# The London Migraine Clinic

## Inspection report

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This report describes our judgement of the quality of care at this service. It is based on a combination of what we found when we inspected, information from our ongoing monitoring of data about services and information given to us from the provider, patients, the public and other organisations.

## Ratings

| | |
|---|---|
| Overall rating for this location | Requires Improvement |
| Are services safe? | Requires Improvement |
| Are services effective? | Requires Improvement |
| Are services caring? | Good |
| Are services responsive to people's needs? | Good |
| Are services well-led? | Requires Improvement |

# Overall summary

**This service is rated as Requires improvement overall.**

The key questions are rated as:

Are services safe? – Requires improvement

Are services effective? – Requires improvement

Are services caring? – Good

Are services responsive? – Good

Are services well-led? – Requires improvement

We carried out an announced comprehensive inspection at The London Migraine Clinic on 8 February 2022 as part of our inspection programme. This was the first CQC inspection of this location.

The London Migraine Clinic is a private clinic offering treatment for migraines, bruxism and hyperhidrosis to adults and children aged over 12 years. All services are private and subject to payment of fees, with no NHS services provided.

The provider is registered with CQC under the Health and Social Care Act 2008 in respect of some, but not all, of the services it provides. There are some general exemptions from regulation by CQC, relating to particular types of service and these are set out in Schedule 2 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014. For example, The London Migraine Clinic refers patients on to a piercer for daith (ear cartilage) piercing as a migraine treatment, which is not within CQC scope of registration. Therefore, we did not inspect these services.

The provider consists of one doctor, who is also the CQC registered manager. A registered manager is a person who is registered with the 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.

**Our key findings were:**

- There were gaps in safeguarding knowledge and training.
- There was an absence of appropriate staff recruitment checks to ensure safety.
- There was no system to manage safety alerts.
- No infection control audit had been completed.
- Blank prescriptions were not stored securely.
- There were gaps and risks in relation to arrangements for emergency medicines and equipment.
- Staff had not completed, and were not required to complete, training and this had not been risk assessed.
- There were no systems to monitor the effectiveness of care and treatment provided, as the provider had not completed any clinical audits or quality improvement activity.
- Treatment outside of National Institute for Health and Care Excellence (NICE) guidelines was not documented as having been communicated to patients.
- There was no system to ensure that staff had the skills, knowledge and experience to carry out their roles.
- Leaders could not demonstrate that they recognised and understood the challenges to quality and sustainability.

# Overall summary

- Some of the service's policies were not service-specific, were missing, did not contain required information, or were not being followed by staff.
- There were no systems, or ineffective systems, in place to manage and mitigate risks, issues and performance.
- Patients were supported to manage their own health and live healthier lives.
- The service treated patients with kindness, respect and compassion.
- Patient feedback was positive about the service and the provider.
- Patients were able to access care and treatment from the service within an acceptable timescale for their needs.
- Staff described the service as open and supportive. Non-clinical staff we spoke with said they felt able to raise any concerns with the provider.

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

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

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

- Review the storage arrangements for records of patients referred to the piercer to ensure they are secure.
- Review arrangements for signing and dating sharps bins when assembling and for secure siting of sharps bins.
- Review the arrangements for alerting patients that there is limited disabled access to the premises.

**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, who was accompanied by a GP specialist advisor.

## Background to The London Migraine Clinic

The London Migraine Clinic is a private clinic offering treatment for migraines, bruxism and hyperhidrosis to adults and children aged over 12 years. All services are private and subject to payment of fees, with no NHS services provided.

The service is registered with CQC for the regulated activity of 'Treatment of disease, disorder or injury'.

The services are offered on an appointment-only basis. The service is currently open for consultations from 11am and 5pm on Tuesdays, Wednesdays and Thursdays. Appointments can be booked by telephone or through the service's website.

The service is situated on the lower ground floor of a commercial building, beneath an optician. The service's premises consists of two consulting rooms, one storage room, and a toilet shared with the optician. Where disabled patients cannot access the lower ground floor via the stairs, there is an arrangement whereby they can be seen in a consulting room on the ground floor, although there is also a step up from street level to the building entrance.

In terms of staff members, the provider was the only doctor and clinician who worked at the service. The doctor was supported by some non-clinical staff members, who were not directly employed by The London Migraine Clinic, but who worked for the optician in the same building and were contracted to provide support for the service; this support included answering telephone calls and emails from patients, booking appointments, meeting and greeting patients, cleaning the consultation rooms, and filing patient records.

Part of the London Migraine Clinic's service involves the provider referring patients on to a piercer for daith (ear cartilage) piercing as a migraine treatment. The piercer is not directly employed by the service, but works independently at a piercing studio. This activity is not within CQC scope of registration and therefore we did not inspect these services.

The service sees approximately 30 patients per month.

**How we inspected this service:**

We reviewed information about the service in advance of our inspection visit. This included:

- Data and other information we held about the service;
- Material we requested and received directly from the service ahead of the inspection;
- Information available on the service's website;
- Patient feedback and reviews accessible on public third-party websites.

During the inspection visit we:

- Spoke with the provider and a non-clinical staff member (who was not directly employed by the service but who was contracted to provide administrative support);
- Reviewed policies, procedures, and patient records;
- Carried out checks and observations of the premises and equipment.

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.

Requires Improvement

# Are services safe?

**We rated safe as Requires improvement because:**

- There were gaps in safeguarding knowledge and training.
- There was an absence of appropriate recruitment checks to ensure safety.
- There was no system to manage safety alerts.
- No infection control audit had been completed.
- Blank prescriptions were not stored securely.
- There were gaps and risks in relation to emergency medicines and equipment.
- Staff had not completed some safety training (such as safeguarding, basic life support, infection control and fire safety) and this had not been risk assessed.

**Safety systems and processes**

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

- The service did not have appropriate systems to safeguard children and vulnerable adults from abuse. The provider had completed adult and child safeguarding training to an appropriate level, however the two non-clinical staff members who supported the service had not completed and were not required to complete any adult or child safeguarding training. Their responsibilities were answering telephone calls and emails from patients, booking appointments, meeting and greeting patients, cleaning the consultation rooms, and filing patient records. When we spoke with one of these staff members during the inspection, they were unable to provide examples of what type of issue might constitute a safeguarding concern, other than if a woman attending with her partner appeared vulnerable. Intercollegiate guidance 'Adult Safeguarding: Roles and Competencies for Health Care Staff' and 'Safeguarding Children and Young People: Roles and Competencies for Healthcare Staff' sets out that people performing a role in a healthcare context, including private or independent contractors, should complete at a minimum level one adult safeguarding training and level one child safeguarding training. Following the inspection, the provider submitted certificates demonstrating that the two non-clinical staff members completed adult and child safeguarding training on 15 February 2022.
- There was an adult safeguarding policy and a child safeguarding policy in place which identified the service's safeguarding lead, set out the process for reporting a safeguarding concern and contained contact details for the Local Authority safeguarding teams.
- The provider had not undertaken Disclosure and Barring Service (DBS) checks for staff (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) prior to us announcing the CQC inspection. When we spoke with the provider on 20 January 2022 to announce the inspection, we queried whether staff not directly employed by the service, but supporting it in an administrative capacity and interacting with patients and their records, had received DBS checks. At that time, the provider confirmed they had not. The process to obtain DBS checks for the two staff members was then instigated after we announced the CQC inspection and the emails confirming the checks were clear were received by the provider on 2 February 2022. During the inspection, the provider confirmed they had not completed any risk assessment to support the decision to allow these staff members to support the service whilst the DBS checks were absent or pending.
- There were no signs displayed advising patients of the availability of chaperones. We were told that patients would usually bring along a friend or family member if they needed a chaperone, or if they did not then the two non-clinical administrative staff members would act as chaperones. Neither of these staff members had received any chaperone training however, and had only had a DBS check in place as of 2 February 2022 following the announcement of the CQC inspection. No risk assessment had been completed in relation to the absence of chaperone training or in relation to the lack of DBS checks prior to 2 February 2022.

Requires Improvement

# Are services safe?

- There were no systems to ensure safe and appropriate recruitment of staff who were contracted to support the service. We asked to see a staff file for a non-clinical staff member who commenced work supporting the service in 2021, but no recruitment checks had been carried out as we were told they were known to the provider through a friend. There was no proof of identity check, no DBS check (until applied for after we announced the inspection), no references, no CV, no record of immunisations as per 'Green Book' guidance, and the staff member had not signed any confidentiality clause or agreement. Following the inspection, the provider told us they had amended the service level agreement with the optician company that directly employed the non-clinical staff, to include a confidentiality agreement, and that they had sought proof of identify, CVs, references, DBS checks, and immunisation status for the staff members.
- There was no induction or appraisal process for the non-clinical staff members and no induction checklist to complete to ensure they were able to carry out their role safely and effectively.
- The provider undertook professional revalidation in order to maintain their registration with the GMC.
- We saw risk assessments had been completed shortly before our inspection to ensure the premises were safe, for example a health and safety risk assessment completed on 31 January 2022 and a fire risk assessment on 1 February 2022. We saw evidence of recent fire alarm servicing and testing on 3 February 2022.
- The provider had carried out a visual inspection of portable electrical equipment to check for faults or damaged leads on 1 February 2022 and had documented this. None of the medical equipment used by the service required calibration.
- We reviewed whether staff had completed safety training, such as safeguarding training, infection control training and fire safety training. The non-clinical administrative staff had not completed and were not required to complete any training to support their work for the service and no risk assessment had been documented to support this decision. The provider had not completed any infection control training or fire safety training. Following the inspection, the provider told us they would produce a policy detailing mandatory training requirements for the service's staff.
- The service did not have effective systems in place to manage infection prevention and control. The service had an infection control policy in place, however this referred to arrangements for linen, bed screens and curtains, despite these not being used at The London Migraine Clinic. The policy did not identify an infection control lead and their specific responsibilities, the policy did not outline infection control training requirements for staff or those contracted to support the service, and the policy did not set out the requirement for infection control audits and the frequency and responsibility of such audits. We were told that no infection control audit had been completed to identify risks and assess cleanliness and hygiene, infection control practices, infection control training, and compliance with infection control standards.
- There were systems for managing healthcare waste and we saw evidence of regular cleaning schedules. However, we found that two sharps bins were not signed and dated on assembly, and one sharps bin was not securely sited (although this was moved to a secure location during the inspection when we brought it to the provider's attention).

**Risks to patients**

We identified gaps and weaknesses in systems to assess, monitor and manage risks to patient safety.

- There were arrangements for planning and monitoring the number and mix of staff needed. As the provider was the only clinician, patients would be contacted, and appointments re-arranged, in the event of unplanned absences. The non-clinical staff arranged leave and cover amongst themselves. Staff we spoke with said there were enough staff to meet demand.
- The service did not use any temporary or locum staff.
- There was no formalised or documented induction system or training programme for non-clinical staff in respect of the tasks they carried out for the service and in relation to their interactions with patients.
- Non-clinical staff we spoke with said they would immediately contact the provider in the event of a medical emergency on the premises.

Requires Improvement

# Are services safe?

- Non-clinical staff had not completed and were not required to complete any basic life support training and no risk assessment had been completed to support this decision.
- We saw the provider had completed online basic life support training in August 2019. Resuscitation Council (UK) guidance recommends that clinical staff should have at least annual updates for basic life support training and no risk assessment had been completed to support the decision around frequency of basic life support training.
- We looked at the arrangements for medical emergencies and asked what medicines and equipment were held for use in an emergency. The service had adrenaline for the treatment of anaphylaxis, but there was no evidence of documented checks of this medicine to ensure it remained in date (it was in date at our inspection when we checked); the provider told us as it is only one medicine they felt they did not need to document this. The provider had not carried out a documented risk assessment to determine what emergency medicines and equipment should be stocked and to support their decision to only hold adrenaline. Following the inspection, the provider created an emergency drugs policy and risk assessment, which included a blank form for documenting checks of emergency medicines.

**Information to deliver safe care and treatment**

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

- Patient records relating to consultations and treatment with the provider were all handwritten and were stored securely in a locked cabinet. However, we did see that records of patients who had been referred on to the piercer, but who had not had a consultation with or treatment by the provider, were kept in a cabinet which was not lockable; these records contained patients' names, dates of birth and contact details (although did not include any medical information). The provider said they were in the processing of moving these records to a lockable cabinet.
- Individual care records were written and managed in a way which kept patients safe, as records we reviewed demonstrated that patients' medical history and 'red flags' were considered and documented.
- Referrals to other services were documented. We reviewed some referral letters to specialists and found they contained appropriate information.
- The service did not arrange or carry out any blood tests.

**Safe and appropriate use of medicines**

We identified some issues with systems for appropriate and safe handling of medicines.

- The service used hard-copy paper prescriptions, however we found that these were not kept securely, but were in a drawer in the consultation room which was not lockable. Following the inspection, the provider told us the blank prescriptions had been moved to a lockable cupboard.
- The service held botulinum toxin (botox) as this was administered by the provider for the treatment of migraines (and occasionally for the treatment of bruxism and hyperhidrosis). This medicine was stored securely and was in date. There was a system to ensure adequate stock.
- The service carried out a minimal amount of prescribing, as its primary treatment for migraines was botox injections. The provider told us they would usually refer patients back to their NHS GP if they required prescriptions for migraine medicines such as triptans or hormone replacement therapy (HRT).
- There was no formal system in place to monitor or follow-up patients to ensure medicines were being used safely. The provider explained that patients prescribed medicines would usually be referred back to their GP and, in the case of botox injections, patients were given the option of booking follow-up appointments when they wanted to attend for further treatment.

Requires Improvement

# Are services safe?

**Lessons learned and improvements made**

The service did not have effective systems in place to learn and make improvements went things went wrong.

- The service's policy for significant events consisted of the follow statement: "*The policy is to record all Significant Events and Complaints in a single book held in Reception. The details will then be held on the templates included here, and will be held in the patient notes*." This document did not include the service's own definition of a significant event or the type of incident that would need to be reported, it did not outline the process for reporting and recording significant events, or how any learning or changes would be shared and implemented.
- The doctor told us there had not been any significant events or incidents at the service.
- Non-clinical staff we spoke with understood their duty to raise concerns and report any incidents to the provider.
- We could not assess adherence to the duty of candour as we were told there had not been any significant events, but the provider told us they understood the importance of being open and honest with patients if unexpected safety incidents occurred.
- There was no system for receiving and acting upon safety alerts. We asked the provider how they manage safety alerts from Medicines and Healthcare Products Regulatory Agency (MHRA) or other drug safety alerts for the service, and were told they were not signed up to receive any alerts.
- There was therefore no evidence that the service learned from external safety events or patient and medicine safety alerts.
- Following the inspection, the provider said they had registered with the MHRA to receive safety alerts; the provider told us they would review alerts received and record whether any action was taken in response.

Requires Improvement

# Are services effective?

**We rated effective as Requires improvement because:**

- The provider had not completed any clinical audits or quality improvement activity.
- Treatment outside of National Institute for Health and Care Excellence (NICE) guidelines was not documented as having been communicated to patients.
- There was no system to ensure that staff had the skills, knowledge and experience to carry out their roles.

**Effective needs assessment, care and treatment**

The provider assessed need and delivered care in line with its own research and protocols, however the departure from evidence-based guidelines was not documented in records.

- The service assessed need and delivered care in line with its own research and protocols. The provider had created their own protocol for administering botulinum toxin (botox) for the treatment of migraines, supported by their research and experience, which differed from the 'PREEMPT' protocol set out in National Institute for Health and Care Excellence (NICE) guidelines. The provider said they make patients aware that the method used by them is different to that in NICE guidelines and told us that is usually why patients attend the service (as the 'PREEMPT' protocol has not been successful). However, the fact that the protocol being used was outside of NICE guidelines was not recorded in patient records or in the consent form signed by patients.
- The provider told us that they engaged in research and attended conferences to keep up to date with current practice and treatments relevant to the service.
- The provider obtained '360 degree' feedback from colleagues as part of their GMC appraisal and we reviewed feedback from September 2019; we saw colleagues referenced attending conferences with the provider, at which the provider presented their clinical and research work, and colleagues stated they engaged in regular clinical discussions with the provider by telephone and email. Although we did not see any evidence of formal peer-reviews of clinical work.
- We saw no evidence of discrimination when making care and treatment decisions.
- Prior to their appointment, patients were sent a link to complete a questionnaire, which included a thorough medical history, self-evaluation of their migraine pain and their responses to any treatments to date.
- In our review of patients records we saw the provider had given patients follow-up advice.
- The provider told us it was important to take a full clinical history from patients, to ensure that any 'red flags' or potentially serious symptoms could be identified and dealt with appropriately.
- We saw that the service's website contained information for patients about migraines, bruxism and hyperhidrosis, and the various treatment options available.

**Monitoring care and treatment**

The service did not have any systems to review the effectiveness and appropriateness of the care provided.

- The provider had not completed any clinical audits or quality improvement activity.
- The provider told us they planned to commence an observational trial of 1000 patients, in conjunction with a piercing studio, looking at the outcomes of daith (ear cartilage) piercing as a migraine treatment. We were told this trial will involve developing software which will send automated emails to patients inviting them to fill in an online feedback questionnaire. The provider said that, in the future, they would want to use this same software to assess patients' response to treatment and gather feedback about their experience at The London Migraine Clinic.

**Effective staffing**

Requires Improvement

# Are services effective?

There was no process in place to ensure that non-clinical staff contracted to support the service had the skills, knowledge and experience to carry out their roles.

- The provider was appropriately qualified and had sufficient time to carry out their role effectively and meet patient demand.
- There was no induction process for the non-clinical staff members and no checklist to complete to ensure that they were able to carry out their role safely and effectively.
- There was no policy in place outlining what training was mandatory for The London Migraine Clinic staff, whether for the provider or for the non-clinical administrative staff members contracted to support the service. When we asked the provider what training they undertake for work at the service, they said they complete whatever training is required by the General Medical Council (GMC) for their appraisal; when we asked what training this is, they said they did not know. The non-clinical staff were not required to complete any training to support their work for the service, and no risk assessment had been documented to support this decision.
- The service did not carry out appraisals for the non-clinical staff members, to assess their performance and identify any training needs.
- The service did not have a formal documented process for managing staff when their performance was poor or variable.
- The provider told us that, as it was such a small team, they had constant contact with the non-clinical staff members and were having frequent check-ins and discussions, albeit these were not formalised or documented.

**Coordinating patient care and information sharing**

Staff worked with other professionals to deliver care and treatment.

- The service asked for details of patients' NHS GP when registering, and we saw this was asked on the new patient registration form.
- We were told that patients would still be treated without them having provided their NHS GP's details, as this was the patient's choice.
- We asked to see an example of a patient being referred back to their own NHS GP, however because the patient records were handwritten the provider was unable to identify an example. The provider told us about instances where patients had been referred back to their GP to ensure continuity of care, for example with advice from the provider for the GP to consider prescribing hormone replacement therapy (HRT).
- The service referred patients to other specialists where appropriate and we saw referral letters contained all the required information.

**Supporting patients to live healthier lives**

Patients were supported to manage their own health and live healthier lives.

- The service provided patients with health and lifestyle advice, for example advice around diet and exercise in relation to migraines.
- The service's website had links to information and further support for patients, such as the National Migraine Centre's fact sheets, and websites for The Migraine Trust and Migraine Action.
- Where patients' needs could not be met by the service, the service would signpost them to alternative services or specific specialists more appropriate for their needs.

**Consent to care and treatment**

Requires Improvement

# Are services effective?

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

- The provider understood the requirements of legislation and guidance when considering consent and decision making.
- The service supported patients to make decisions about their care and treatment.
- Patients were given the opportunity to discuss costs prior to consultations and treatment.
- We saw examples of documented consent for patients, which were thorough and included possible side effects and detailed how long the treatment was likely to last. Although we saw that the method used by the provider for botox injections for migraines being outside of NICE guidelines was not documented in the consent forms. The provider said they communicate this to all patients, but would add it to the consent form patients are required to sign.

Good

# Are services caring?

**We rated caring as Good because:**

- The service treated patients with kindness, respect and compassion.
- Patient feedback was positive about the service and the provider.

**Kindness, respect and compassion**

The service treated patients with kindness, respect and compassion.

- Staff understood patients' personal, cultural and social needs.
- The service gave patients timely support and information.
- The provider obtained '360 degree' feedback from patients as part of their GMC appraisal and we reviewed feedback from September 2019. Out of 35 patient responses: 100% said the doctor was good or very good at being polite, making them feel at ease, listening to them, and explaining their condition or treatment; 100% said they were confident in the doctor's ability to provide care; and 100% said they would be completely happy to see the doctor again. Patients described the provider as professional, empathetic, caring and knowledgeable.
- We reviewed feedback left on 'Google' and saw nine reviews had been left in the last year, with all nine reviews being positive and rating the service as five out of five stars; patients said they would recommend the service, describing it as caring, and stating that the doctor is knowledgeable.

**Involvement in decisions about care and treatment**

Staff helped patients be involved in decisions about their care, although interpretation services were not available.

- The provider obtained '360 degree' feedback from patients as part of their GMC appraisal and we reviewed feedback from September 2019. Out of 35 patient responses, 97% of patients said the doctor was good or very good at involving them in decisions about their treatment, with 3% saying this was satisfactory. A number of patients commented that they felt listened to.
- The service did not offer interpretation services to patients for whom English was not their first language. The provider said that patients have always attended with a friend of family member if they required information to be translated.
- We saw the service's website contained information for patients about migraines, bruxism and hyperhidrosis, and detailed the various treatment options available.
- Consent forms for botox treatment were thorough and included possible side effects and detailed how long the treatment was likely to last.
- The service's website had links to information and further support for patients, such as the National Migraine Centre's fact sheets, and websites for The Migraine Trust and Migraine Action.

**Privacy and Dignity**

Staff recognised the importance of patients' privacy and dignity.

- Patient records for consultations and treatment at the service were handwritten and stored securely. Although we saw records of patients who had been referred on to the piercer, but who had not had a consultation with or treatment by the provider, were kept in a cabinet which was not lockable; the provider told us these were in the process of being moved across to the locked cabinet with the other records.
- We were told that the doors would be closed during appointments and conversations taking place in consulting rooms could not be overheard.

Good

# Are services caring?

- Non-clinical staff we spoke with were able to describe how they kept patient information secure. We were told that, if patients wanted to discuss sensitive issues or appeared distressed, they would take them to a private room away from other patients to discuss their needs.
- The provider obtained '360 degree' feedback from patients as part of their GMC appraisal and we reviewed feedback from September 2019. Out of 35 patient responses, 94% of patients agreed with the statement that the doctor would keep information about the patient confidential.

Good

# Are services responsive to people's needs?

**We rated responsive as Good because:**

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

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

The service organised and delivered services to meet patients' needs.

- The facilities and premises were appropriate for the services delivered.
- The service made reasonable adjustments when patients found it hard to access services. For example, if patients could not use the stairs down to the lower ground floor, the provider was able to use a consultation room on the ground floor. However, there was also a step up from street level to the building entrance which could prevent patients with mobility issues or a disability from accessing the premises; this was not communicated on the service's website or in the appointment confirmation email. The provider said they would look to add this information to make patients aware.
- The service made patients aware of what services were offered, and set out the costs of specific treatments before they attended for treatment.

**Timely access to the service**

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

- Services were offered on a private, fee-paying basis only, and therefore were accessible to people who chose to use them.
- The service had altered its opening hours due to the COVID-19 pandemic, and was open for consultations from 11am and 5pm on Tuesdays, Wednesdays and Thursdays.
- The appointment system was easy to use; patients could book by telephone or via the service's website.
- The provider obtained '360 degree' feedback from patients as part of their GMC appraisal and we reviewed feedback from September 2019. One of the patients commented that the provider was always prompt.
- We reviewed feedback left on 'Google' and saw nine reviews had been left in the last year, with all nine reviews being positive and rating the service as five out of five stars; one patient described the service is punctual and another commented on the excellent service from appointment booking through to aftercare.

**Listening and learning from concerns and complaints**

The service had a system for managing complaints.

- The service had a complaints policy in place and the website also signposted patients to contact the provider by email or telephone if they had a complaint or feedback.
- The complaints policy stated that details of all verbal and written complaints must be recorded in a complaints register. When we asked the provider about this, they said that if patients contacted them with queries or feedback after consultations, they would contact the patients directly and invite them to attend to discuss and resolve the issue, although this was not the process as set out in the service's own complaints policy.
- The provider said no complaints had been received within the last 12 months. Therefore, there were no examples of changes made as a result of patient feedback or complaints.

Requires Improvement

# Are services well-led?

**We rated well-led as Requires improvement because:**

- Leaders could not demonstrate that they recognised and understood challenges to quality and sustainability.
- Some of the service's policies were not service-specific, were missing, did not contain required information, or were not being followed by staff.
- There were no systems to monitor the effectiveness of care and treatment provided.
- There were no systems, or ineffective systems, in place to manage and mitigate risks, issues and performance, for example in relation to verifying parental responsibility, training requirements, recruitment checks, infection control, emergency medicines and equipment, and safety alerts.

**Leadership, culture and vision**

The service's culture was described in positive terms by staff, however leaders could not demonstrate that they recognised and understood challenges to quality and sustainability.

- The provider, as the only member of staff for The London Migraine Clinic, was responsible for the organisational direction and development of the service and the day to day running of it.
- Leaders could not demonstrate that they recognised and understood challenges to quality and sustainability, as they had failed to identify and act on risks to patients which we found during the inspection.
- The provider told us they sought to provide a superlative service and to push forward research and improve treatment outcomes for patients.
- In terms of objectives for the service, the provider said they want to start the observational research for daith piercings, improve audit facilities for treatment outcomes, and consider implementing an online self-assessment tool for patients to use.
- Non-clinical staff who were contracted to support the service told us that leaders were open and worked closely with them. Staff described the service as open and supportive. Non-clinical staff we spoke with said they felt able to raise any concerns with the provider.
- The service had a whistleblowing policy, in which staff were signposted to CQC as an alternative reporting route.
- The provider told us they were aware of the duty of candour and of the importance of being open and honest with patients, although could not show us any examples of adhering to this duty as there had not been any complaints or significant events.

**Governance framework and systems to manage risks, issues and performance**

There were weaknesses in the governance arrangements and ineffective processes for managing risks, issues and performance.

- Staff we spoke with understood their roles and responsibilities in relation to day-to-day operations at the service.
- Some of the service's policies were not service-specific, were missing, did not contain required information, or were not being followed by staff, for example:

- The service's recruitment policy set out that employment checks will be carried out (including for those contracted to provide services), including DBS checks and references. However, this policy was not adhered to as no checks were carried out for the non-clinical staff members, including one who commenced work in 2021, until the provider applied for DBS checks for the staff members following our telephone call on 20 January 2022 announcing the CQC inspection.

Requires Improvement

# Are services well-led?

- The service's policy for significant events consisted of the following statement: "*The policy is to record all Significant Events and Complaints in a single book held in Reception. The details will then be held on the templates included here, and will be held in the patient notes*." This document did not include the service's own definition of a significant event or the type of incident that would need to be reported, it did not outline the process for reporting and recording significant events, or how any learning or changes would be shared and implemented.

- The service's prescribing policy was not specific to the service and did not refer to the specific medicines that were prescribed for patients. The policy stated: "*Doctors receive written notifications from the MHRA on drug safety updates*", however this was not the case, as the provider was not signed up to receive any safety alerts. The policy also referred to a deceased person's medicines being returned to the practice for disposal after their death, despite the service not providing palliative care.

- The service's infection control policy referred to arrangements for linen, bed screens and curtains, despite these not being used at The London Migraine Clinic. The policy did not identify an infection control lead and their specific responsibilities, the policy did not outline infection control training requirements for staff or those contracted to support the service, and the policy did not set out the requirement for infection control audits and the frequency and responsibility of such audits.

- There was no policy in place outlining what training was mandatory for The London Migraine Clinic staff and risk assessing any decisions around training requirements.

- When we asked the provider about their policies and procedures, they said they accept they relied on a number of templates provided to them by a CQC consultant when registering with CQC.
- The service's policies were not accessible to the non-clinical staff contracted to support the service; they told us that the provider holds these policies.
- The provider told us that, as it was such a small team, they had constant contact with the non-clinical staff members and were having frequent check-ins and discussions, albeit these were not formalised or minuted meetings.
- There were no systems, or ineffective systems, in place to manage and mitigate risks, issues and performance, for example:

- There was no process to ensure that adults attending with children had parental responsibility. There was no policy in place in relation to this, and no documented risk assessment had been completed to support the decision not to have a process to verify parental responsibility. When we asked about this, the provider said it is very apparent with adolescents what the relationship is between the adult and child and they feel confident in making that judgement.

- There was no system to assess and oversee training requirements, including in relation to safeguarding, chaperoning, basic life support, information governance, fire safety, and infection control.

- There was no system to ensure safe and appropriate recruitment of staff.

- There was no system to manage and act upon safety alerts to ensure patient safety.

- There was no system for infection control audits.

- There was no system in place to determine and risk assess the necessity for specific emergency medicines and equipment.

Requires Improvement

# Are services well-led?

- The service had a business continuity plan in place.
- The provider was registered as a data controller with the Information Commissioner's Office.
- Changes had been made to infection control arrangements and premises to protect staff and patients using the service during the COVID-19 pandemic, for example social distancing, mask wearing, enhanced cleaning between patients, and installation of high efficiency particulate air (HEPA) filters.

**Engagement with patients, staff and external partners**

The service involved patients and staff to support the service.

- The service did not carry out its own patient surveys, but the provider said they hoped to develop software to gather feedback from patients about their treatment and experience at the service.
- The provider obtained '360 degree' feedback from patients and colleagues as part of their GMC appraisals.
- Staff told us they felt able to raise concerns and give feedback to the provider about the service.
- The provider worked with other healthcare professionals, for example by referring patients to specialists to ensure their needs were met, or by engaging with other doctors at conferences.

**Continuous improvement and innovation**

Systems and processes for learning, continuous improvement and innovation were not wholly effective.

- The service did not have any systems to review the effectiveness and appropriateness of the care provided, as no clinical audits or quality improvement activity had been completed.
- We were unable to review and assess any learning from incidents, as the provider said there had not been any complaints or significant events.
- The provider told us they planned to commence an observational trial of 1000 patients, in conjunction with a piercing studio, looking at the outcomes of daith piercing as a migraine treatment.
- The provider told us that they engaged in research and attended conferences to keep up to date with current practice and treatments relevant to the service. The provider showed us an article they had had published in Aesthetic Medicine in February 2016 about treating migraines with botox simply and effectively.

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 were not being met.

| Regulated activity | Regulation |
|---|---|
| Treatment of disease, disorder or injury | Regulation 12 HSCA (RA) Regulations 2014 Safe care and treatment<br><br>The registered persons had not done all that was reasonably practicable to mitigate risks to the health and safety of service users receiving care and treatment. In particular:<br><br>• There were gaps in staff safeguarding knowledge and training.<br><br>• There was an absence of appropriate recruitment checks.<br><br>• There was no system to manage safety alerts.<br><br>• No infection control audit had been completed.<br><br>• Blank prescriptions were not kept securely.<br><br>• We found gaps and risks in relation to emergency medicines and equipment.<br><br>• There were gaps in staff training and no clarity around mandatory training for the service.<br><br>**These matters are in breach of regulation 12(1) of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014** |

| Regulated activity | Regulation |
|---|---|
| Treatment of disease, disorder or injury | Regulation 17 HSCA (RA) Regulations 2014 Good governance<br><br>There were no systems, or ineffective systems, in place to assess, monitor and mitigate the risks to patients and staff and improve the quality and safety of the services being provided. In particular: |

This section is primarily information for the provider

# Enforcement actions

- There were no systems to monitor the effectiveness of care and treatment provided, as no clinical audits or quality improvement activity had been completed.
- Treatment outside of guidelines was not documented as having been communicated to patients.
- Some of the service's policies were not service-specific, were missing, did not contain required information, or were not being followed by staff.
- There were no systems, or ineffective systems, to manage and mitigate risks, issues and performance; for example, in relation to verifying parental responsibility, assessing training requirements, recruitment checks, managing safety alerts, infection control audits, and arrangements for emergency medicines and equipment.

**These matters are in breach of regulation 17(1) of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014**