The Burghwood Clinic Ltd

The Burghwood Clinic

Inspection report

34 Brighton Road,
Banstead,
SM7 1BS
Tel: 01737361177
Website: www.burghwoodclinic.co.uk

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Overall summary

We carried out an announced comprehensive inspection on 14 November 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 providing safe care in accordance with the relevant regulations

Are services effective?

We found that this service was 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 service was meeting the legal requirements and regulations associated with the Health and Social Care Act 2008 and to follow up on the warning notice issued during the March 2018 comprehensive inspection.

CQC inspected the service on 7 and 22 March 2018 and asked the provider to make improvements regarding the way safe care and treatment was provided to patients.

We checked these areas as part of this comprehensive inspection and found this had been resolved.

Previously the provider had not:

- Ensured that prescription only medicines and Enzyme Potentiated Desensitisation (EPD) were legally authorised by an appropriate practitioner.
- Monitored the temperatures of the fridges to ensure they were working correctly.
- Comprehensively risk assessed the laboratory area.
- Completed the actions required from the fire risk assessment from February 2017.
- Calibrated equipment.
- Reviewed a policy detailing the environment that allergy vaccines should be stored in (including room and fridge temperature control) and the shelf life of allergy vaccines made.

At this inspection we found:

- The doctors were prescribing medicines and Enzyme Potentiated Desensitisation (EPD) as legally required.

Summary of findings

- Fridge temperatures were being monitored to ensure they were working correctly.
- There was a comprehensively risk assessed for the laboratory area which included infection control.
- The actions required from the fire risk assessment from February 2017 had been completed with the exception of one action. The provider had organised a further fire risk assessment for further guidance.
- All equipment had been calibrated.
- There was a policy detailing the environment that allergy vaccines should be stored in and the shelf life of allergy vaccines made.

The Burghwood Clinic is situated in a converted building which has been refurbished specifically in an environmentally friendly fashion. There are two consulting rooms, two clinical rooms for skin testing and intravenous infusions and a client waiting area. The premises also includes an administration office, a manager's office and a laboratory. There is disabled access and parking is also available.

The service investigates and aims to identify dietary, environmental or nutritional factors related to health problems. It also offers advice and treatment, including dietary modification and desensitisation. The service also manufactures, supplies and administers vaccines and intravenous infusions to patients.

At the time of our inspection this service was 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 which relate 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. Services are provided to patients regardless of where they live. Patients who are seen in the clinic, but do not reside in England are out of CQC scope of registration.

At the time of the inspection The Burghwood Clinic did not have a registered manager. A registered manager is a person who is registered with the Care Quality Commission to manage the service. Like registered providers, they are 'registered persons'. Registered persons have legal responsibility for meeting the requirements in the Health and Social Care Act 2008 and associated Regulations about how the service is run.

Our key findings were:

- Staff had the relevant skills, knowledge and experience to deliver the care and treatment offered by the clinic.
- All vaccines were being manufactured by the doctor as required by The Medicines and Healthcare products Regulatory Agency (MHRA).
- The clinic had good facilities, and was well equipped, to treat patients and meet their needs.
- Assessments of a client's treatment plan were thorough with a full health history assessment taking place before treatment options were discussed.
- Patients received full and detailed explanations of any treatment options.
- The service encouraged and valued feedback from patients and staff.
- The service had systems in place to identify, investigate and learn from incidents relating to the safety of patients and staff members.
- There were processes in place to safeguard patients from abuse.
- There was an infection prevention and control policy; and procedures were in place to reduce the risk and spread of infection.

- However, staff mandatory training and administration staff appraisals were overdue
- Some risk assessment had been completed but documents reviewed did not always show evidence of this.
- Some risk assessment and the review of some policies were overdue.

We identified regulations that were not being met and the provider must**:**

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

You can see full details of the regulations not being met at the end of this report.

There were areas where the provider could make improvements and should:

- Review and implement any findings from the Legionella risk assessment.

Summary of findings

Professor Steve Field CBE FRCP FFPH FRCGPChief Inspector of General Practice

The Burghwood Clinic

Detailed findings

Background to this inspection

We carried out an announced comprehensive inspection of The Burghwood Clinic on 14 November 2018. The Burghwood Clinic had previously been inspected before om the 7 and 22 March, where a warning notice was issued. We reviewed the concerns from the warning notice during this inspection.

The Burghwood Clinic is an independent health clinic which specialises in the investigation and treatment of all types of food and environmental intolerances and problems associated with the immune system. The clinic provides guidance and a range of treatments and tests to help identify the cause.

The clinic is run from 34 Brighton Road, Banstead, SM7 1BS

Opening times are Monday to Thursday 9am-5pm

The Burghwood Clinic is situated in a converted building which has been refurbished specifically in an environmentally friendly fashion. There are two consulting rooms, two clinical rooms for skin testing and intravenous infusions and a client waiting area. The premises also includes an administration office, a manager's office and a laboratory. There is disabled access and parking is also available.

The inspection team was led by a CQC inspector and included GP specialist advisor, a practice manager specialist advisor, a nurse specialist advisor and member of the CQC medicines team .

During our visit we:

- Spoke with the doctor, two nurses, a laboratory technician and administration staff.
- Reviewed patient records and reviews.
- Looked at documents the clinic used to carry out services, including policies and procedures.

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 this service was providing safe care in accordance with the relevant regulations.

Safety systems and processes

The service had clear systems to keep people safe and safeguarded from abuse. However, some administration staff training for safeguarding was overdue.

- The provider conducted safety risk assessments. It had appropriate safety policies, which were regularly reviewed and communicated to staff. Staff received safety information from the service as part of their induction and refresher training. The service had systems to safeguard children and vulnerable adults from abuse. Policies were regularly reviewed and were accessible to all staff. They outlined clearly who to go to for further guidance.
- 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).
- Clinical staff had received up-to-date safeguarding and safety training appropriate to their role. However, not all administration staff had received recent training. All staff knew how to identify and report concerns, they were aware of the policies and who to contact if they had any concerns.
- There was a system to manage infection prevention and control. There was appropriate guidance and equipment available for the prevention and control of infection. The lead nurse was the infection control lead.
- Data sheets for the Control of Substances Hazardous to Health (COSHH) were not available.
- 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.

Risks to patients

There were 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 staff tailored to their role. However, no new staff had been employed for a number of years. Most staff were long serving, for example we spoke with two staff member who had been at the clinic for 18 and 26 years.
- Staff understood their responsibilities to manage emergencies and to recognise those in need of urgent medical attention.
- 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.
- Cleaning schedules were in place. A cleaning agency was employed three days out of four during the week. The clinic was also deep cleaned on an annual basis. Nurses cleaned the treatment rooms and completed cleaning sheets to evidence the frequency of the cleaning.
- We noted there was no hand washing sink available in one of the treatment rooms. However, we were informed that no examinations took place in this room and was for consultations only. The doctor who used this room had access to hand washing facilities nearby and we noted that all rooms contained hand sanitiser.
- On the day of the inspection the clinic had organised a fire assessment with the local fire department. The previous fire assessment had highlighted that action needed to have taken place in some areas. We were able to see that most issues had been rectified. For example, at the previous inspection it was noted that the cupboard under the stairs had the potential of being a fire hazard. At this inspection the cupboard had been cleared and made fire proof. All fire exit doors now contained easy exit locks (no key required) and a trip hazard identified had been rectified. There was one issue outstanding. The clinic had booked a further fire assessment.
- A legionella assessment had taken place in November 2018 and water temperatures were being monitored. The clinic was waiting on the outcome of the report to rectify any problems found.
- Staff had received basic life support training and anaphylaxis training which was annually updated.

Are services safe?

- The clinic ensured that adrenaline, used in the event of anaphylaxis (a serious allergic reaction that is rapid in onset and can be fatal if not responded to) was readily available.
- The clinic had bought a defibrillator and we saw evidence that all staff had received recent basic life support training which included using the defibrillator.
- All equipment had been calibrated and the clinic had replaced older equipment where needed.

Information to deliver safe care and treatment

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

- Individual care records were written and managed in a way that kept patients safe. The care records we saw showed that information needed to deliver safe care and treatment was available to relevant staff in an accessible way.
- The service had systems for sharing information with staff and other agencies to enable them to deliver safe care and treatment.
- The service had a system in place to retain medical records in line with DHSC guidance.
- Clinicians made appropriate and timely referrals in line with protocols and up to date evidence-based guidance.
- Patients accessing the service were asked to complete a full health questionnaire form prior to their consultation. This questionnaire included the client answering questions in relation to their previous medical history, symptoms, known allergies and whether the client was taking any medicines.
- The clinic required all patients receiving vaccines to complete annual questionnaire in relation to their health. If the patient did not respond further vaccines were not sent to the patient until a consultation was had to ensure that health risks had not changed.
- There were effective protocols for verifying the identity of patients during remote or online consultations.

Safe and appropriate use of medicines

The service had reliable systems for appropriate and safe handling of medicines.

- The doctor at the clinic manufactured 'vaccines' made from allergens, preservatives and other pharmaceutical excipients. Medicines made in this way are referred to as 'specials' and are unlicensed. MHRA guidance states that unlicensed medicines may only be supplied against the valid special clinical needs of an individual patient. The General Medical Council's prescribing guidance specifies that unlicensed medicines may be necessary where there is no suitable licensed medicine. Treating patients with unlicensed medicines represents a higher risk than treating patients with licensed medicines. This is because unlicensed medicines may not have been assessed for safety, quality and efficacy.
- We saw recorded in patient notes, signed understanding of the explanation of the vaccines created, with the knowledge that they were unlicensed and they had consented to their use. We also saw that information was given to patients for the different treatments available.
- The systems and arrangements for managing medicines, including vaccines, emergency medicines and equipment minimised risks.
- Processes were in place for checking medicines and staff kept accurate records of medicines. We saw evidence that the vaccines were made by the doctor and checked by the laboratory technician before being given to the patient. Records were kept of the extracts used for each vaccine created and to which patient they had been given.
- The clinic had guidance on how to manufacture the vaccines. This included a standard operating procedure on how to extract the allergen, form a diluent and make a vaccine.The guidance included information about safety issues related to handling some of the diluents for example benxyl alcohol.
- To ensure the dilutions that were being made were sterile, the clinic had planned to send a batch sample to the local hospital to be tested independently. This showed that the clinic was proactively seeking ways to ensure the products they were manufacturing were sterile and contained ingredients stated.
- Staff kept records of the extracts of allergens used and the vaccines created for easy identification. Extracts, diluents and vaccines were stored in refrigerators and bottles contained the dates they were created. We saw that most extracts of allergens had been created in the past three years. The clinic did have extracts that were older than 10 years, however, these were waiting to be destroyed and we saw that the same extracts had been recently created and were being used.

Are services safe?

- All the equipment used to extract and manufacture the vaccines were calibrated and PAT tested (including: fridges to store the dilutions and vaccines and weighing scales used to measure allergens).
- All vaccines were being manufactured by Dr A Econs. Dr Econ had reduced the number of sessions he carried out, to spend more time manufacturing. Vaccines were manufactured 24-48 hrs after the prescription was written. Once vaccines were manufactured and checked, they were sent to patients via post or collected on the same day.
- Vaccines were supplied to patients to administer by injection or inhale at home. Labels affixed to the vials of vaccine meet legal requirements. Labels included name of the person the vaccine was for, dosage, administration instructions, the address of the clinic, the date of dispensing and expiry date.
- There were no controlled drugs at the clinic.
- The provider had conducted an audit in December 2017 on the prescribing of antimicrobial use to optimise patient outcomes. This was a two-cycle audit, which showed patient improvement in their conditions.

Track record on safety

The service had a good safety record.

- 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.
- The clinic had arrangements in place to receive and comply with patient safety alerts, recalls and rapid response reports issued through the Medicines and Healthcare products Regulatory Authority (MHRA).
- The building's five yearly electrical checks were up to date. All electrical equipment was checked to ensure it was safe to use and was in good working order.

Lessons learned and improvements made

The service learned and made 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.
- There were adequate systems for reviewing and investigating when things went wrong. The service learned and shared lessons identified themes and took action to improve safety in the service.
- 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 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 found that this service was providing effective care in accordance with the relevant regulations.

Effective needs assessment, care and treatment

Patients needs were fully assessed. A full health questionnaire was completed for each person prior to the consultation with the doctors. The questionnaire included information regarding previous medical history, symptoms and whether the client was taking any medicines. This information was used to determine the most appropriate course of treatments.

- We saw no evidence of discrimination when making treatment decisions.
- Clinic staff advised patients what to do if they experienced side effects from any treatments. Patients were also issued with treatment information.
- Patients' immediate and ongoing needs were fully assessed.
- Clinicians had enough information to make or confirm a diagnosis
- Arrangements were in place to deal with repeat patients. Patients could request additional appointments and treatment appointments were given based on the patients individual requirements. Patients were expected to complete an annual review of their health and treatment plans and where necessary a further consultation with the doctor was arranged.

Monitoring care and treatment

The service was actively involved in quality improvement activity.

- The service used information about care and treatment to make improvements. The service made improvements through the use of completed audits. There was evidence of quality improvement initiatives including audits. This included an audit of patient notes and medicines dispensed. The provider completed audits and asked for an annual review from patients to monitor the effectiveness of the treatments provided. We viewed ten annual reviews from patients, which showed they were happy with the effectiveness of the treatment provided.

Effective staffing

Staff had the skills, knowledge and experience to carry out their roles. However, some mandatory training was now overdue.

- All staff were appropriately qualified. The provider had an induction programme for all newly appointed staff.
- Relevant professionals (medical and nursing) were registered with the General Medical Council (GMC)/Nursing and Midwifery Council and were up to date with revalidation
- The provider understood the learning needs of staff. For example, the nurse who completed skin testing for substances that patients could be allergic to, had received seven months of training and observation of their work before working independently. (Doctors were always present at the clinic when tests were taking in place in case of emergencies). Both nurses had completed IV training. Staff were encouraged to attend further training or seminars relevant to the clinic and their roles.
- However, we noted that some mandatory training, although completed in previous years, was now overdue. Staff were aware of this and had plans to address the training at the next planned team meeting.

Coordinating patient care and information sharing

Staff worked 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. For example with the patients own GP.
- Before providing treatment, doctors at the service ensured they had adequate knowledge of the patient's health, any relevant test results and their medicines history.
- Patient 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.

Are services effective?

(for example, treatment is effective)

- Risk factors were identified and highlighted to patients. For example, the clinic provided testing for a number of food and environmental intolerances and provided individual advice for each client following consultation and testing.
- 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 obtained consent to care and treatment in line with legislation and guidance.

- Staff understood the requirements of legislation and guidance when considering consent and decision making.
- Staff supported patients to make decisions. Where appropriate, they assessed and recorded a patient's mental capacity to make a decision.
- We saw evidence that all patients were asked for consent to share details of their consultation and any medicines prescribed with their registered GP.
- The service monitored the process for seeking consent appropriately.

Are services caring?

Our findings

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

Kindness, respect and compassion

Staff] patients with kindness, respect and compassion.

- 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.

Involvement in decisions about care and treatment

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

- Patient records we reviewed showed that up to date medical histories and consent were routinely undertaken.
- Staff helped patients be involved in decisions about their care. A full health history was explored before treatment options were discussed. Treatment options were fully explained, including the cost of treatments, and patients reported they were given good advice.
- Written and verbal information and advice was given to patients about treatment options available to them.
- Information leaflets were available to patients.

Privacy and Dignity

The service respected patients' privacy and dignity.

- Staff recognised the importance of people's dignity and respect.
- Patients were collected from the waiting area by the nurses and were kept informed should there be a delay to their appointment.
- The reception area and waiting room were separate from the treatment room and consultation rooms. Consultations with the doctors took place behind closed doors and staff knocked when they needed to enter. We noted that conversations in consultation rooms could not be overheard.

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

- The provider understood the needs of their patients and improved services in response to those needs.
- The facilities and premises were appropriate for the services delivered. The clinic was situated over two floors in a converted building. The clinic had a waiting area, two doctor consulting rooms, two large skin testing and treatment rooms and a laboratory area.
- Reasonable adjustments had been made so that people in vulnerable circumstances could access and use services on an equal basis to others. Patients with a limited mobility could be seen on the ground floor. There were also toilet facilities available for all patients and visitors to the clinic.

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.
- Waiting times, delays and cancellations were minimal and managed appropriately.
- Patients booked appointments by calling the receptionists. Staff informed us that patient requirements were taken on board and appointments could be flexible.

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. 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 service had complaint policy and procedures in place. The service learned lessons from individual concerns and complaints and also from analysis of trends. It acted as a result to improve the quality of care.
- The providers contingency plans also included what to do if a patient fedback there had been a problem with the therapy they were receiving (for example, vaccines). The policy included stopping production of the vaccine, informing patients, contacting The Medicines and Healthcare products Regulatory Agency (MHRA) and a full investigation to identify the cause.

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. This was because:-

- Some staff mandatory training was overdue
- Administration staff appraisals were overdue
- Some risk assessment had been completed but documents reviewed did not always show evidence of this
- Some risk assessment were overdue
- The review of some policies were overdue

Leadership capacity and capability;

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

- At the time of the inspection the provider did not have a practice manager or a registered manager in post. The provider was recruiting for this position but was yet to find the right candidate.
- Leaders 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 of the service.

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. The service had a realistic strategy to achieve priorities.
- Staff were aware of and understood the vision, values and strategy and their role in achieving them
- The service monitored progress against delivery of the strategy.

Culture

The service had a culture of quality sustainable care. However, we noted that some mandatory training and appraisals for administration staff were overdue.

- 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.
- 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.
- Both the nurses had received recent appraisals and were encouraged to attend outside training and seminars in order to increase their knowledge . However, we noted that administration staff appraisals were overdue. It was recognised this was partly due to the position of practice manager not having been filled. We also noted that some mandatory training was overdue for all staff. Staff were aware of the delay in training. They told us that usually the practice manager would organise the training and planned to have this as an agenda item at the next team meeting.
- Staff were supported to meet the requirements of professional revalidation where necessary. Clinical staff, including nurses, were considered valued members of the team. They were given 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. It identified and addressed the causes of any workforce inequality. Staff had previously received equality and diversity training in May 2017 and this was now overdue. Staff felt they were treated equally.
- There were positive relationships between staff and teams.

Governance arrangements

There were 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,

Are services well-led?

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

understood and effective. The governance and management of partnerships, joint working arrangements and shared services promoted interactive and co-ordinated person-centred care.
- Staff were clear on their roles and accountabilities
- Leaders had established proper policies, procedures and activities to ensure safety and assured themselves that they were operating as intended. However, some polices review date were no overdue.

Managing risks, issues and performance

There were clear and effective processes for managing risks, issues and performance. However, some dates for review had passed and some information of risks reviewed had not been recorded.

- There was an effective, process to identify, understand, monitor and address current and future risks including risks to patient safety. However, this process was not being followed in some areas.
- We saw there was a policy in relation to the frequency of the completion of health and safety risks, audits and training. We saw that some dates had passed and that reviews had not been completed. For example, the fire safety book we reviewed did not show the monthly checking of smoke alarms and emergency lighting. The cleaning schedule audit showed that the cleaning of the (window) curtains within consulting rooms should happen every six months. However, the last recorded clean happening in December 2017. We also noted the cleaning schedule for the cupboard and fridge behind the admin area was last completed in July 2018. However, it was noticeable clean in these areas and staff re-assured us that the cleaning was taking place as scheduled but had not been recorded.
- The service had processes to manage current and future performance. Performance of clinical staff could be demonstrated through audit of their consultations and prescribing.
- All staff members had oversight of safety alerts, incidents, and complaints.
- Clinical audit had a positive impact on quality of care and outcomes for patients. There was clear evidence of action to change services, when necessary, to improve quality.
- The provider had plans in place and had trained staff for major incidents.
- Doctors issued an annual review of all patients receiving treatment. There was a system in place to ensure that repeat prescriptions would not be issued unless an annual review had been conducted.
- There was an audit trail from manufacturing the extract to vaccine. This assured us that, if there were any safety alerts or recalls issued on a specific batch of vaccines, then the provider would be able to take appropriate action.
- The clinic had stopped making any new batches of extracts and dilutions, because they had been receiving conflicting advice from MHRA. It was not clear as to who was authorised to make the extracts and vaccines. As a result, the clinic had reduced the number of new patients they saw.

Appropriate and accurate information

The service acted on appropriate and accurate information.

- Quality and operational information was used to ensure and improve performance. Performance information was combined with the views of patients.
- Quality and sustainability were discussed in relevant meetings where all staff had sufficient access to information.
- The service used performance information which was reported and monitored and management and staff were held to account
- The information used to monitor performance and the delivery of quality care was accurate and useful. There were plans to address any identified weaknesses.
- 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.
- All patients were given written information about the use of unlicensed vaccine and consented. A copy of their consent was kept in the patients notes.

Engagement with patients, the public, staff and external partners

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

- The publics', patients', staff and external partners' views and concerns were encouraged, heard and acted on to shape services and culture.

Are services well-led?

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

- Staff were able to describe to us the systems in place to give feedback.
- We saw evidence of feedback opportunities for staff and how the findings were fed back to staff.
- The service was transparent, collaborative and open with stakeholders about performance.

Continuous improvement and innovation

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

- There was a focus on continuous learning and improvement.
- Learning was shared and used to make improvements.
- Leaders and managers encouraged staff to take time out to review individual and team objectives, processes and performance.
- There were systems to support improvement and innovation work.

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
Diagnostic and screening procedures Treatment of disease, disorder or injury	Regulation 18 HSCA (RA) Regulations 2014 Staffing Requirements in relation to staffing **How the regulation was not being met** The service provider had failed to ensure that persons employed in the provision of a regulated activity received such appropriate training and appraisal as was necessary to enable them to carry out the duties they were employed to perform. In particular: • The provider had not assured themselves that roles previously completed by the practice manager had been undertaken. For example, appraisals for admin staff. • Mandatory training had not been completed for all staff. Including but not limited to, Equality and Diversity, Infection control, Complaints, Information security and Fire Safety.

Regulated activity	Regulation
Diagnostic and screening procedures Treatment of disease, disorder or injury	Regulation 17 HSCA (RA) Regulations 2014 Good governance Systems or processes must be established and operated effectively to ensure compliance with the requirements of the fundamental standards as set out in the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 **How the regulation was not being met**

This section is primarily information for the provider

Requirement notices

The registered person had systems or processes in place that operating ineffectively in that they failed to enable the registered person to assess, monitor and mitigate the risks relating to the health, safety and welfare of service users and others who may be at risk. In particular:

- The provider had not assured themselves that all risk assessments previously completed by the practice manager had been undertaken.
- Not ensuring that all health and safety risk assessment have been completed as required. For example, monthly fire checks, cleaning schedules for curtains and blinds, the recording of completed cleaning of the store cupboard and fridge in admin area, the three monthly audit of the external cleaning,
- Not having COSHH data sheets
- Not recording Immunisation status for all staff