

The Burghwood Clinic Ltd

The Burghwood Clinic

Inspection report

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Overall summary

We carried out an announced comprehensive inspection on 7 and 22 March 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 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.

The Burghwood Clinic is an independent health clinic which specialises in the investigation and treatment 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 of food and environmental intolerances.

The service is provided by two doctors, two nurses, two laboratory technicians, reception and administration staff and a practice manager.

The practice manager is also 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.

We received feedback from five clients about the clinic. All replies were very positive. Comments included excellent personal care. Clients felt staff were friendly, knowledgeable and professional.

Our key findings were:

Summary of findings

- Staff had the relevant skills, knowledge and experience to deliver the care and treatment offered by the clinic.
- The service was offered on a private, fee paying basis but had a small number of referrals from GP practices.
- The clinic had good facilities, and was well equipped, to treat clients 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.
- Clients received full and detailed explanations of any treatment options.
- The service encouraged and valued feedback from clients and staff.
- Feedback from clients was positive.
- The service had systems in place to identify, investigate and learn from incidents relating to the safety of clients and staff members.
- There were processes in place to safeguard clients from abuse.
- There was an infection prevention and control policy; and procedures were in place to reduce the risk and spread of infection.
- However, the risk assessment including the infection control risk, was not comprehensive for the laboratory area.
- The clinic had not fully completed the actions required from the fire risk assessment from February 2017.
- The clinic had not calibrated the equipment used to ensure it was working correctly.

- There was no policy on the stability of allergy vaccines made and the correct environment that these should be stored in.
- Vaccines, which were prescription only medicines, were not being prescribed as required by an appropriate practitioner such as a doctor or a nurse independent prescriber.
- Fridge temperatures were not always being monitored to ensure they were working correctly.

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

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

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 the risk assessment for the products used for cleaning as required by Control of Substances Hazardous to Health Regulations 2002.
- Review and implement any findings from the booked Legionella risk assessment and review the frequency of further assessments required.
- Review the frequency of health assessments being reviewed and recorded within clients notes and the frequency of individual client consent forms being completed.

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.

We have told the provider to take action (see full details of this action in the Warning Notice at the end of this report).

- There were systems in place for identifying, investigating and learning from incidents relating to the safety of clients and staff members.
- There were systems and processes in place to safeguard clients from abuse.
- The staffing levels were appropriate for the care and treatment provided by the clinic.
- Risk management processes were in place to manage and prevent harm. With the exception of a detailed risk assessment for the laboratory area and the cleaning chemicals used within the clinic.
- Fire equipment was appropriately monitored and fit for use. A fire risk assessment had been carried out in February 2017 but not all actions required had been completed.
- The service had an infection control policy and procedures were in place to reduce the risk and spread of infection. With the exception of detailed infection control and cleaning procedures required in the laboratory area.
- Emergency medicines and equipment were easily accessible. The provider did not have a defibrillator but this had been risk assessed. Treatments given were considered a low risk and therefore a defibrillator was not required within the clinic.
- No equipment had been calibrated to ensure that it was working correctly.
- There was no policy for the stability of allergy vaccines made and the correct environment that these should be stored in including the extracts used to create allergy vaccines stored with the fridge.
- Fridge temperatures were not always being monitored to ensure they were working correctly.
- Medicines were not being supplied in accordance with regulation 214(1) of the Human Medicines Regulations (2012). The doctors were not providing prescriptions for the supply of allergy vaccines, (which were prescription only medicines) Both the doctor and the registered manager told us that they did not think that prescriptions were required to authorise the supply of these vaccines.

Are services effective?

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

- The medicines used at the clinic were not licensed. Treating patients with unlicensed medicines is higher risk than treating patients with licensed medicines. The provider completed audits to monitor the effectiveness of the treatments provided.
- Staff had the relevant skills, knowledge and experience to deliver the care and treatment offered by the service.
- Client consent and relevant information was sought before their information was shared with other services.
- A health questionnaire and medical history was undertaken prior to recommending treatments.
- Staff demonstrated they understood the relevant consent and decision making requirements of legislation and guidance, including the Mental Capacity Act 2005 and Gillick competencies. (Gillick competence is a term used in medical law to decide whether a child (under 16 years of age) is able to consent to his or her own medical treatment.
- Staff received training appropriate to their role. We saw copies of training certificates including life support training.

Summary of findings

Are services caring?

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

- Feedback from clients who used the service demonstrated a high level of satisfaction. Staff we spoke with were professional and friendly.
- We also saw that staff treated clients with dignity and respect.
- We were told by staff that clients were fully involved in decisions about their treatment.
- Information for clients about the services available was accessible and clearly stated the costs involved.

Are services responsive to people's needs?

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

- Clients could book appointments in person at the clinic or by telephoning direct.
- Clients received a personalised information in relation to their health needs. This included a health assessment and any tests required before treatment options were discussed.
- The clinic was well equipped to treat clients and meet their needs and was accessible to those with mobility requirements.

Are services well-led?

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

- The clinic had a clear vision and strategy to deliver high quality care. Staff understood the company vision and their responsibilities in relation to it.
- There was a clear leadership structure and staff felt supported by management. The clinic had policies and procedures to govern activity.
- The clinic encouraged a culture of openness and honesty.
- Staff received inductions, performance reviews and received relevant training.
- The clinic proactively sought feedback from staff and clients.
- The clinic reflected on clinical actions taken and where necessary reviewed policies and procedures to ensure that clients received an improved service.
- However, we found that some governance arrangements and managing risk were not always effective.

The Burghwood Clinic

Detailed findings

Background to this inspection

We carried out an announced comprehensive inspection of The Burghwood Clinic on 7 and 22 March 2018. 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 a consultant clinical immunologist, a nurse specialist advisor and a medicines inspector.

Prior to the inspection we gathered and reviewed information from the provider. There was no information of concern. During our visits we:

- Spoke with the practice manager, the doctor, two nurses, a receptionist and two laboratory technicians.
- Reviewed comment cards where clients shared their views and experiences of the service.
- 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 that this service was not always providing safe care in accordance with the relevant regulations. This was due to the provider not supplying medicines in accordance with regulation 214(1) of the Human Medicines Regulations (2012), calibrating equipment, not having completed all of the actions required from the fire risk assessment, not completing a risk assessment for the cleaning chemicals used within the clinic, not having a policy or detailed procedures for the stability and storage of allergy vaccines and not having a detailed risk and infection control assessment of the laboratory area. We have told the provider to take action (see Warning Notices).

Safety systems and processes

The clinic had clear systems to keep clients safe and safeguarded from abuse.

- The provider had policies in place for safeguarding children and vulnerable adults. All staff had received training to an appropriate level in relation to protecting children and vulnerable adults and there was a nominated safeguarding lead within the service. There was clear contact information accessible to staff for local child and adult support teams. Staff demonstrated an understanding of how to identify and raise a safeguarding concern.
- We saw evidence that recruitment checks had been carried out prior to employment including proof of identity and a full employment history. The clinic carried out staff checks, including checks of professional registration where relevant. Disclosure and Barring Service (DBS) checks were undertaken. (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).
- There was a system to manage infection prevention and control. There was appropriate guidance and equipment available for the prevention and control of infection. All staff had received up-to-date training in infection control. The lead nurse was the infection control lead. However, we noted there was no Control of Substances Hazardous to Health (COSHH) assessments for any cleaning chemicals used. (COSHH is the law that requires employers to control substances that are hazardous to health, so as to prevent ill health).

- Electrical and clinical equipment had been tested within the past year. However, no equipment had been calibrated to ensure it was working correctly
- There were systems for safely managing healthcare waste.

Risks to patients

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

- We noted that not all of the actions required after the fire risk assessment in February 2017 had been completed. For example, we noted that an action for the cupboard under the stairs which housed electrical equipment should be fire proofed, had not been completed. The stairs were the only means of escape from the first floor and this would be compromised if a fire were to start in this area.
- There was no risk assessment for the laboratory area nor a detailed infection control audit. The laboratory area was used for creating allergy vaccines for clients. This could involve creating allergy vaccines from food. We saw there was no risk assessment for cross contamination when creating these allergy vaccines. There was no risk assessment or policy for the safe storage of allergy vaccines and no comprehensive details for how this area should be cleaned.
- There was an effective induction system for staff tailored to their role.
- Staff had received basic life support training and anaphylaxis training which was annually updated.
- 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.
- All clinical staff had appropriate professional indemnity cover in place.

Information to deliver safe care and treatment

- The practice manager conducted a clinical notes audit every six months. Each audit conducted reviewed 20 client notes for both doctors. We noted that on several occasions it was recorded that clinical notes were incomplete or not stored with the client record. The doctors were reminded of the importance of ensuring all information was recorded onto the clients notes.
- Clients accessing the service were asked to complete a full health questionnaire form prior to their

Are services safe?

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 care records we saw showed that information needed to deliver safe care and treatment was available to relevant staff in an accessible way. Paper records were stored in a locked filing cabinet in the treatment room.

Safe and appropriate use of medicines

- Medicines were not being supplied in accordance with regulation 214(1) of the Human Medicines Regulations (2012) this included the administration of Enzyme Potentiated Desensitisation (EPD) injections by the nurse. The allergy vaccines created by the provider are classed as prescription only medicines and can only be legally authorised by an appropriate practitioner. Clients gave permission for skin prick testing to take place, to determine which food or environmental intolerances the client was suffering from. This was authorised by the doctor, who at the same time gave permission for the nurse to then prescribe the allergy vaccine required. However, neither of the nurses were legally able to authorise the prescribing of medicines. The doctor and the registered manager told us that they did not think that prescriptions were required to authorise the supply of vaccines. The nurses we spoke with confirmed they were not independent prescribers and that they supplied vaccines to clients, including when there was no doctor on the premises and with the absence of a prescription.
- Allergy vaccines were made and stored within the laboratory area. We saw these were clearly labelled with a date that the allergy vaccine had first started to be used. We reviewed records that detailed when an extract was made and this was given a reference number. When the extract was used to create the allergy vaccine a second reference number was used and cross referenced. When creating individual allergy vaccines for clients a reference number was recorded.
- Staff told us that allergy vaccines could be stored in a room temperature environment for up to one year. However, the room allergy vaccines were stored in had no temperature control and was not being monitored for variations in temperature. The laboratory had a large window which during the summer months could increase the temperature in the room. There was no policy written to determine if an increase or decrease in temperature could affect the stability of the allergy vaccine.
- Extracts used to create allergy vaccines were stored within dedicated fridges. Two fridges within the laboratory area did not have their temperatures monitored and staff were unable to tell us if the extracts stored in them needed to be stored within a certain temperature range. A fridge within the store room was also not being temperature monitored and we found medicines that indicated a storage range of between 2 and 8 degrees. The clinic could not evidence that the fridge had stayed within this range. A further pharmacy fridge being used for the storage of allergy vaccines was being monitored to ensure it maintained the correct temperature range.
- The doctor explained that there was no published research or guidance to refer to in relation to safe storage. The clinic told us they had conducted their own research and all allergy vaccines could be stored within a room temperature environment for up to one year and that allergy vaccines stored within the fridge would increase the shelf life significantly. However, we were unable to see written notes on this research. We also noted that the clinic did not have their own policy recording information on how long an extract or allergy vaccine could be stored. We also noted there was no risk assessment for the safe storage including temperature ranges these should be stored at.
- Emergency medicines were readily available and in date.

Track record on safety

The clinic had a good safety record.

- There were comprehensive policies and procedures in relation to safety issues.
- The clinic 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).

Are services safe?

- 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. However, equipment had not been calibrated.

Lessons learned and improvements made

The clinic learned and made improvements when things went wrong.

- There was a system for recording and acting on significant events and incidents. Staff understood their duty to raise concerns and report incidents and near misses.
- There were adequate systems for reviewing and investigating when things went wrong. The clinic learned and shared lessons, identified themes and took action to improve safety in the clinic.
- There was a system for receiving and acting on safety alerts.

Are services effective?

(for example, treatment is effective)

Our findings

Effective needs assessment, care and treatment

Clients' 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 clients what to do if they experienced side effects from any treatments. Clients were also issued with treatment information.

Monitoring care and treatment

There was evidence of quality improvement initiatives including audits. This included an audit of clients notes and medicines dispensed. The provider completed audits to monitor the effectiveness of the treatments provided. However, we noted that audit exclusions could limit the effectiveness of the audit to demonstrate good quality care.

Effective staffing

Staff had the skills, knowledge and experience required to carry out their roles. For example, nurses had received updates from the British Society of Ecological Medicines, attended allergy shows and was part of the Food Matters Forum. Staff told us they had access to the training they required.

- All staff providing clinical services had the training required to perform their duties. For example, the nurses received yearly update training for Intravenous (IV) therapy. (IV therapy is a process by which health care professionals infuse medications and other fluids directly into a client's veins).

- All nurses were supported to undertake revalidation. Revalidation is the process that all nurses and midwives in the UK need to follow to maintain their registration with the Nursing and Midwifery Council (NMC), which allows them to practise.
- There was an induction programme for newly appointed staff. This included supervised practice and competency assessments.
- All staff were up to date with their mandatory training. This included basic life support, fire safety, infection control, safeguarding vulnerable adults and children and information governance.

Coordinating patient care and information sharing

The provider shared relevant information with the clients consent. We saw evidence of the clinic contacting a client's own GP because of concerns identified.

Supporting patients to live healthier lives

Clients were assessed and given individually tailored advice. 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.

Consent to care and treatment

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

- Staff understood the relevant consent and decision-making requirements of legislation and guidance, including the Mental Capacity Act 2005. When providing care and treatment for children and young people, staff carried out assessments of capacity to consent in line with relevant guidance. We noted that consent was required at the beginning of a treatment plan, which could continue for a variety of time lengths, but not required again.
- Written and verbal information was given to clients using the service. This included information on the different treatments including risks and benefits prior to administration.

Are services caring?

Our findings

Kindness, respect and compassion

- Staff treated clients with respect and professionalism. We observed staff to be respectful and courteous to clients, treating them with kindness and compassion.
- Staff understood clients' personal, cultural, social and religious needs. The clinic gave clients timely support and information.
- We received three Care Quality Commission comment cards and spoke with two clients. Comments received were positive about the service experienced. Clients described the service as being excellent, efficient, respectful, and of a high standard. Comments about staff were also positive and feedback remarked on all staff being friendly, professional and helpful.

Involvement in decisions about care and treatment

- Staff helped clients 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 clients reported they were given good advice.
- Written and verbal information and advice was given to clients about treatment options available to them.
- Information leaflets were available to clients.

Privacy and Dignity

- Staff recognised the importance of client's dignity and respect. 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.
- Clients were collected from the waiting area by the nurses and were kept informed should there be a delay to their appointment.
- CQC comment cards supported the view that the service treated clients with respect.
- All client records were kept in secured filing cabinets within a locked room. Staff complied with information governance.

Are services responsive to people's needs?

(for example, to feedback?)

Our findings

Responding to and meeting people's needs

The clinic organised and delivered services to meet clients' 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. Clients with a limited mobility could be seen on the ground floor. There were also toilet facilities available for all clients.
- Equipment and materials needed for consultation, assessment and treatment were available at the time of clients attending for their appointments.
- Information was available on the clinic's website, informing people about the services and treatment available and the costs involved.
- The clinic provided private treatment for both adults and children.

Timely access to the service

- The service was open Monday to Thursday 9am to 5pm. The website contained details of current opening times.
- Clients who needed a course of treatments were given future appointments to suit the client.
- Clients were able to book appointments over the telephone or in person.

Listening and learning from concerns and complaints

There was a complaints system in place. The service had a complaints policy which detailed how and the time frame in which the service responded to complaints. The policy included details of other agencies to contact if a client was not satisfied with the outcome of the clinic's investigation into their complaints.

Five complaints had been received by the clinic in the past year. The clinic recorded both formal and informal complaints. All complaints were annually reviewed for any trends and to ensure that any action required had been completed. We reviewed two complaints and saw these had been handled in a timely fashion. The clinic sought client feedback via an annual internal client survey and results were discussed with staff and where needed actions were taken from feedback.

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. We have told the provider to take action (see full details of this action in the Warning Notice at the end of this report).

Leadership capacity and capability;

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

- There was a registered manager in post who understood their responsibilities.
- The nursing team had the experience, capacity and skills to deliver the clinic strategy and address risks to it.
- Staff were knowledgeable about issues and priorities relating to the quality and future of services offered.

Vision and strategy

The provider had a clear vision to provide a high quality service that put caring and client safety at its heart.

Culture

Candour, openness, honesty and transparency and challenges to poor practice were evident.

- Staff we spoke with were proud to work in the clinic and said they felt respected, supported and valued.
- The clinic focused on the needs of clients and ensured that staff had the correct knowledge and training to do this.
- Staff were encouraged to attend training.
- The provider had a whistleblowing policy and staff we spoke with were aware of this policy.

Governance arrangements

Staff were clear on their roles and accountabilities including safeguarding and infection prevention and control. However, there was a misunderstanding and oversight of governance and risk with regards to the treatments provided. The provider believed that the allergy vaccines did not need to be authorised by a legally authorised appropriate practitioner (i.e. the doctor) in accordance with regulation 214(1) of the Human Medicines Regulations (2012).

The provider had established policies and procedures to ensure safety and assured themselves that they were operating as intended. Policies we reviewed were all relevant and up to date. The practice manager was the first point of contact for staff regarding any issues.

Managing risks, issues and performance

There were some processes to identify, understand, monitor and address current and future risks including risks to client safety. We noted that steps were taken in response to any issues found.

- The provider and staff had oversight of MHRA alerts, incidents, and complaints.
- Clinical audit had a positive impact on quality of care for clients. There was clear evidence of action to change practice to improve quality. For example, the clinic had conducted an audit after recognising a reduced efficiency in one of the low dose immunotherapies offered. The clinic had changed their practice to use a filtered needle and suspected this was why there had been a decrease in efficiency. As a result the preparation had been changed and there was a plan to re-audit the effectiveness after one year.
- However, some risks were not being managed correctly. For example, fridge temperatures were not being monitored, equipment had not been calibrated, actions required from the fire risk assessment had not been completed, there was no risk assessment for the cleaning chemicals used within the clinic (COSHH), there was no comprehensive risk assessment for the laboratory area, there was no policies detailing the environment that allergy vaccines should be stored in and the expected shelf life of allergy vaccines made.

Appropriate and accurate information

- The clinic used systems to monitor and improve the quality of care.
- Client records were securely stored on the information technology system only accessible via staff log-in. Paper notes were stored securely and could only be accessed by staff.
- The practice manager conducted a clinical notes audit every six months. Each audit conducted reviewed 20 client notes for both doctors.

Engagement with patients, the public, staff and external partners

Are services well-led?

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

- The clinic involved clients and staff to promote and support high-quality sustainable services.
- Clients were encouraged to provide feedback.

Continuous improvement and innovation

- Staff were encouraged to continually develop and improve their knowledge.
- There was evidence of improvement to the service clients received as a result of feedback.

Enforcement actions

Action we have told the provider to take

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

Regulated activity	Regulation
Diagnostic and screening procedures Treatment of disease, disorder or injury	<p>Regulation 12 HSCA (RA) Regulations 2014 Safe care and treatment</p> <p>The registered persons had not done all that was reasonably practicable to ensure care and treatment was provided in a safe way. In particular:</p> <ul style="list-style-type: none">• By not ensuring that prescription only medicines and Enzyme Potentiated Desensitisation (EPD) were legally authorised by an appropriate practitioner.• By not monitoring the temperatures of the fridges the extracts and other medicines were stored in to ensure they were working correctly.• By not having a comprehensive risk assessment (including a comprehensive infection control) for the laboratory area.• By not having completed the actions required from the fire risk assessment from February 2017.• By not calibrating equipment.• By not having 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. <p>This was in breach of regulation 12(1) of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014.</p>