involved in decisions about their care.
- Patients told us through comment cards, that they felt listened to and supported by staff and had sufficient time during consultations to make an informed decision about the choice of treatment available to them.
- For patients with additional needs family and carers were appropriately involved.

Privacy and Dignity

The service respected patients' privacy and dignity.

- The consultation rooms were set up to maintain patients' privacy and dignity during therapy sessions.
- The clinic complied with the Data Protection Act 2018 and had policies and processes in place to ensure this.
- Staff recognised the importance of people's dignity and respect.

Are services responsive to people's needs?

(for example, to feedback?)

Our findings

We found that this service was providing responsive care in accordance with the relevant regulations.

Responding to and meeting people's needs

The service organised and delivered services to meet patients' needs. It took account of patient needs and preferences.

- Patient's individual needs and preferences were central to the planning and delivery of tailored services. Clinic services were flexible, provided choice and ensured continuity of care.
- They provided services to patients with an ethos of providing individualised care and treatment, considering and respecting the wishes of its patients.
- The facilities and premises were appropriate for the services delivered.
- Reasonable adjustments had been made so that people with mobility issues, could access and use services on an equal basis to others. For example, the provider ensured patients had access to a ground floor consultation room, if they required it, and assisted them when necessary.
- The clinic did not provide an emergency service. Patients who had a medical emergency were advised to ask for immediate medical help via 999 or if more appropriate to contact their own GP or NHS 111.
- There were limited facilities and arrangements for those patients who are hard of hearing and whose first language is not English. Following the inspection, the provider has reviewed this and will be installing a hearing loop this year and has registered with Language Line for those patients who may require interpreter services.

Timely access to the service

Patients could access care and treatment from the service within an appropriate timescale for their needs.

- Patients had access to a member of staff during out of hours if required, via mobile telephone.
- Patients had timely access to initial assessment, test results, diagnosis and treatment.
- Waiting times, delays and cancellations were minimal and managed appropriately.
- Patients reported that the appointment system was easy to use.
- Referrals and transfers to other services were undertaken in a timely way. For example, referral to specialist dermatology services.

Listening and learning from concerns and complaints

The clinic took complaints and concerns seriously and responded to them appropriately to improve the quality of care.

- There was a policy and procedures in place for handling complaints and concerns.
- The Registered Manager was the designated responsible person for handling complaints in the clinic.
- There had been no formal complaints made since the practice had opened in 2018.
- The complaints policy and procedures were in line with recognised guidance.
- Staff treated patients who made complaints with kindness and compassion.
- The service learned lessons from individual concerns. It acted as a result to improve the quality of care. For example, because of feedback, patients are called back within twenty-four hours following treatment, to ascertain patients' well-being and any problems highlighted are dealt with immediately.

Are services well-led?

(for example, are they well-managed and do senior leaders listen, learn and take appropriate action?)

Our findings

We found that this service was providing well-led care in accordance with the relevant regulations.

Leadership capacity and capability;

Lead clinicians had the capacity and skills to deliver high-quality, sustainable care.

- The lead clinicians had the experience, capacity and skills to deliver the clinic strategy and address risks to it. They understood the challenges and were addressing them.
- Senior members of staff were visible and approachable. They worked closely with staff to make sure they prioritised compassionate and inclusive leadership.
- The provider had effective processes to develop leadership capacity and skills.

Vision and strategy

The provider had a clear vision and credible strategy to deliver high quality care and promote good outcomes for patients.

- The provider had a mission statement and statement of purpose which included its aim and objectives. The key objective was to provide a bespoke patient-centred healthcare service specialising in bio-identical hormones to adults which meets and exceeds patients' expectations, to provide effective care in a transparent manner and to ensure compliance with legal requirements.
- The service developed its vision, values and strategy jointly with staff, who were aware of and understood the vision, values and strategy and their role in achieving them
- The service monitored progress against delivery of the strategy and as a result had expanded the services offered to patients.

Culture

The service had a culture of high-quality sustainable care.

- The clinic comprised a small expert group whose focus was the needs of patients.
- The lead clinician and clinical team were aware of the need for openness, honesty and transparency with patients about their care and treatment and when responding to incidents and complaints.
- Staff felt respected, supported and valued and were proud to work for the service.
- The service focused on the needs of patients.
- The management team acted on behaviour and performance inconsistent with the vision and values.
- Openness, honesty and transparency were demonstrated when responding to incidents and complaints. The provider had an open policy under which it was committed to addressing complaints, investigating them and offering apologies to patients concerned in a timely way. The provider was aware of and had systems to ensure compliance with the requirements of the duty of candour.
- There was regular dialogue between the clinicians, and there were opportunities to raise and resolve any concerns.
- Staff told us they could raise concerns and were encouraged to do so. They had confidence that these would be addressed.
- There were positive relationships between staff and managers.

Governance arrangements

There were clear responsibilities, roles and systems of accountability to support good governance and management in most respects.

- Structures, processes and systems to support good governance and management were clearly set out, understood and effective. The governance and management of the doctors' partnership, and joint working arrangements promoted person-centred care.
- Staff were clear on their roles and accountabilities.
- There were a range of practice policies in place but they did not all contain appropriate information.
- Some core training for staff had not been completed on a regular basis. Following the inspection, the provider has arranged for staff to undertake specific training and we will review at the next inspection.

Are services well-led?

(for example, are they well-managed and do senior leaders listen, learn and take appropriate action?)

Managing risks, issues and performance

There were clear and effective processes for managing most risks, issues and performance.

- The provider had arrangements in place to identify, understand, monitor and address current and future risks including risks to patient safety. However, there was no updated documented risk assessment of the decision not to have emergency medicines for the treatment of allergy available in the clinic and the action taken to mitigate the risks to patient safety. Following the inspection the provider has added emergency medicines which would be used in the instance of an allergic reaction.
- An action point in the fire safety risk assessment that had not been completed, fire safety training had not been undertaken by all staff and there were some shortcomings in relation to IPC processes and training. Following the inspection, the provider has arranged for fire doors to be installed and staff to undertake specific training and we will review at the next inspection.
- The provider had processes to manage current and future performance. Performance of clinical staff could be demonstrated through audit of their consultations and prescribing decisions.
- Although clinical audits had been completed for one cycle only, there was some evidence of action to change services to improve quality.
- Lead clinicians had oversight of safety alerts, incidents, and complaints.
- Clinicians told us that they continuously reviewed their own clinical practice in line with new guidance and guidelines. The doctors regularly engaged in peer review with colleagues at a local and international level.

Appropriate and accurate information

The service acted on appropriate and accurate information.

- Patient assessments, treatments and medications, including ongoing reviews of their care, were recorded on a secure electronic system. We reviewed patients records and found that the assessments included clear information and recommendations and notes from all the previous consultations were accessible.
- Care and treatment records were complete, legible and accurate, and securely kept.
- The provider had supporting documents regarding data storage from the Information Commissioner's Office (ICO) and had protocols for safe sharing and storage of sensitive information. The provider was also registered with the ICO.
- Quality and sustainability were discussed in clinic meetings where all staff were involved and learning was shared.
- The service used performance information which was reported and monitored and management and staff were held to account.

Engagement with patients, the public, staff and external partners

The clinic worked to involve patients, the public, staff and external partners to support high-quality care.

- Patients', staff and external partners' views and concerns were encouraged, heard and acted on to shape services and culture.
- Staff could describe to us the systems in place to give feedback. The clinic proactively gathered feedback from patients after each appointment.
- We saw evidence of feedback from patients, and how findings were shared with staff to make improvements.

Continuous improvement and innovation

There was evidence of systems and processes for learning, continuous improvement and innovation.

- The clinic consistently sought ways to improve and we found an ethos of continuous learning and improvement was evident.
- The clinicians regularly attended local, national and international peer networks regarding the different approaches, impacts, side effects and developments related to the use of bio-identical hormones. This enabled the various experiences to be shared among the clinicians to treatment options available to patients.
- Lead clinicians encouraged staff to use protected time to review individual and team objectives, processes and performance.
- There were systems to support improvement and innovation work. For example, 23MD offers two scholarship awards for tuition fees on appropriate education courses for doctors and nurses who are committed to making a career in Aesthetics or Age Management Medicine.

Are services well-led?

(for example, are they well-managed and do senior leaders listen, learn and take appropriate action?)

- The lead clinicians had made strenuous efforts to ensure that equipment purchased and used by the clinic had been purchased from sources that could demonstrate a positive record on human rights.

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 Treatment of disease, disorder or injury	Regulation 12 HSCA (RA) Regulations 2014 Safe care and treatment Care and treatment must be provided in a safe way for service users **How the regulation was not being met:** The provider did not have established and effectively operated systems to ensure care and treatment to patients was provided in a safe way in relation to: Regulation 12 HSCA (RA) Regulations 2014 Safe care and treatment Care and treatment must be provided in a safe way for service users **How the regulation was not being met:** The provider did not have established and effectively operated systems to ensure care and treatment to patients was provided in a safe way in relation to: • The safe management of medicines, having regard to the availability of emergency medicine in the instance of a patient having an allergic reaction: a written risk assessment had not been completed. • Health and safety of premises and equipment: an action point from a fire safety risk assessment related to self-closing fire doors in the basement had not been completed. The risk associated with cords on blinds in the patient's treatment rooms had not been mitigated, or an appropriate risk assessment conducted and documented. • Infection prevention and control (IPC) measures: Not all staff in direct clinical contact had undertaken the requisite blood tests and vaccinations to keep staff and patients safe; and there was cross contamination in relation to cleaning equipment.

This section is primarily information for the provider

Requirement notices

• Confirmation of the suitability of staff in terms of their qualifications, competence, skills and experience to provide safe care and treatment. There were gaps in training regarding the appropriate level of safeguarding children training for their roles, IPC, information governance and fire safety.

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