Harpal Clinic Ltd

Harpal Clinic

Inspection report

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Date of inspection visit: 28 February 2018
Date of publication: 27/06/2018

Overall summary

We carried out an announced comprehensive inspection on 28 February 2018 to ask the service the following key questions; Are services safe, effective, caring, responsive and well-led?

Our findings were:

Are services safe?

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

Are services effective?

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

Are services caring?

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

Are services responsive?

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

Are services well-led?

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

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

The Harpal Clinic provides a bespoke service to patients of preventative medicine for non-debilitating medical issues (such as constant tiredness, recurrent mild headaches and low libido), help with more serious medical issues (such as hypothyroidism, polycystic ovarian syndrome and constant fatigue syndrome), as well as smoking cessation, help with reducing alcohol consumption, stress, and diet. Treatment is carried out using nutritional therapy and education and bioidentical hormone replacement therapy. Only people over the age of 18 were treated at the clinic.

The company director of Harpal Clinic is the registered manager. A registered manager is a person who is registered with the Care Quality Commission to manage the service. Like registered providers, they are 'registered persons'. Registered persons have legal responsibility for meeting the requirements in the Health and Social Care Act 2008 and associated Regulations about how the service is run.

Six people provided positive feedback about the service.

Our key findings were:

- The service had not undertaken any clinical audits.

Summary of findings

- Patient consultations were undertaken before treatment commenced. This included the taking of a medical history and if any physical concerns identified, patients were referred to their GP before any further treatment.
- The service had systems to manage risk so that safety incidents were less likely to happen. When incidents did happen, the service had a system to learn from them and improve.
- The service used both the evidence based guidance of the National Institute for Clinical Excellence (NICE), and of the research undertaken in America
- The practice prescribed some off-lable medicines (a medicine licenced used for a different indication to that for which it is prescribedlicensed). Medicines used outside of their licence have not been assessed for quality, safety and efficacy by the Medicines and Healthcare Products Regulatory Agency (MHRA) to the same standard as licensed medicines.
- Staff involved and treated patients with compassion, kindness, dignity and respect.
- Services were provided to meet the needs of patients.
- Patient feedback for the services offered was consistently positive.
- There were responsibilities, roles and systems of accountability to support governance and management.

There were areas where the provider must make improvements:

- Establish effective systems and processes to ensure good governance in accordance with the fundamental standards of care. For example the development of a programme of quality improvement, including clinical audit.
- Ensure care and treatment is provided in a safe way to patients.

There were areas where the provider could make improvements:

- Review systems for monitoring safety alerts.

Summary of findings

The five questions we ask about services and what we found

We always ask the following five questions of services.

Are services safe?

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

- There were systems in place for recording significant events and incidents.
- The practice did not adequately monitor patients while undertaking treatments. For example no checks such as blood pressure monitoring and the recording of height and weight were carried out.
- The practice had minimal contact with the patients GP except for in an emergency.
- Safety alerts were being identified but there was no formal system for monitoring.
- Staff demonstrated that they understood their responsibilities and all had received training on safeguarding children and vulnerable adults relevant to their role.
- The service had adequate arrangements to respond to major incidents.

Are services effective?

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

- There was no system for carrying out quality improvement activities, including clinical audits but there was some evidence of other quality improvement being carried out in relation to the improvements to consent forms.
- Staff used both the evidence based guidance of the National Institute for Clinical Excellence (NICE), and of the research undertaken in America.
- Staff had the skills and knowledge to deliver effective care and treatment.
- Staff had appraisals with personal development plans.

Are services caring?

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

- Feedback from patients was positive and indicated that the service was caring and that patients were listened to and supported.
- The provider had systems in place to engage with patients and seek feedback using a survey handed to all patients after their appointment.
- Systems were in place to ensure that patients' privacy and dignity were respected.

Are services responsive to people's needs?

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

- The understood its patient profile and used this understanding to meet the needs of users.
- Treatment costs were clearly laid out and explained in detail before treatment commenced.
- Patient feedback indicated they found it easy to make an appointment, with most appointments the same day.
- Facilities were not suitable to patients with walking difficulties; however the practice had an agreement with a local clinic to refer patients on.
- Patient feedback was encouraged and used to make improvements. Information about how to complain was available and complaints were acted upon, in line with the provider policy.

Are services well-led?

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

Summary of findings

- The provider had a clear vision and strategy and there was evidence of good leadership within the service.
- There were systems and processes in place to govern activities. Some systems were in need of further development, such as responding to alerts and undertaking clinical audit.
- Risks were assessed and managed.
- There was a culture which was open and fostered improvement.
- The provider took steps to engage with their patient population and adapted the service in response to feedback.

Harpal Clinic

Detailed findings

Background to this inspection

The Harpal Clinic is based at 4 Moorfields, London, EC2Y 9AA.

At the Harpal Clinic patients can access a service of preventative medicine. This includes nutritional therapy and education along with bioidentical hormone replacement therapy (the use of hormones that are identical on a molecular level with endogenous (natural) hormones) for conditions ranging from constant tiredness, recurrent mild headaches and chronic fatigue syndrome. The clinic also provides a service for smoking cessation, alcohol consumption and age related changes such as menopause and andropause. The practice provides services for patients that walk in to the practice for appointments as well as appointments booked via email.

The practice is situated in a property above shops in Central London close to Moorgate and Liverpool Street rail stations. The building is not accessible to people who use a wheelchair or mobility aid. The area is well served by public transport.

Two doctors work at the practice, one who is also the managing director of the company, a manager and two administrative staff.

Opening hours were:

Monday - 10.30am to 7.00pm

Tuesday 10.30am to 6.30pm

Wednesday 10.30am to 7.00pm

Thursday 10.30am to 7.30pm

Friday 10.30am to 6.30pm

Appointments were available within 24 hours. Patients can book by telephone or e-mail or by walking in to the practice.

We visited the Harpal Clinic on 28 February 2018. The team was led by a CQC inspector, with a GP specialist advisor.

Before the inspection we reviewed any notifications received from and about the service, and a standard information questionnaire completed by the service.

During the inspection, we received feedback from people who used the service, interviewed staff, made observations and reviewed documents.

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

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

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

Are services safe?

Our findings

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

Safety systems and processes

There were systems, processes and practices in place to keep people safe and safeguarded from abuse. Staff had received training appropriate to their role (for example, safeguarding children level 3 for GPs) and understood their responsibilities. Safeguarding procedures were documented and staff were aware of the practice lead. Clinical staff were trained to safeguarding level 3 and non-clinical staff had received level 1 safeguarding training. The principal doctor was the lead for safeguarding.

Chaperones were available and patients were asked at the start of a consultation if they wished a chaperone to be present. There was no signage in the waiting room to advertise the service. Chaperones had received training for the role and had received a Disclosure and Barring Service (DBS) check in line with the provider's policy for all 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.

Recruitment procedures also checked on staff members' identity, past conduct (through references) and, for clinical staff, qualifications and registration with the appropriate professional body. Medical staff were supported with their professional revalidation. All clinicians had adequate indemnity insurance.

We observed the clinic to be clean and there were arrangements to prevent and control the spread of infections. The practice had a variety of other risk assessments and procedures in place to monitor safety of the premises such as control of substances hazardous to health and infection control and legionella (Legionella is a term for a particular bacterium which can contaminate water systems in buildings). Equipment was monitored and maintained to ensure it was safe and fit for use. The clinic had an infection control policy that was dated 2014 and currently under review by the manager. Infection control audits had been undertaken in 2017.

Risks to patients

Staffing levels were monitored and there were procedures in place to source additional trained staff when required.

Risks to patients (such as fire) had been assessed. Actions that needed to be taken to manage the risks had been identified and were currently being actioned.

There were arrangements in place to respond to emergencies and major incidents:

- Staff records we checked (one clinical staff, two non-clinical) showed that these staff had completed annual basic life support (BLS) training, in line with guidance.
- There was a defibrillator, oxygen, and a supply of emergency medicines. A risk assessment had been carried out to determine which emergency medicines to stock. All expiry dates of emergency equipment and medicines were checked by the practice regularly to make sure they would be effective when required.
- There was minimal contact with a patients GP. A consent form would be signed for the practice to allow information to be shared with GPs however this was not routinely done due to the treatments undertaken by the clinic and the clinics choice to observe patient privacy. Patients would be advised to seek advice from their GP if an issue arose from their medical history (sought by the clinic) or any pre treatment tests undertaken.

There was a business continuity plan for major incidents such as power failure or building damage. This contained emergency contact details for suppliers and staff.

Information to deliver safe care and treatment

The practice used a computer based record system.

Information needed to plan and deliver care and treatment was available to relevant staff in a timely and accessible way through the service's patient record system. This included investigation and test results.

There were arrangements in place to check the identity of patients including the collection of photographic identification.

Safe and appropriate use of medicines

Patients attended consultations with the doctor and were prescribed treatment for a number of conditions including non-debilitating medical issues (such as tiredness and recurrent mild headaches), more serious medical problems

Are services safe?

(intractable hypothyroidism and chronic fatigue syndrome) and age related changes (menopause and andropause). The practice mainly prescribed nutritional supplements but some hormone injections were prescribed. Medicines were dispensed by the clinic in line with the Human Medicines Regulations.

The practice prescribed some off-lable medicines (a medicine used for a different indication to that for which it is licensed). Medicines used outside of their licence have not been assessed for quality, safety and efficacy by the Medicines and Healthcare Products Regulatory Agency (MHRA) to the same standard as licensed medicines.

One medicine used by the practice was spironolactone. At its licenced use for treatment of 100mg it can be used to treat hypertensive patients. The practice used it at a lower dose to block the conversion of testosterone to DHT (Dihydrotestosterone) which causes acne. The practice use this for the treatment of acne rather than established evidence-based medicines. The practice also prescribed metformin off label as an anti-ageing treatment. Metformin is a medicine used for the treatment of type 2 diabetes to control blood sugar levels. The decision to use these medicines for the treatment of conditions other than what the medicines were licenced for was based on American research and guidance.

The use of off-label medicines was discussed with patients during initial consultations where treatment plans were developed. Patients were given information to take away with them following the consultation which explained the reasons for using the medicine licenced for a different indication. If the patient decided to proceed with the treatment, consent was sought for the use of the medicine before treatment commenced. No physical checks (blood pressure, height, weight) were carried out prior to treatment commencing except for when a patient complained of a physical symptom related to the treatment. Blood and salivary tests and stool samples are undertaken on a regular basis throughout treatment to monitor patients conditions. Where there was a concern, the patient would be referred on to their own NHS GP or a private GP for further investigations before treatment commenced. This did not take into account that there may have been an undiagnosed health issue which could adversely affect any treatment. The practice undertakes blood tests to ensure that bioidentical hormone therapy is suitable for the patient.

The practice did not prescribe high risk medicines.

Medicines stocked on the premises were stored appropriately and monitored.

Track record on safety

There were systems in place for reporting incidents. The practice had a number of procedures to ensure that patients remained safe. The practice recorded one significant event in 2017. Events recorded were used in meetings to provide learning to staff.

We found that there was no clear policy for handling alerts from organisations such as the Medicines and Healthcare products Regulatory Agency (MHRA). Alerts were received by email and those deemed appropriate to the practice were discussed in staff meetings. However, there was no log of alerts to ensure they were being received and followed.

Lessons learned and improvements made

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.

When there were unexpected or unintended safety incidents, the policy stated that:

- The service would give 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?

(for example, treatment is effective)

Our findings

We found the practice was not providing all care effectively and in line with the regulations. The practice did not have a system for undertaking clinical audit to ensure quality improvement to the service.

Effective needs assessment, care and treatment

The treatments offered at the clinic were of an alternative and cosmetic nature and not all fit into the conventional guidelines developed by the National Institute for Health and Care Excellence (NICE). The practice adheres to NICE guidelines for the treatment of menopause, testosterone therapy, thyroid issues and polycystic ovarian syndrome, but for other treatments such as bioidentical hormone replacement therapy, which is used for the treatment of conditions such as acne and boosting immunity as an anti-aging treatment, the practice used the guidelines set out in American research, which was undertaken into the use of hormone replacement therapy and how this can be used to treat other conditions, for which the doctor at the clinic attended training courses for and used the same methods for treatment. We were provided with evidence of the research undertaken and the guidance that the practice followed. The guidelines followed for unconventional treatments to be administered, for example, metformin (a diabetic drug) for anti-ageing or rifaximin (an antibiotic used only by specialists in the NHS) for the treatment of small intestinal bacterial overgrowth. The practice made patients aware that the use of some treatments were outside of their product licence during their initial consultation when treatment plans were developed. Information was given to the patient at that point explaining the use of the medicine before consent to proceed with the treatment was sought from the patient

The doctor was aware of the potential side effects of using medicines off-lable and explained these to patients before consent was sought for treatment to commence.

Patients completed a questionnaire before consultation to provide a medical history. The forms would be discussed in the consultation and if there were any further health concerns arising from the discussion, patients would be referred to a GP for follow up before treatment commenced.

Records were kept of all consultations and we found comprehensive history and treatment plans including what was prescribed. Records of what was dispensed to patients were kept on a separate system used for payments.

Monitoring care and treatment

The provider had undertaken a limited first cycle audit of consent forms to ensure all relevant information was included. However, no clinical audits had been undertaken.

Effective staffing

Staff had the skills, knowledge and experience to carry out their roles. Staff demonstrated how they stayed up to date.

- The practice understood the learning needs of staff and provided protected time and training to meet them. Up to date records of skills, qualifications and training were maintained. Staff were encouraged and given opportunities to develop.
- The practice provided staff with on-going support. This included an induction process, one-to-one meetings, appraisals, coaching and mentoring, clinical supervision and support for revalidation. The induction process for healthcare assistants included the requirements of the Care Certificate.
- There was a clear approach for supporting and managing staff when their performance was poor or variable.

Coordinating patient care and information sharing

Patients contacted the practice for specific medical procedures. Patients were asked if they were registered with an NHS GP but their GP was not contacted unless in an emergency. Clinical staff were aware of their responsibilities to share information under specific circumstances (where the patient or other people were at risk) and we were told of examples where doctors had succeeded in getting consent to share information, after explaining the risks to the patients.

Where patients required a referral (for diagnostic tests or review by a secondary care clinician) this was generally arranged directly through a private provider.

Supporting patients to live healthier lives

Are services effective?

(for example, treatment is effective)

The service supported patients to live healthier lives by providing consultations aimed at improving lifestyle, such as smoking and alcohol cessation and weight management.

Consent to care and treatment

Staff understood and sought patients' consent to care and treatment in line with legislation and guidance. All clinical staff had received training on the Mental Capacity Act 2005.

Treatment costs were on display in the waiting area and explained in detail before treatment commenced.

Are services caring?

Our findings

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

Kindness, respect and compassion

We observed that members of staff were courteous and helpful to patients and treated people with dignity and respect.

All feedback we saw about patient experience of the service was positive. We made CQC comment cards available for patients to complete two weeks prior to the inspection visit. We received six completed comment cards all of which were positive and indicated that patients were treated with kindness and respect. Comments included that patients felt the service offered was excellent and in a clean environment. Cards also stated that staff were caring, professional and treated them with dignity and respect.

The practice had given patients feedback forms in January 2018 and were in the process of analysing these. So far the indicators were that the feedback was positive about the service provided. Staff we spoke with demonstrated a patient centred approach to their work and this was reflected in the feedback we received in CQC comment cards and through the provider's patient feedback results.

Involvement in decisions about care and treatment

Feedback from patients indicated that staff listened to their concerns and involved them in decisions made about their care and treatment. A chaperone service was available for patients who requested this.

Privacy and Dignity

The provider respected and promoted patients' privacy and dignity.

- Staff recognised the importance of patients' dignity and respect.
- The service had systems in place to facilitate compliance with data protection legislation and best practice.

Are services responsive to people's needs?

(for example, to feedback?)

Our findings

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

Responding to and meeting people's needs

The clinic ran a bespoke service for patients that wanted treatments not available on the NHS. Patients generally used the service when NHS treatments were not working or not offered in order to gain relief from their symptoms.

Discussions with staff indicated the service was person centred and flexible to accommodate people's needs.

The facilities and premises were not suitable for people with mobility issues due to the staircase used to reach consulting rooms.

Timely access to the service

Consulting hours were:

Monday - 10.30am to 7.00pm

Tuesday 10.30am to 6.30pm

Wednesday 10.30am to 7.00pm

Thursday 10.30am to 7.30pm

Friday 10.30am to 6.30pm

Appointments were available within 24 hours. Patients could book by telephone or e-mail or by walking in to the practice. Telephone answering was monitored to ensure that calls were answered swiftly.

Appointment lengths were tailor made to the type of consultation and treatment being offered.

Listening and learning from concerns and complaints

The provider encouraged and sought patient feedback.

Information on how to complain was available in the waiting room and on the provider's website. There had been five complaints recorded in the past 12 months. These were handled in accordance with the service policy, and the final responses included details of the procedure if the complainant was dissatisfied with the outcome.

There was evidence of improvement in response to complaints and feedback, including a change in the chaperone policy following a complaint. Staff received information about complaints at practice meetings.

Are services well-led?

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

Our findings

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

Leadership capacity and capability

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

- Leaders had the experience, capacity and skills to deliver the service strategy and address risks to it.
- They were knowledgeable about issues and priorities relating to the quality and future of services. They understood the challenges and were addressing them.
- Leaders at all levels were visible and approachable. They worked closely with staff and others to make sure they prioritised compassionate and inclusive leadership.
- The provider had effective processes to develop leadership capacity and skills, including planning for the future leadership.

Vision and strategy

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

- There was a clear vision and set of values in place. The service had a realistic strategy and supporting business plans to achieve priorities.
- Staff were aware of and understood the vision and values and their role in achieving them.
- The service monitored progress against delivery of the strategy.

Culture

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

- Staff we spoke to said they felt respected, supported and valued.
- The service focused on the needs of patients.
- The management acted on behaviour and performance inconsistent with the vision and values.
- Openness, honesty and transparency were demonstrated when responding to incidents and complaints. The provider was aware of and had systems to ensure compliance with the requirements of the duty of candour.
- Staff we spoke with told us they were able to 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 had received annual appraisals in the last year. Staff were supported to meet the requirements of professional revalidation where necessary.
- Clinical staff were considered valued members of the practice team. They were given protected time for professional development and evaluation of their clinical work.
- There was a strong emphasis on the safety and well-being of all staff.
- The service actively promoted equality and diversity. Staff had received equality and diversity training. Staff felt they were treated equally.
- There were positive relationships between staff teams. There were regular staff meetings and minutes showed evidence that actions identified at meetings were followed up.

Governance arrangements

There were responsibilities, roles and systems of accountability to support governance and management.

- There were processes and systems to support the governance of the practice, however we found that there were some gaps to be addressed, for example the creation of a formal process for responding to and recording alerts from organisations such as the MHRA, and the carrying out a programme of quality improvement.
- There was no system for routinely communicating with patients GPs.

Are services well-led?

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

- There was no system in place for undertaking physical checks such as blood pressure, height and weight recording prior to treatment commencing and as an aid to monitoring a patients wellbeing throughout treatment.
- Staff were clear on their roles and accountabilities including in respect of safeguarding and infection prevention and control.

Managing risks, issues and performance

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

- There was an effective, process to identify, understand, monitor and address current and future risks including risks to patient safety.
- The practice did not have a programme of quality improvement, including clinical audit. The practice management had oversight of complaints.
- The service had plans in place and had trained staff for major incidents.

Appropriate and accurate information

The service acted on appropriate and accurate information.

- Quality and sustainability were discussed in relevant meetings where all staff had sufficient access to information.
- The service submitted data or notifications to external organisations as required.
- There were satisfactory 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 sought the views of patients and staff and were in the process of analysing these to be used as feedback to improve the quality of services.

Continuous improvement and innovation

There were systems and processes for learning, continuous improvement and innovation.

Incidents and feedback, including complaints, were used to make improvements.

This section is primarily information for the provider

Requirement notices

Action we have told the provider to take

The table below shows the legal requirements that were not being met. The provider must send CQC a report that says what action they are going to take to meet these requirements.

Regulated activity	Regulation
Treatment of disease, disorder or injury	Regulation 12 HSCA (RA) Regulations 2014 Safe care and treatment The registered person did not do all that was reasonably practicable to assess, monitor, manage and mitigate risks to the health and safety of service users. The practice did not carry out physical examinations (where deemed necessary) before prescribing a course of treatment and as an aid to monitoring a patients welbeing. The practice did not liaise with a patients GP unless in an emergency. This was 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 The registered person did not have all processes in place to ensure good governance. There was no evidence of or system for quality improvement activity including clinical audit. This was in breach of regulation 17(1) of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014.