

## The Monteiro Clinic Limited The Monteiro Clinic Limited Inspection report

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#### Ratings

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

### **Overall summary**

**This service is rated as Inadequate overall.** (Previous inspection September 2018, at which point the service was unrated. At that time the service was found not to be providing safe, effective or well led care.)

The key questions are rated as:

Are services safe? - Inadequate

Are services effective? - Inadequate

Are services caring? - Good

Are services responsive? - Good

Are services well-led? – Inadequate

We carried out this announced comprehensive inspection at The Monteiro Clinic on 9 May 2019. We had previously carried out an announced comprehensive inspection on 4 September 2018. At that time the service was judged to be meeting the standards for providing caring and responsive care and treatment but not to be providing safe, effective or well led care.

The areas where we said that the provider must make improvement were:

## Summary of findings

- Ensure care and treatment is provided in a safe way to patients. This should include ensuring systems are in place to assure medicines management, infection control and equipment to manage emergencies and full infection control processes.
- Ensure persons employed in the provision of the regulated activity receive the appropriate support, training, professional development, supervision and appraisal necessary to enable them to carry out the duties. This should include ensuring staff are trained in relevant areas, supervision of the nurses working at the service, and completion of appraisals.

The area where we said the provider should make improvements was:

• Review privacy arrangements in clinical rooms.

#### At this inspection we found that the practice had addressed some of the issues from the last inspection. However, we noted that there were other breaches in the safe, effective and well led domains.

We found that:

- The service did not provide care in a way that kept patients safe and protected them from avoidable harm.
- Patients received effective care and treatment that met their needs in some areas, but there were inadequate systems to ensure that staff were fit for the role they were undertaking and the management of consent.
- Staff dealt with patients with kindness and respect and involved them in decisions about their care.
- The service organised and delivered services to meet patients' needs. Patients could access care and treatment in a timely way.

• 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.

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 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



## The Monteiro Clinic Limited Detailed findings

### Background to this inspection

The Monteiro Clinic Limited is an independent provider of medical services. The service provides a full range of General Practice services. The service is provided primarily for patients for whom Spanish or Portuguese are their first language who make up 70% of the services list. Services are provided at 2 Clapham Road, Oval, London, SW9 0JG in the London borough of Lambeth. All patients attending the service referred themselves for treatment; none are referred from NHS services. The patients seen at the service are sometimes just for one appointment, while many patients attend for follow up of long term conditions. The majority of patients who use the service are adults, but some children are also seen.

The service is open Monday to Friday from 8:30am to 7pm and Saturday 8:30am to 4pm. The service does not offer elective care outside of these hours.

The premise is located on two floors. The property is leased by the provider and the premises consist of a patient reception area, five consulting rooms and a dispensary.

The service is operated by a general practitioner who works at the service. The service also employs three nurses, a service manager and four receptionists. There are six other GPs who work at the service, they are not employed by the service, working on a contract basis. The lead clinician is the registered manager. A registered manager is a person who is registered with the Care Quality Commission (CQC) 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.

The service is registered with the CQC to provide treatment of disease, disorder or injury and diagnostic and screening procedures.

During the inspection we used a number of methods to support our judgement of the services provided. For example, we interviewed staff, and reviewed documents relating to the service.

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

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

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

Our inspection team was led by a CQC lead inspector. The team also included a GP specialist advisor.

## Are services safe?

### Our findings

#### We rated safe as Inadequate because:

We carried out this announced comprehensive inspection on 9 May 2019. We had previously carried out an announced comprehensive inspection on 4 September 2018. At that time the service was not providing safe services. At the inspection on 4 September 2018 found the following:

- The service did not have systems in place for the appropriate management of medicines.
- Nurses who were administering medicines to patients did not have Patient Group Directions in place.
- The temperatures of the vaccine fridge were not being monitored every day, and where the temperatures were above 8 degrees no action was taken. It also appeared that the thermometer was not being reset after each time the fridge was reset
- Vaccines were also noted to have been pushed to the back of the refrigerator. The service was told by the inspector to contact Public Health England in this regard, as they were not aware that they needed to do so.
- The service did not stock atropine (required in the event of heart rate slowing when contraceptive coils are fitted) or chlorphenamine (required for allergic reactions).
- The service discussed NICE updates and NHS England notifications, but it was unclear as to which formulary the practice was working, and this was not clear in policies and procedures.
- Fire alarms had not been tested regularly since May 2018, although before then they were tested weekly.
- The premises were clean, but the service had not adopted annual infection control audit. Sharps bins and curtains at the service had not been labelled.

At the inspection of 6 April 2019, we saw that the service had addressed the issues relating to storage and monitoring of vaccines, and the availability of medicines. However, we also found the following:

• Patients who were attending for medicals (such as those requiring clearance to drive heavy goods vehicles) were not having identity checks recorded, as such the service could not guarantee the identity of the patient.

- In three of the 11 records that we reviewed, there was no record on the database that pathology results had been checked by a doctor.
- The service did not have a failsafe system to follow up urgent referrals.
- The service did not have safeguarding registers in place.
- The service was not assessing patients at risk of sepsis.
- The service was clean and the cleaner signed a form stating that cleaning had been completed, but there was no cleaning schedule of exactly what should be cleaned and when.
- The service did not have adequate prescription security measures in place.
- The service did not record where chaperones had been offered or when they had been in the consultation even where intimate examinations and procedures were required.

#### Safety systems and processes

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

- The provider conducted safety risk assessments. It had appropriate safety policies, which were regularly reviewed and communicated to staff including locums. They outlined clearly who to go to for further guidance. Staff received safety information from the service as part of their induction and refresher training.
- The service did not have formalised systems in place to assure that an adult accompanying a child had parental authority to give consent.
- The service worked with other agencies to support patients and protect them from neglect and abuse. Staff were aware of their responsibilities to report safeguarding concerns, but there was no formal register in place for those who were at risk of abuse.
- The provider carried out staff checks at the time of recruitment and on an ongoing basis where appropriate. 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).
- The provider was in the process of increasing the level of safeguarding training for staff at the practice. However, three staff whose records we reviewed were trained to

### Are services safe?

child safeguarding level 2 only. However, staff we spoke with knew how to identify and report concerns. Staff who acted as chaperones were trained for the role and had received a DBS check.

- The practice was clean and there were audits in place to make sure that best practice for infection control was maintained. However, there was no formal cleaning schedule in place.
- The provider ensured that facilities and equipment were safe, and that equipment was maintained according to manufacturers' instructions. There were systems for safely managing healthcare waste.
- The provider carried out appropriate environmental risk assessments, which took into account the profile of people using the service and those who may be accompanying them.

#### **Risks to patients**

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

- There were arrangements for planning and monitoring the number and mix of staff needed.
- There was an effective induction system for agency staff tailored to their role.
- Staff understood their responsibilities to manage emergencies and to recognise those in need of urgent medical attention. They knew how to identify and manage patients with severe infections, for example sepsis. However, the service did not have a system for assessing patients at risk of sepsis.
- When there were changes to services or staff the service assessed and monitored the impact on safety.
- There were appropriate indemnity arrangements in place to cover all potential liabilities.

#### Information to deliver safe care and treatment

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

• Individual care records were not written and managed in a way that kept patients safe. The care records system was bespoke to the practice and key information such as where blood tests were checked by the doctor and where chaperones was offered was missing from the record. Three of the 11 records that we reviewed had pathology results which had no recorded review by a doctor.

- 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. However, the practice had no formal system in place to follow up urgent referrals, although we did not see that any had not been processed.
- Patients who were attending for medicals (such as those requiring clearance to drive heavy goods vehicles) were not having identity checks recorded, as such the service could not guarantee the identity of the patient.

#### Safe and appropriate use of medicines

### The service did not have 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. However, the service did not have adequate prescription security measures in place.
- The service had not adopted a specific formulary that they were asking clinicians to use.

#### Track record on safety and incidents

### The had systems in place to monitor safety and incidents.

- There were comprehensive risk assessments in relation to safety issues.
- The service monitored and reviewed activity. This helped it to understand risks and gave a clear, accurate and current picture that led to safety improvements.

#### Lessons learned and improvements made

### The service learned some lessons and made some 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. Leaders and managers supported them when they did so.
- We saw that the practice had raised four incidents in the last year, although they were all of a relatively minor nature. There were no formal mechanisms in place to share learning from these events with all staff.

### Are services safe?

- The provider was aware of and complied with the requirements of the Duty of Candour. The provider encouraged a culture of openness and honesty. The service had systems in place for knowing about notifiable safety incidents
- The service acted on and learned from external safety events as well as patient and medicine safety alerts. The service had an effective mechanism in place to disseminate alerts to all members of the team including sessional and agency staff.

### Are services effective?

(for example, treatment is effective)

### Our findings

#### We rated effective as Inadequate because:

We carried out this announced comprehensive inspection on 9 May 2019. We had previously carried out an announced comprehensive inspection on 4 September 2018. At that time the service was not providing effective services. At the inspection on 4 September 2018 found the following:

• The service had not ensured that all staff had been appraised. Nurses had not been appraised in line with regulatory requirements. The service was asking nursing staff to cover the full range of duties that a practice nurse might carry out without checking that they were qualified and competent to do so.

This area had not been addressed at the time of the second inspection of 9 May 2019. We also found the following:

- Records showed that doctors were not prescribing first choice antibiotics for urinary tract infections.
- Consent was not being recorded appropriately for the fitting of contraceptive implants.

#### Effective needs assessment, care and treatment

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

- We saw that guidelines were reviewed by the lead clinician and disseminated to all other clinical staff at team meetings. However, there was no formalised formulary in place at the service. As a consequence we noted that clinicians were not always treating with first choice antibiotics. For example, a clinician had treated a urinary tract infection with co-amoxiclav, rather than trimethoprim or nitrofuratin.
- After care plans were provided to patients where required.
- Clinicians had enough information to make or confirm a diagnosis
- We saw no evidence of discrimination when making care and treatment decisions.

- Arrangements were in place to deal with patients attending on a regular basis, but there were not adequate systems to determine if these patients should be seen by a nurse or a GP.
- Staff assessed and managed patients' pain where appropriate.

#### Monitoring care and treatment

### The service was not fully involved in quality improvement activity.

- The service provided yearly audits of antibiotic prescribing and of referrals being completed. Following a referral audit the practice had developed leaflets to give to patients in English, Spanish and Portuguese to ensure that patients followed up their referrals. However, we noted that although audits were taking place, first choice antibiotics were not always prescribed.
- The lead clinician attended Independent Doctors Federation (IDF) meetings, 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).
- Due to the limitations of the clinical IT system, the provider could not demonstrate that it was systematically providing 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.

- The service had an induction programme in place for newly appointed staff.
- The service had not ensured that all staff had been appraised. Nurses had not been appraised in line with regulatory requirements. The service was asking nursing staff to cover the full range of duties that a practice nurse might carry out without checking that they were qualified and competent to do so. From the records we reviewed, there was no evidence that nurses at the service were trained and competent to undertake reviews of long term conditions, and there were no policies or procedures limiting the areas in which nurses ought to be working.

### Are services effective?

### (for example, treatment is effective)

• Staff received training that included basic life support and information governance. Staff had access to and made use of e-learning training modules and in-house training.

#### Coordinating patient care and information sharing

# Staff did not work 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. However, there were no systems in place to ensure that referrals made urgently were followed up.
- All patients were asked for consent to share details of their consultation and any medicines prescribed with their registered GP on each occasion they used the service. If a patient had refused to provide these details and the service found a medical condition that would require further care, the patient was told that the GP would have to be told and information was provided to GPs securely.
- The provider had not risk assessed the treatments they offered. They had not identified medicines that were not suitable for prescribing.
- 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.

#### 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.
- Where patients needs could not be met by the service, staff redirected them to the appropriate service for their needs.

#### **Consent to care and treatment**

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

- In most areas staff understood the requirements of legislation and guidance when considering consent and decision making. However, the consent form for the fitting of contraceptive device did not contain sufficient information.
- Staff supported patients to make decisions. Where appropriate, they assessed and recorded a patient's mental capacity to make a decision.
- We were unable to review evidence that the service monitored the process for seeking consent appropriately.

## Are services caring?

### Our findings

#### We rated caring as Good

#### 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 seven completed Care Quality Commission comment cards which were all positive about care they had received and staff at the clinic.
- Feedback from patients was positive about the way staff treat people
- Staff understood patients' personal, cultural, social and religious needs. They displayed an understanding and non-judgmental attitude to all patients.
- The service gave patients timely support and information.
- The service had not undertaken its own patient survey.

#### Involvement in decisions about care and treatment

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

- Interpretation services were available for patients who did not have English as a first language. We saw notices in the reception areas, including in languages other than English, informing patients this service was available. Patients were also told about multi-lingual staff who might be able to support them. Most of the staff at the practice spoke Portuguese and/or Spanish. These were the first languages for 70% of the patients at the practice.
- 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 learning disabilities or complex social needs family, carers or social workers were appropriately involved.

#### **Privacy and Dignity**

#### The service respected patients' privacy and dignity.

- Staff recognised the importance of people's dignity and respect.
- Staff knew that if patients wanted to discuss sensitive issues or appeared distressed they could offer them a private room to discuss their needs.
- The clinic complied with the Data Protection Act 2018 and had policies and processes in place to ensure this.

## Are services responsive to people's needs?

(for example, to feedback?)

### Our findings

#### We rated responsive as Good.

#### Responding to and meeting people's needs

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

- 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.
- The service was based on two floors, but patients could request to see a clinician on the ground floor, so it was therefore accessible to all patients.
- 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.

#### 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 initial assessment, test results, diagnosis and treatment.

- The service was offered on a private, fee-paying basis only, and as such was accessible to people who chose to use it. Waiting times, delays and cancellations were minimal and managed appropriately.
- 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.
- Patients reported that the appointment system was easy to use.

#### 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.

- Information about how to make a complaint or raise concerns was available in English, Spanish and Portuguese. Staff treated patients who made complaints compassionately.
- The service informed patients of any further action that may be available to them should they not be satisfied with the response to their complaint.
- The deputy practice managers were the designated responsible persons for handling complaints in the clinic.
- 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.

### Are services well-led?

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

### Our findings

#### We rated well-led as Inadequate because:

We carried out this announced comprehensive inspection on 9 May 2019. We had previously carried out an announced comprehensive inspection on 4 September 2018. At that time the service was not providing well led services. At the inspection on 4 September 2018 found the following:

- The service did not have systems to ensure safe care.
- The service had a governance framework in place in some areas. However, the service did not have sufficient protocols and measures in place to ensure that patients were safe and staff trained.

These areas had not been addressed at the inspection of 9 May 2019. We also found that:

- There were no formalised processes whereby safeguarding and serious events were regularly discussed.
- The database at the practice did not allow easy review of the care of groups of patients, such as those with specific long term conditions.

#### 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 trained and competent to undertake the roles they had undertaken.
- Leaders at all levels were visible and approachable. They worked closely with staff and others to make sure they prioritised compassionate and inclusive leadership.

#### **Vision and strategy**

#### While the service had a clear vision they were not able to translate this into the provision of high quality safe care.

- The service did have a clear vision and credible strategy to deliver high quality care but did not always deliver high quality safe care and provide 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 focused on the needs of patients.
- Leaders and managers acted on behaviour and performance inconsistent with the vision and values.
- 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.
- Staff told us they could raise concerns and were encouraged to do so. They had confidence that these would be addressed.
- There were processes for providing all staff with the development they need. This included appraisal and career development conversations. All staff, including nursing staff, received regular annual appraisals in the last year. However, these appraisals did not include sufficient review to ensure that staff were trained and competent to undertake their roles.
- There was a strong emphasis on the safety and well-being of all staff.

### Are services well-led?

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

- The service actively promoted equality and diversity. It identified and addressed the causes of any workforce inequality. Staff felt they were treated equally.
- There were positive relationships between staff and teams.

#### **Governance arrangements**

# There were no clear responsibilities, roles and systems of accountability to support good governance and management.

- Structures, processes and systems to support good governance and management were clearly set out. However, these did not clearly set out staff responsibilities, and nursing staff were being asked to undertake work outside of the limits of their known competence.
- There were no formalised processes whereby safeguarding and serious events were regularly discussed.
- The database at the practice did not allow easy review of the care of groups of patients, such as those with specific long term conditions.

#### 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. This was managed by GP consultations by opportunistic review
- The patient record system at the service did not show a record that test results for patients were reviewed by a GP once they had been received, although we could see that actions had been taken in some cases after receipt of this information.

#### 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.
- There were robust 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 involved patients, the public, staff and external partners to support high-quality sustainable services.

- Staff could describe to us the systems in place to give feedback, for example, patients were encouraged to use feedback forms in reception. We saw evidence of feedback opportunities for staff and how the findings were fed back to staff.
- 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 was little evidence of innovation or service development. The clinical and non-clinical leaders could not demonstrate that improvement was a clear priority that action had been taken on the basis of reflective practice.

## **Enforcement actions**

### 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
	Warning Notice issued.
	Urgent condition placed suspending the nursing service
	Care and treatment must be provided in a safe way for service users
	How the regulation was not being met:
	<ul> <li>Patients who were attending for medicals (such as those requiring clearance to drive heavy goods vehicles) were not having identity checks recorded, as such the service could not guarantee the identity of the patient.</li> </ul>
	<ul> <li>In three of the 11 records that we reviewed, there was no record on the database that pathology results had been checked by a doctor.</li> </ul>
	<ul> <li>The service did not have a failsafe system to follow up referrals made requiring a two week appointment.</li> </ul>
	• The service did not have safeguarding registers in place. The lead GP said that they had not made any safeguarding referrals, however we found a referral was made for a patient who had been the victim of domestic violence in the period leading to the inspection.
	<ul> <li>The service was clean and the cleaner signed on visits, but there was no cleaning schedule of exactly what should be cleaned.</li> </ul>
	<ul> <li>The service did not have adequate prescription security measures in place.</li> </ul>

### **Enforcement actions**

• The service did not record where chaperones had been offered or when they had been in the consultation even where intimate examinations and procedures were required.

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

### **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:

- The service did not adequately record consent. Forms for consent to the fitting of implants were not sufficiently detailed.
- There were insufficient governance issues in place to review and manage the issues identified in this inspection that required improvement.
- The database at the practice could not be audited, and doctors at the practice seemed unaware where on the patient record to include information.

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