

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.

Ratings

Overall rating for this location	Inadequate	
Are services safe?	Inadequate	
Are services effective?	Inadequate	
Are services caring?	Requires improvement	
Are services responsive?	Requires improvement	
Are services well-led?	Inadequate	

Overall summary

We carried out an announced comprehensive inspection on 17 April 2019 to ask the service the following key questions; Are services safe, effective, caring, responsive and well-led?

This service is rated as Inadequate

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 inspection at the Monteiro Clinic North 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 took action immediately regarding the practice nurses and imposed an urgent condition on the provider by issuing a s.31 notice under the Health and Social Care Act 2008. This condition prevented the practice nurses from operating until they were appropriately trained and competency checked to carry out the roles they were employed to perform.

We issued the provider with two Warning Notices under the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014:

•Regulation 12 Safe care and treatment.

•Regulation 17 Good governance.

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. This is the first inspection of the service. 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.

As part of our inspection, we asked for CQC comment cards to be completed by patients prior to our inspection. We received 13 completed CQC comment cards which were all positive about the level of service and the care provided, and patients felt that they were treated with dignity and respect. We did not speak with patients directly at the inspection.

Our key findings were:

•Practices nurses did not have the required training, knowledge and experience to carry out the roles they were undertaking.

•There was limited evidence of system and processes in place regarding safeguarding children and vulnerable adults.

•Not all GPs' had undertaken safeguarding training at an appropriate level.

•The service did not have a system or policy in place to safely manage patients who had been prescribed high risk medicines.

•Staff had not undertaken training to enable them to screen patients for red flag signs.

•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.

•The provider was aware of their responsibility to respect people's diversity and human rights.

•Patients could access care and treatment from the clinic within an appropriate timescale for their needs and information leaflets were available in Spanish, Portuguese and English.

Overall summary

•Staff told us the service offers new patients a free health check consultation.

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

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

•Establish effective systems and processes to ensure good governance in accordance with the fundamental standards of care.

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

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 population group, 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 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 pharmacist specialist, a practice manager specialist adviser, practice nurse specialist adviser and a CQC inspector.

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:

•ls it safe?

- •Is it effective?
- •ls 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?

We rated safe as Inadequate because:

Safety systems and processes

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

•The service had limited systems to safeguard children and vulnerable adults from abuse.

•They 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.

•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 could not demonstrate that it had systems in place to check a person's identity, age and, where appropriate, parental authority.

•The provider carried out staff checks at the time of recruitment and on an ongoing basis where appropriate, and this included Disclosure and Barring Service (DBS) checks were undertaken where required. (DBS checks identify whether a person has a criminal record or is on an official list of people barred from working in roles where they may have contact with children or adults who may be vulnerable).

•Non-clinical and administration staff had received up-to-date safeguarding appropriate to their role. However, not all GPs' had undertaken safeguarding children training at level three . Four out of seven GPs' had completed level two training for children only. Following the inspection, all clinical staff had completed safeguarding adults and children at level three.

•Reception staff who acted as chaperones were trained for the role and had received a DBS check.

Risks to patients

The service did not have systems to assess, monitor and manage risks to patient safety.

•The provider could not demonstrate they had a failsafe system or policy in place to ensure patients test results had been reviewed and actioned, if required, by a GP. •Staff told us the service did not have a failsafe 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 provide 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, for example, a medicine called valproate.

•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 provider ensured that facilities and equipment were safe and that equipment was maintained according to manufacturers' instructions.

•There were some systems in place to safely manage healthcare waste, however, guidelines and audits in relation to this had not been undertaken.

•The provider regularly carried out appropriate environmental risk assessments.

•There was an effective induction system for agency staff tailored to their role.

Information to deliver safe care and treatment

Are services safe?

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

•Due to the limitations of the clinical IT system, we could not be assured that all care records for patients were appropriately managed. We reviewed some individual care records, for patients who had an NHS GP and saw they were written and managed in a way that kept patients safe.

•However, the provider could not demonstrate that care records for patients who did not have access to NHS care, were managed in a safe and effective way.

•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.

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

•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.

•The service kept prescription stationery securely and monitored its use.

•The service had an automatic external defibrillator (AED) on the premises and kept a supply of emergency medicines in line with national guidance.

•Processes were in place for checking emergency medicines and equipment, staff kept accurate records and this was maintained in line with national guidance.

•Processes were in place for checking medicines and staff kept accurate records of medicines. However, the practice pharmacist was unable to access patients records when dispensing medicines, which would have provided an additional layer of scrutiny in relation to patient safety.

•Pharmacists and dispensary staff could provide medicines labels in Spanish and Portuguese for those patients who first language was not English. •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 dispensary did not have a sink in situ. To mix medicines, staff had to use the water dispenser in reception.

•The provider had maintained appropriate cold chain procedures and records but the vaccine fridge had only one thermometer in situ. In the instance of having one vaccine fridge in place, the provider should ensure this is calibrated monthly.

Track record on safety and incidents

The service had a good safety record.

•Some comprehensive risk assessments had been conducted to assess and manage risks appropriately, 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.

Lessons learned and improvements made

The service had limited systems to learn and improve 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. We reviewed evidence that there was learning from significant events, but not all significant events were recorded and learning was not shared with all staff.

Are services safe?

•Staff were open and transparent when we conducted interviews. The provider was aware of and complied with the requirements of the Duty of Candour and encouraged a culture of openness and honesty.

When there were unexpected or unintended safety incidents:

•The service gave affected people reasonable support, truthful information and a verbal and written apology

•They kept written records of verbal interactions as well as written correspondence.

Are services effective?

We rated effective as Inadequate because:

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

Effective needs assessment, care and treatment

The provider did not have systems to keep clinicians up to date with current evidence-based practice. We saw evidence that clinicians did not assess needs and delivered care and treatment in line with current legislation, standards and guidance (relevant to their service).

•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. However, we could not be assured that test results were always reviewed by a doctor and that patients who were referred urgently to specialist care were followed up.

•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 service was not involved in quality improvement activity.

•The clinic was involved in limited quality improvement activity. We reviewed audits regarding patient feedback, staff satisfaction and repeat prescribing. For example, the antibiotic audit was carried out in 2017 and did not stipulate which location the audit related to. In addition, there was no action plan to address the issues identified in the audit.

•The lead clinician attended Independent Doctors Federation (IDF) meetings. (IDF is recognised as the nationwide voice of independent doctors in all matters relating to private medicine, their education and revalidation).

•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.

Effective staffing

Staff did not have the skills, knowledge and experience to carry out their roles.

•Practices nurses did not have the appropriate training, knowledge and experience to carry out the specific extended roles they were undertaking, for example, cervical screening, review of long-term conditions; dressings; childhood immunisations; blood tests; travel medicine and vaccines and ear irrigation.

•The provider had an induction programme for all newly appointed staff.

•Relevant professionals (medical and nursing) were registered with the General Medical Council (GMC), the General Pharmaceutical Council (GPhC) and the Nursing and Midwifery Council (NMC).

•Staff could undertake comprehensive regular training within protected time, for example, basic life support, fire safety training, infection prevention and control (IPC) and information governance, but the IPC lead had not undertaken enhanced IPC training.

•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.

Coordinating patient care and information sharing

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

•Patients were referred to other services when appropriate. For example, urgent referral to specialist services where cancer is suspected, and to gynaecology services.

•For those patients who had access to NHS care, the provider asked for consent to share details of their consultation and any medicines prescribed with their registered GP on each occasion they used the service.

•The provider had risk assessed the treatments they offered. They had identified medicines that were not

Are services effective?

suitable for prescribing if the patient did not give their consent to share information with their GP, or they were not registered with a GP. For example, medicines liable to abuse or misuse.

•Where patients agreed to share their information, we saw evidence of letters sent to their registered GP in line with GMC guidance.

•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. However, staff told us the practice did not follow on people who had been referred to other services.

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.

•Where appropriate, staff gave people advice so they could self-care.

•Risk factors were identified, highlighted to patients and where appropriate highlighted to their normal care provider for additional support, for example, we reviewed evidence of letters sent to patients NHS GPs'.

•Patients were referred to appropriate services elsewhere, including specialist teams, when required.

Consent to care and treatment

The service did not always obtain consent to care and treatment in line with legislation and guidance.

•Some staff did not understand the requirements of legislation and guidance when considering consent and decision making, for example, Gillick competence. The provider could not demonstrate that staff supported patients to make decisions.

•We were unable to review evidence that the service monitored the process for seeking consent appropriately.

Are services caring?

We rated caring as Requires improvement because:

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 thirteen completed Care Quality Commission comment cards which were all 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 and caring. 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. For example, we observed the pharmacist giving a patient advice on how to take their medicines in both English and Portuguese as this was their preferred language.

Involvement in decisions about care and treatment

Staff helped patients to be 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, but did not provide evidence to support this.
- 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.
- The provider could not demonstrate they had undertaken patient feedback surveys.
- The provider could not demonstrate they had a register of carers in place, and that for patients with additional needs, that family and carers were appropriately involved.

Privacy and Dignity

The service respected patients' privacy and dignity.

- Some of the consultation rooms were set up to maintain patients' privacy and dignity during consultations, for example, the nurses room did not contain privacy curtains.
- 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.
- Staff knew that if patients wanted to discuss sensitive issues or appeared distressed they could offer them a private room to discuss their needs.

Are services responsive to people's needs?

We rated responsive as Requires improvement because:

Responding to and meeting people's needs

- The service had not conducted an analysis of the needs of its patient population groups, for example, the practice did not systematically plan for patients with long term conditions.
- 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 majority of the facilities and premises were appropriate for the services delivered. However, the practice did not provide water in the dispensary to facilitate the preparation of medicines.
- The clinic did not provide out of hours care, and the premises did not have information available to signpost patients to the nearest out of hours care provider. The provider could not demonstrate what arrangements were in place patients' who did not have access to NHS out of hours care.
- There were limited facilities and arrangements for those patients who are hard of hearing and whose first language is not English, apart from Brazilian, Spanish and Portuguese.
- 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.

Timely access to the service

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

- Patients had timely access to appointments, diagnostic services 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 service 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 deputy practice managers were the designated responsible persons for handling complaints in the clinic.
- The complaints policy and procedures did not contain information as recommended by the Independent Doctors Federation (IDF), regarding an external complaints process for patients'. The IDF operates a Patients' Independent Sector Complaints Advisory Service (ISCAS), an independent body, that patients may access to make a complaint regarding an independent health organisation member.
- Staff treated patients who made complaints with kindness and compassion.
- The service learned some lessons from individual concerns. It acted as a result to improve the quality of care. For example, a staff member slipped on a wet floor in reception and the provider addressed this immediately by installing non-slip floor covering.

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.

- 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 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.

Vision and strategy

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

- The service did have a clear vision and credible strategy to deliver high quality care but did not always deliver high quality care and deliver good outcomes for patients.
- Staff were aware of and understood the vision, values and strategy and their role in achieving them. There was no evidence of quality improvement and monitoring of clinical outcomes. Staff did not always act on the latest information, for example, acting on medical safety alerts.

Culture

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

- Staff felt respected, supported and valued. They were proud to work for the service.
- The service did not always focus on the needs of patients, for example, lack of knowledge regarding patients with long term conditions and who had clinical oversight for these patients.
- Staff were open, honest and transparent during the inspection and we reviewed evidence this was

demonstrated when responding to incidents and complaints. For example, staff were candid when interviewed regarding systems and processes in the service but did not always learn from significant events.

- We found that staff were committed to providing a good service to all patients. However, the provider had not actively considered how it would meet the needs of different population groups, for example the practice did not systematically plan for patients with long term conditions.
- All staff had received regular annual appraisals in the last year but the provider could not demonstrate this had been effective in identifying practice nurses training needs.
- Clinicians who worked exclusively at the service were supported to meet the requirements of professional revalidation where necessary. However, for those clinicians who worked elsewhere, the provider had not undertaken checks on training and appraisals and relied on checking an individual's registration with the GMC.
- The service actively promoted equality and diversity. Staff had received equality and diversity training and felt they were treated equally.
- There were good relationships between staff and teams.

Governance arrangements

There was a lack of clarity regarding responsibilities, roles and there were limited systems of accountability to support good governance and management.

- Staff were clear on their roles and accountabilities
- We reviewed service policies, some contained insufficient information. For example, the significant event policy. This focused on complaints and incidents relating to interactions with patients and no reference to system issues, such as test results, referrals, and cold chain.

Managing risks, issues and performance

There was no clarity around processes for managing risks, issues and performance.

• 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.

Are services well-led?

- 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.
- We reviewed evidence that the provider had not ensured there was an effective, process to identify, understand, monitor and address current and future risks including risks to patient safety.
- The provider could not provide evidence that a policy or protocol was in place for monitoring patients who had been prescribed high-risk medicines. For example, we reviewed evidence that for three patients who had been prescribed these medicines, the provider had not undertaken appropriate blood monitoring.
- We found evidence that test results for patients were not reviewed by a GP once they had been received.
- The provider had failed to respond in a timely manner to previous Warning Notices issued against its Clapham location regarding Patient Group Directions (PGDs). We reviewed evidence that PGD's were operated from 12 September 2018 until March 2019, at this location, without appropriate prescribing authorisations being in place.

Appropriate and accurate information

The service did not have appropriate and accurate information.

- We were unable to review evidence that the provider used performance data to make improvements to the quality of care. The clinical IT system did not easily facilitate audit to enable review of patient care.
- We were unable to review plans the provider had to address any identified weaknesses.

• There were ineffective arrangements in line with data security standards for the availability, integrity and confidentiality of patient identifiable data, records and data management systems.

Engagement with patients, the public, staff and external partners

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

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

Continuous improvement and innovation

There was no evidence of systems and processes for learning, continuous improvement and innovation.

- There little evidence of innovation or service development. The clinical and non-clinical leaders could not demonstrate that improvement was a priority and there was limited evidence of learning and reflective practice.
- When asked the practice could not provide evidence of how technology and/or equipment has been used to improve treatment and promote patient independence.

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	Regulation 12 HSCA (RA) Regulations 2014 Safe care and treatment
	Warning Notice issued.
	Care and treatment must be provided in a safe way for service users
	How the regulation was not being met:
	•The provider had limited systems in place regarding the safeguarding of children and vulnerable people.
	•The provider could not demonstrate safe arrangements in place for the safe management of medicines. This included arrangements to monitor polypharmacy reviews; patients who are prescribed high risk medicines; unlicensed medicines; and travel vaccines.
	•The provider did not have a system or process in place to safely manage test results.
	•The provider had not reviewed its infection prevention and control practices to ensure they were safe and in line with national guidance.
	•The provider did not ensure that persons providing care or treatment to service users have the qualifications, competence, skills and experience to do so safely.
	•The provider did not have an embedded system to manage patient safety alerts.
	•The provider had not ensured that all non-clinical staff were trained in identifying deteriorating or acutely unwell patient's suffering from potential illnesses such as sepsis.
	This was in breach of Regulation 12 (1) of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014.

Enforcement actions

Regulated activity

Diagnostic and screening procedures

Treatment of disease, disorder or injury

Regulation

Regulation 17 HSCA (RA) Regulations 2014 Good governance

Warning Notice issued.

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.

In particular we found:

•Governance arrangements lacked clarity. The arrangements regarding practice policies, staff training and risk assessments were not operated effectively, for example, the chaperone policy did not contain appropriate information and were not reviewed on a regular basis.

•The provider did not have a system and policy in place to safely manage two week wait referrals and test results.

•The provider's process for learning from significant events and complaints did not lead to timely and effective improvement.

•The practice did not yet have embedded systems of continuous improvement and clinical oversight to ensure that patient care was provided in line with best practice.

•Access to services for those patients with additional communication needs was insufficient, for example the practice did not have a hearing loop for those people who are hard of hearing.

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