The Monteiro Clinic North

Inspection report

7 Craven Park Road
London
NW10 8SE
Tel: 020 8961 1117
www.monteiroclinic.co.uk

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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.

Overall summary

This service is not rated in this inspection. (There was one previous inspection. The first on 17 April 2019 rated the practice as inadequate. It was rated as inadequate for safe, effective and well led care, and requires improvement for caring and responsive care.)

We carried out an announced inspection at the Monteiro Clinic North to follow up on the previous 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.

Following the inspection, we acted immediately regarding: and imposed an urgent condition on the provider by issuing a s.31 notice under the Health and Social Care Act 2008 regarding:

- Regulation 12 Safe care and treatment.
- Regulation 17 Good governance

This condition prevented the provider from operating medical services with immediate effect.

The Monteiro Clinic Limited is an independent provider of medical services and offers a full range of private general practice services predominantly to the Brazilian, Portuguese and Spanish communities. The service has a sister practice in Clapham, South London.

Dr Monteiro is the lead clinician and 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 service had a policy in place to manage patients who had been prescribed high risk medicines. However, we found further serious concerns regarding the management of patients prescribed these medicines.
- We found concerns regarding the management of patient care that was not provided in accordance with best practice and national guidance.
- Practices nurses had not undertaken specific role training or been competency checked and we found they had been working whilst subject to an urgent condition to prevent them from doing so.
- There was limited evidence of a safe system and processes in place regarding safeguarding children and vulnerable adults.
- The clinical IT system at the practice was difficult to audit and doctors at the practice seemed unaware where on the patient record to include information.
- All GPs' had undertaken safeguarding training at an appropriate level.
- The service did not have an Import Licence for medicines imported from Portugal.
- Yellow Fever vaccines had been administered to patients, but the service was not registered as a Yellow Fever Centre.
- There was a lack of clinical governance and oversight for patient care.
- The service did not recognise or record all significant events.
- The service did not have an adequate clinical audit system in place to ensure quality improvement.

At this inspection we found that the practice had addressed some of the issues from the warning notices. However, we noted that there were areas that had not been addressed, and a clinical records review showed clinical care which was inadequate.

We found that:

- The service did not provide care in a way that kept patients safe and protected them from avoidable harm.
- Patients did not receive effective care from clinicians at the practice, and there were inadequate systems to ensure that staff were fit for the role they were undertaking and the management of consent.
- The way the practice was led and managed did not promote the delivery of high-quality, person centre care. There was a lack of governance systems, protocols and systems to provide safe and effective care.

The areas where the provider **must** make improvements as they are in breach of regulations are:

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

Overall summary

- Ensure systems and processes are established and operated effectively to ensure compliance with the requirements of good governance.

Following the previous inspection of 17 April 2019, this service had warning notices placed against it. Insufficient improvements have been made to ensure that patients were receiving safe, effective and well led care. We have also found significant concerns about the care being provided to patients through clinical record review.

Therefore, we are acting in line with our enforcement procedures to prevent the provider from operating medical services and may only provide dental services at this location. We have taken immediate action to prevent the provider from providing regulated services from this location.

Dr Rosie Benneyworth BM BS BMedSci MRCGP Chief Inspector of Primary Medical Services and Integrated Care.

Our inspection team

Our inspection team was led by a CQC lead inspector. The team included a GP specialist adviser, a CQC inspector, a CQC pharmacist specialist and a practice manager specialist adviser.

Background to The Monteiro Clinic North

The Monteiro Clinic North is located at 7 Craven Park Road, Harlesden, London, NW10 8SE, in the London borough of Brent.

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

Services provided include: management of long-term conditions; gynaecological assessment; dressings; childhood immunisations; blood and other laboratory tests; travel vaccines; and ear syringing. Patients can be referred to other services for diagnostic imaging and specialist care.

The service is open Monday to Friday from 9am to 7pm and on Saturday 9am to 4pm and does not offer out of hours care. The provider's website can be accessed at www.monteiroclinic.co.uk

How we inspected this service:

Before the inspection we reviewed a range of information submitted by the service in response to our provider information request. During our visit we interviewed staff, observed practice and reviewed documents.

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?

At our previous inspection on 17 April 2019, we found the following areas of concerns in relation to the provision of safe services that contributed to our decision to issue a warning notice regarding:

- The service had limited systems to safeguard children and vulnerable adults from abuse. There are four examples of this:
- The service 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 are safeguarding concerns, to ensure they are reviewed.
- We found all GPs' had undertaken safeguarding training at level three for children. Four out of seven GPs' had completed level two training only.
- There was no evidence of a system in place to safety net and protect young girls and women for whom there are safeguarding concerns regarding FGM, to ensure they are reviewed.
- The provider had reviewed and updated several practice policies. However, the safeguarding policy did not contain pertinent information. For example, the service makes no reference to the legal requirement to report FGM.
- The provider could not demonstrate they had a fail-safe system or policy in place to ensure patients test results had been reviewed and actioned, if required, by a GP.
- The service did not have a system or process in place to safely manage patients who were prescribed high risk medicines, to ensure they receive appropriate blood monitoring and were regularly reviewed.
- The provider could not demonstrate they had carried out regular medicines audits to ensure prescribing was in line with best practice guidelines for safe prescribing.
- Staff told us the service did not have a fail-safe system or process in place regarding urgent referrals and they did not follow up patients to ensure they had attended for appointments.
- The provider could not demonstrate evidence that medical indemnity insurance was in place for one GP; one pharmacist; one practice nurse and one dispensary assistant.
- The provider told us they did not have a sepsis toolkit within their clinical IT system.
- Staff told us there was no system or policy in place to safely manage MHRA alerts and the provider could not demonstrate they had conducted and saved searches on the clinical system regarding the latest medical safety alerts to ensure risks to patients were minimised.
- The service had a limited mechanism in place to disseminate relevant alerts to all members of the team including sessional and agency staff.
- There was a limited system to manage infection prevention and control.
- Practice staff told us how they would screen patients for potential medical emergencies, but staff had not undertaken appropriate training to undertake this role.
- We did not see evidence that all staff in direct clinical contact had the requisite blood tests and vaccinations to keep patients safe, in line with Public Health England guidance. For example, MMR, Varicella and BCG, or had certificated evidence of immunity.
- The service imported its medicines from Portugal and did not hold a valid license. MHRA guidance states that unlicensed medicines may only be supplied against valid special clinical needs of an individual patient. The General Medical Council's prescribing guidance specifies that unlicensed medicines may be necessary where there is no suitable licensed medicine. The provider could not demonstrate that patients had been appropriately assessed before prescribing such medicines. Treating patients with unlicensed medicines is a higher risk than treating patients with licensed medicines, because unlicensed medicines may not have been assessed for safety, quality and efficacy.
- Staff had administered Yellow Fever vaccines to patients but was not registered as a Yellow Fever centre.
- The practice dispensary did not have a sink in situ. To mix medicines, staff had to use the water dispenser in reception.
- Due to the limitations of the clinical IT system, we could not be assured that all care records for patients were appropriately managed.
- The service had one vaccine fridge that had only one thermometer in situ and you had not ensured this was calibrated on a monthly basis.
- The provider did not have safe recruitment procedures in place for doctors who did not work exclusively for their service.
- Some comprehensive risk assessments had been conducted to assess and manage risks appropriately,

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however, some aspects were not operated effectively. The service had undertaken a Legionella risk assessment but had not conducted water testing at the temperatures required for healthcare establishments.
- We reviewed evidence where it is stated that practice nurses should introduce a consent form for minor surgical procedures and prepare a minor surgery trolley prepared for use when required. The provider is not registered with the Commission for surgical procedures for medical services.
- There were some systems in place to safely manage healthcare waste, however, guidelines and audits in relation to this had not been undertaken.

At our inspection on 4 July we found the following:

- The provider told us they had made improvements to their safeguarding systems. However, we reviewed evidence which highlighted gaps in their systems to safeguard children and vulnerable adults from abuse. For example, we reviewed patients record and saw that a patient who suffered domestic abuse had been referred for further help to a safeguarding organisation and had not had appropriate alerts placed on their record. This had not been recognised as a safeguarding concern by the service.
- The provider had introduced an alert system for children and for patients who are vulnerable. However, the alerts we reviewed did not specify what the alert was for, for example, if it was a medicine allergy alert or one for safeguarding a child.
- The provider had ensured that all GPs had undertaken safeguarding training at level three for adults.
- The provider had developed a policy on FGM. However, this did not contain information regarding the fact that FGM is a criminal offence.
- The provider had developed and could demonstrate they had a fail-safe system or policy in place to ensure patients test results had been reviewed and actioned, if required, by a GP.
- Since the last inspection, the provider had implemented a protocol regarding the safe management of high-risk medicines. However, we found unsafe prescribing in a number of sampled patient medical records where such high-risk medicines had been prescribed repeatedly.
- For example, for one such high risk medicine there is a requirement for careful monitoring, which should include monitoring the full blood count (FBC), renal and liver function of the patient. Inappropriate prescribing of this such medicine could prove fatal. Initial monitoring is more frequent than routine monitoring, for example, every one to two weeks after initiating treatment. Thereafter, routine monitoring must occur at least every three months. We found five patients who were currently recorded as being prescribed this medicine by the service. Of these five patients, our review of patients' records found unsafe care for four patients prescribed this medicine.
- In one example, we found that a patient was prescribed this medicine by a doctor unrelated to the practice in Brazil. There was no information on the patient's record to evidence this. Our review of this patient identified that there were no blood tests on record. The most recent prescription was issued on 29 April 2019 for 56 tablets. The patient was advised to take two tablets per week. This equates to a supply of medicine for 28 weeks.
- In the second example, a patient was prescribed this medicine on 25 June 2019 for 28 tablets. Our review of the medical patient's record identified that a full blood count (FBC) had been undertaken on 9 March 2019 but no further blood tests were recorded on the patient's record.
- In the third example, a patient was prescribed this medicine. Our review of the medical patient's record identified that this was first prescribed by doctors at Monteiro Clinic North on 3 June 2019 and not by secondary care clinicians. There was no appropriate blood monitoring on record and the medical patient had been issued with a two months' supply of this medicine. There was no information on the patient's record to provide a rationale as to why this medicine was prescribed.
- In the fourth example, we found a patient record for a patient who resided in Ethiopia who had not been a patient at this location. In May 2019, the service prescribed 6 months' supply of this medicine in the name of this patient. There was no information on the patient's medical record of any blood monitoring recorded or evidence of direct communication with the said patient. Staff told us that the prescription was collected by an advocate on behalf of the patient, filled by an English pharmacy and posted on to Ethiopia. The evidence recorded regarding this prescription related to a scanned document dated 24 February 2012 which was unsigned and undated and there was no proof of identity of the prescriber recorded.

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- We have reviewed three patients on two medicines used of the treatment of mental health conditions. Both medicines require regular blood monitoring for full blood count; thyroid functions tests; blood glucose and urea and electrolytes. We found no evidence of ongoing blood monitoring and assessment of cardiovascular risk including regular electrocardiography, in line with national prescribing guidelines. There are significant harmful side effects from these medicines which include: Anaemia; type 2 Diabetes; Hyponatraemia (an electrolyte imbalance); Hypothyroidism, and Thrombocytopenia (low platelet cells which help with blood clotting).
- We found in all cases that baseline tests were not undertaken prior to commencing treatment and this included no evidence on ongoing blood monitoring cardiovascular risk assessments in line with national guidelines issued to ensure patients are being treated safely.
- The service did not have appropriate arrangements in place to manage and monitor the prescribing of a non-steroidal medicine. Since our last inspection on 17 April 2019 date, we found evidence that 488 patients had been prescribed this medicine somewhere other than at the Monteiro Clinic North. We looked at 6 patient records who had been prescribed this medicine and found in all those patient records reviewed, we found no recorded evidence that first line treatment had been offered in line with national prescribing guidelines. This medicine increases the risk of cardiac problems and stroke, particularly in long term use of high doses and in patients who are already at high risk because of their pre-existing conditions.
- The service had implemented a system to follow up all referrals. However, the system did not differentiate between urgent and non-urgent referrals. The system involved two text reminders to the patient. This was not a fail-safe system.
- The provider submitted information regarding medical indemnity insurance. However, this was not a certificate and does not include any specific information regarding who is covered and to what level.
- The provider had improved their system to include information on diagnosis of sepsis.
- We saw the provider has made improvements as to how they managed patient safety alerts. However, we reviewed information where it had been recorded that alerts had been discussed at a clinical meeting, but the meeting had not taken place.
- The provider had improved their system to safely manage infection prevention and control.
- The service had provided sepsis and 'red flag' training for staff to enable them to safely screen patients.
- The provider had undertaken some improvements regarding staff immunisations for those in direct patient, to keep patients safe, in line with Public Health England guidance. For example, diphtheria, polio and tetanus or had certificated evidence of immunity. However, this was incomplete.
- The provider had applied for an import licence to enable them to import medicines from Portugal. However, the licence was not yet in place, and they were using medicines which had been imported without this licence.
- The provider had sent an email memo to staff on 21 May 2019 to inform them the service could not provider Yellow Fever vaccines to patients as this location was not registered as a Yellow Fever Centre.
- The practice dispensary did not have a sink in situ. To mix medicines, staff had to use taps in the practice nurses' room.
- Due to the limitations of the clinical IT system, we could not be assured that all care records for patients were appropriately managed.
- The service had one vaccine fridge that had only one thermometer,and this had not been calibrated on a monthly basis. Staff told us they had a data logger to use in the vaccine fridge which would monitor temperatures independently. However, this was not in place and we did not see evidence of a data logger.
- The provider had made improvements to recruitment procedures in place for doctors who did not work exclusively for their service.
- The provider had made improvements to their risk assessment for Legionella and regarding water testing checks.
- We saw evidence the provider had undertaken waste audits. However, the service could not provide management of waste guidelines.

Are services effective?

At our previous inspection on 17 April 2019, we found the following areas of concerns in relation to the provision of safe services that contributed to our decision to issue a warning notice regarding:

- Due to the limitations of the clinical IT system, the provider could not demonstrate that it had systematically provided patients with long-term conditions, who did not have access to NHS care, with a structured annual review to check that their health and medicines needs were being met.
- The provider had not assured themselves that the practice nurses were competent to undertake the roles they had undertaken, for example, cervical screening, review of long-term conditions; dressings; childhood immunisations; blood tests; travel medicine and vaccines; and ear irrigation.
- The provider had undertaken recruitment training checks for doctors who worked only in the practice and had evidence of their revalidation. For doctors who worked elsewhere, the provider relied on checking GMC registration only.
- The provider did not have an adequate clinical audit system in place to ensure quality improvement.

At our inspection on 4 July we found the following:

- We reviewed 10 clinical records with COPD, diabetes and hypertension. In all 10 records, we found evidence that GPs did not work in accordance with national guidance and guidelines. It was not evident what guidelines they were following, if not recognised national guidance, as there were no in-house policies or procedures for clinical staff to follow.
- The practice had implemented some training for nursing staff, but it was insufficient to remove the condition which had suspended the nursing service at a provider level. We found evidence that practice nurses have potentially been undertaking nursing duties during the period that the service had been suspended and had been documenting consultations that GPs' have undertaken.
- The provider had made improvements regarding their systems for checking training records for specialist sessional clinical staff to demonstrate they were competent in their specialist field.
- The provider had not made any improvements regarding a clinical audit system to ensure quality improvement.

Are services well-led?

At our previous inspection on 17 April 2019, we found the following areas of concerns in relation to the provision of safe services that contributed to our decision to issue a warning notice:

- 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 GP consultations by opportunistic review.
- The provider had installed its own clinical IT system which was difficult to navigate and did not facilitate audits of high-risk medicines for example. For example, the provider could not appropriately review patients records due to the limitations of the clinical IT system.
- 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 proactive systematic risk.
- The provider did not hold whole staff meetings to enable and share learning across teams.
- We found you did not recognise or record all significant events. There had been two significant events recorded in the past 12 months, in addition to two more which had not been recognised and documented as such and one significant event had been documented in Portuguese.
- We reviewed several practice policies which require updates. For example, the safeguarding policy makes no reference to the legal requirement to report FGM, there is no reference to urgent procedures, staff concerns about other staff and no reference to external whistle blowing options. In addition, the policy references to cultural differences, which could be conflicting with requirements to report.
- We found evidence that access to services for patients who have additional communication needs was inadequate. e.g. a hearing loop for people who are hard of hearing and interpreter services for patients who speak languages other than English, Spanish and Portuguese.
- We saw evidence that the provider did not have information displayed to ensure patients' have access to information for GP services when the practice is closed.

At our inspection on 4 July we found the following:

- The database at the practice had previously been difficult to audit and therefore clinical records could not easily be reviewed. Since the last comprehensive inspection, the practice had incorporated several searches. We found the system remained limited and was difficult to audit. For example, it was possible to search for six conditions only: arthritis; asthma; COPD; diabetes; epilepsy and hypertension.
- The practice did not have systems in place where it could assure itself that clinicians were prescribing in line with best practice and they did not audit their work. The clinical records that we reviewed detailed care that was not in line with best practice guidance, showed that follow up consultations were not being carried out and that patients with potentially serious issues were not being managed. As a result, the practice was unaware of the risks of harm to patients and had not taken any action to improve the level of care and treatment provided to patients.
- Following our previous inspection, the practice nurses had been prevented from working until they had undertaken further training and been competency checked. Therefore, it was not possible to review whether PGDs' had been operated effectively.
- The practice had not improved their systems 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 further evidence of a lack of clinical governance.
- We saw evidence that one meeting of the whole service team had taken place.
- We reviewed evidence the service was striving to make improvements. However, the service still did not recognise all significant events and record them appropriately.
- We saw evidence that access to services for patients who have additional communication needs had been partly improved. A hearing loop had been introduced to assist those patients with a hearing disability. However, the provider could not demonstrate that they had improved communication systems for patients who speak languages other than English, Spanish and Portuguese.
- We saw evidence the provider had appropriate information displayed to ensure patients' have access to information for GP services when the practice is closed.

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 the service provider was not meeting. The provider must send CQC a report that says what action it is going to take to meet these. We took enforcement action because the quality of healthcare required significant improvement.

Regulated activity	Regulation
Diagnostic and screening procedures Treatment of disease, disorder or injury	Section 31 HSCA Urgent procedure for suspension, variation etc. **Urgent imposition of a condition on the providers registration under section 31 of the Health and Social Care Act 2008.** **Care and treatment must be provided in a safe way for service users.** • The provider could not demonstrate they had an effective system in place to safely monitor and manage patients who had been prescribed high-risk medicines. • The provider could not demonstrate they had effective processes in place to ensure that clinicians were aware of relevant and current evidence-based guidance and standards and were practising in line with national guidance. • The provider did not have appropriate arrangements in place to manage and monitor the prescribing of some high-risk medicines.