

The Burghwood Clinic

Inspection report

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

Ratings

Overall rating for this location

Good 

Are services safe?

Requires improvement 

Are services effective?

Good 

Are services caring?

Good 

Are services responsive?

Good 

Are services well-led?

Good 

Overall summary

This service is rated as Good overall. (Previous inspections 14 November 2018 and 7 and 22 March – where non-compliance was found)

The key questions are rated as:

Are services safe? – Requires improvement

Are services effective? – Good

Are services caring? – Good

Are services responsive? – Good

Are services well-led? – Good

We carried out an announced comprehensive inspection at The Burghwood Clinic 26 November 2019 as part of our inspection programme to rate all independent health and to follow up on breaches of regulations.

At our previous inspection on 14 November 2018 we asked the provider to ensure all staff received appropriate training, supervision and appraisal and to establish effective governance arrangements. We checked these areas as part of this comprehensive inspection and the provider was now complying with the regulations. For example:-

- All staff had received an appraisal and staff training was up to date.
- Documents we reviewed showed that risk assessments had been completed
- Policies had been reviewed and updated
- Findings from the Legionella risk assessment had been implemented

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 clients.

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 clients regardless of where they live. Clients who are seen in the clinic, but do not reside in England are out of CQC scope of registration.

Dr Econs 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.

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 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.
- 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 people from abuse.
- There was an infection prevention and control policy; and procedures were in place to reduce the risk and spread of infection.
- We saw that the provider had taken steps to provide assurances that the products being manufactured were free from unacceptable contamination.
- The clinic had not adhered to specialist advice that required the products to have a maximum expiry date of six years.

Overall summary

The areas where the provider must make improvements as they are in breach of regulations are:

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

(Please see the specific details on action required at the end of this report).

Dr Rosie Benneyworth BM BS BMedSci MRCGP

Chief Inspector of Primary Medical Services and Integrated Care

Our inspection team

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

Background to The Burghwood Clinic

We carried out an announced comprehensive inspection of The Burghwood Clinic on 26 November 2019. The Burghwood Clinic had previously been inspected before on the 17 November 2018 and 7 and 22 March. We found areas of non-compliance during our last 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.

For information about practice services, opening times and appointments please visit their website at www.burghwoodclinic.co.uk.

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.

During our visit we:

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

To get to the heart of clients' 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?

The provider is rated as requires improvement for providing safe services because:

- The clinic had not adhered to specialist advice that required the products to have a maximum expiry date of six years.

Safety systems and processes

The service had clear systems to keep people safe and safeguarded from abuse.

- The provider conducted safety risk assessments. It had appropriate safety policies, which were regularly reviewed and communicated to staff. They outlined clearly who to go to for further guidance. Staff received safety information from the service as part of their induction and refresher training. The service had systems to safeguard children and vulnerable adults from abuse.
- The service had systems in place to assure that an adult accompanying a child had parental authority.
- 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).
- All staff received up-to-date safeguarding and safety training appropriate to their role. They knew how to identify and report concerns.
- There was an effective system to manage infection prevention and control.
- Data sheets for the Control of Substances Hazardous to Health (COSHH) were available.
- There were systems for safely managing healthcare waste.
- A legionella assessment had taken place in November 2018 and water temperatures were being monitored.
- The provider ensured that facilities and equipment were safe and that equipment was maintained according to manufacturers' instructions.
- The provider carried out appropriate environmental risk assessments, which considered the profile of people using the service and those who may be accompanying them.

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 agency staff tailored to their role.
- Staff understood their responsibilities to manage emergencies and to recognise those in need of urgent medical attention.
- There were suitable medicines and equipment to deal with medical emergencies which were stored appropriately and checked regularly.
- When there were changes to services or staff the service assessed and monitored the impact on safety.
- There were appropriate indemnity arrangements in place.

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 clients 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 Department of Health and Social Care (DHSC) guidance in the event that they cease trading.
- Clients accessing the service were asked to complete a full health questionnaire prior to their consultation. This questionnaire included questions about the client's previous medical history, symptoms, known allergies and whether the client was taking any medicines.
- The clinic required all clients receiving vaccines to complete an annual questionnaire in relation to their health. If the client did not respond, further vaccines were not sent to the client until a consultation had taken place to ensure that health risks had not changed.
- There were effective protocols for verifying the identity of clients during remote or online consultations.

Safe and appropriate use of medicines

Are services safe?

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

- Medicines were ordered, transported, and disposed of in a way that was satisfactory. In some cases, products were posted to clients. If necessary, they were sent with a cool pack to maintain the temperatures of the products. However, the provider was unable to assure us that medicines manufactured on site were safe for use. This was because the sterility data that was obtained was not applicable for use at this location.
- In the previous inspection report for this location, the provider had agreed to send some products for sterility testing to assure themselves that they were safe. Whilst the 'Organism Identification Test Reports' were related to a sister clinic, we saw that the provider had taken steps to provide assurances that the products being manufactured were free from unacceptable contamination.
- In the sterility tests, products were stored at 20-25 degrees and then at 30-35 degrees Celsius (therefore not refrigerated) for a total of 14 days. Three of the samples out of a total of nine had bacterial growth detected and therefore failed the sterility test.
- We were told that the risk of products being contaminated at this clinic was minimal because all the products manufactured were refrigerated and contained bacteriostatic chemicals.
- We saw records that proved that emergency medicines and equipment was checked weekly. Oxygen cylinders were full and in date. We saw that staff had access to appropriate medicines disposal facilities.
- The temperatures of medicines storage areas were monitored on the days when the clinic was open. If the temperature readings were out of range, staff informed the doctor in charge. The doctor then made a judgement according to risk on how the products should be managed.
- Some of the medicines used at the clinic were manufactured on site by the doctor from allergens, preservatives and other pharmaceutical excipients.
- The clinic had a facility for the administration of intravenous products available. This room had a nurse present and administration was signed for by a trained witness (another nurse, or the laboratory technician). If a client receiving an intravenous product was assessed as being at high risk of anaphylaxis, the doctor was present during administration of any intravenous products.
- The allergen extracts were made up by the clinic doctor personally. A laboratory technician then made further dilutions of these products. These diluted products were then combined according to an individualised prescription written by the doctor. A doctor then combined dilutions according to an individualised prescription to manufacture the final unlicensed medicine for client use. The final products made by the clinic were for administration orally, sublingually or via subcutaneous injection. Products manufactured at the clinic were posted out to patients to self-administer in their own homes.
- The Medicines and Healthcare products Regulatory Agency (MHRA) state that 'an unlicensed medicinal product may only be supplied in order to meet the special needs of an individual client'. The General Medical Council's (GMC) prescribing guidance specifies that unlicensed medicines may be necessary where there is no suitable licensed medicine. Treating clients with unlicensed medicines is higher risk than treating clients with licensed medicines, because unlicensed medicines may not have been assessed for safety, quality and efficacy.
- The products used in the clinic were specially manufactured to meet individual client need. We also saw evidence that the clinic ensured that clients were made aware of the unlicensed nature of the products that they were being prescribed here. This was explained to each client and they gave informed consent in accordance with GMC guidance.
- The clinic had a 'low dose immunotherapy dispensary handbook' which provided guidance on how to manufacture the allergens and their dilutions (vaccines). There was a standard operating procedure on how to make the extract of the allergen. There was also guidance on how to make a dilution from the allergen extract and how to make the final vaccine for individual client use.
- 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 were told that the expiry dates for all these products were checked on a weekly basis, however we did see one

Are services safe?

extract that had expired in 2003. Staff explained that this particular extract should have been disposed of and did this immediately. Apart from this, all extracts had been made within the last eight years. This was not in line with information the provider had been given about the use of these products at another location. Specialist advice had required the products to have an expiry date of six years.

Track record on safety and incidents

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.

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
- The service acted on and learned from external safety events as well as client 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?

Effective needs assessment, care and treatment

We saw evidence that clinicians assessed needs and delivered care and treatment in line with current legislation, standards and guidance (relevant to their service).

- Clients' needs were fully assessed. A full health questionnaire was completed for each client 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.
- Clinicians had enough information to make or confirm a diagnosis.
- We saw no evidence of discrimination when making care and treatment decisions.
- Arrangements were in place to deal with repeat clients. Clients could request additional appointments and treatment appointments were given based on the clients' individual requirements. Clients 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. Clinical audit had a positive impact on quality of care and outcomes for clients. For example, the GP had conducted an annual audit of users of low dose vaccines for efficacy and safety. The GP also asked all clients to complete an annual review to monitor the effectiveness of the treatments provided by completing a questionnaire or attending a review appointment. Further vaccines were not authorised until this had been completed.
- Clients were asked to complete a satisfaction questionnaire which had achieved a 78% satisfaction rate.
- The nurses completed an audit of consent recorded in clients notes on a six monthly basis. We saw from the last audit that all of the 40 random clients selected had a record of consent in their files.

- Nurses had also conducted an audit of cannulisation on 20 clients over a three week period. The nurses asked these clients to complete a questionnaire to ensure the effectiveness of this element of their role. The audit showed a success rate of 100%
- The nurses completed infection control audits. We saw that any actions required had been resolved.

Effective staffing

Staff had the skills, knowledge and experience to carry out their roles.

- All staff were appropriately qualified. The provider had an induction programme for all newly appointed staff.
- All staff had completed up to date mandatory training with the exception of one new administrative staff member who had yet to complete their Basic Life Support training but we saw that a date had been planned for this.
- 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 clients 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 intravenous cannulation training. Staff were encouraged to attend further training or seminars relevant to the clinic and their roles.

Coordinating patient care and information sharing

Staff worked together, and worked well with other organisations, to deliver effective care and treatment.

- Clients received coordinated and person-centred care. Staff referred to, and communicated effectively with, other services when appropriate.
- Before providing treatment, doctors at the service ensured they had adequate knowledge of the client's health, any relevant test results and their medicines history. We saw examples of clients being signposted to more suitable sources of treatment where this information was not available to ensure safe care and treatment.

Are services effective?

- All clients were asked for consent to share details of their consultation with their registered GP.

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.
- Risk factors were identified and highlighted to clients.
- Where clients' 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 clients to make decisions. Where appropriate, they assessed and recorded a client's mental capacity to make a decision.
- The service monitored the process for seeking consent appropriately. The nurses completed six monthly audits of clients notes picked at random, where consent was reviewed in each file to ensure that it had been recorded. We noted that for the last two audits completed there had been consent recorded in each client record.

Are services caring?

Kindness, respect and compassion

Staff treated patients with kindness, respect and compassion.

- The service sought feedback on the quality of clinical care clients received
- Feedback from clients was positive about the way staff treat people
- Staff understood clients' personal, cultural, social and religious needs. They displayed an understanding and non-judgmental attitude to all clients.
- The service gave clients timely support and information.

Involvement in decisions about care and treatment

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

- Clients told us through comment cards, that they felt listened to and supported by staff and had sufficient time during consultations to make an informed decision about the choice of treatment available to them.
- 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

The service respected patients' privacy and dignity.

- Staff recognised the importance of people's dignity and respect.
- Staff knew that if clients wanted to discuss sensitive issues or appeared distressed they could offer them a private room to discuss their needs.
- Clients 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?

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 clients 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. Clients with a limited mobility could be seen on the ground floor. There were also accessible toilet facilities available for all clients and visitors to the clinic.
- The provider had installed air purifiers in all rooms due to the nature of the clinic. This helped those clients who suffered from severe allergies or were sensitive to perfumes or scents.

Timely access to the service

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

- Clients had timely access to initial assessment, test results, diagnosis and treatment.
- Waiting times, delays and cancellations were minimal and managed appropriately.

- Clients reported that the appointment system was easy to use.

Listening and learning from concerns and complaints

The service took complaints and concerns seriously and responded to them appropriately to improve the quality of care.

- Information about how to make a complaint or raise concerns was available. Staff treated clients who made complaints compassionately.
- The service informed clients 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, complaints and from analysis of trends. It acted as a result to improve the quality of care. For example, the provider had received a complaint about the time it took for the phone to be answered and the curt manner of the receptionist. We saw that the provider had apologised to the client and investigated the concern raised. In response a new phone line was installed and additional staff employed.
- The providers contingency plans also included what to do if a client feedback there had been a problem with the therapy they were receiving (for example, vaccines). The policy included stopping production of the vaccine, informing clients, contacting The Medicines and Healthcare products Regulatory Agency (MHRA) and a full investigation to identify the cause.

Are services well-led?

Leadership capacity and capability;

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

- 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 and supporting business plans to achieve priorities.
- The service developed its vision, values and strategy jointly with staff.
- Staff were aware of and understood the vision, values and strategy and their role in achieving them.

Culture

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

- Staff felt respected, supported and valued. They were proud to work for the service.
- The service focused on the needs of clients.
- 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 told us they could raise concerns and were encouraged to do so. They had confidence that these would be addressed.
- There were processes for providing all staff with the development they need. This included appraisal and career development conversations. All staff received regular annual appraisals in the last year. 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 protected time for professional 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 received equality and diversity training. Staff felt they were treated equally.
- There were positive relationships between staff and teams.

Governance arrangements

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

- Structures, processes and systems to support good governance and management were clearly set out, 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.

Managing risks, issues and performance

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

- There was an effective, process to identify, understand, monitor and address current and future risks including risks to client safety.
- The service had processes to manage current and future performance. Performance of clinical staff could be demonstrated through audit of their consultations and prescribing.
- Leaders had oversight of safety alerts, incidents, and complaints.
- Clinical audit had a positive impact on quality of care and outcomes for clients. There was evidence of action to change services to improve quality.
- The provider had plans in place and had trained staff for major incidents.

Are services well-led?

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 clients.
- 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. 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.
- The service submitted data or notifications to external organisations as required.
- There were robust arrangements in line with data security standards for the availability, integrity and confidentiality of client identifiable data, records and data management systems.

Engagement with patients, the public, staff and external partners

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

- The service encouraged and heard views and concerns from the public, clients, staff and external partners and acted on them to shape services and culture.
- Staff could 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. We also saw staff engagement in responding to these findings.
- The service was transparent, collaborative and open with stakeholders about performance.

Continuous improvement and innovation

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

- There was a focus on continuous learning and improvement.
- 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 the service provider was not meeting. The provider must send CQC a report that says what action it is going to take to meet these requirements.

Regulated activity	Regulation
Treatment of disease, disorder or injury	<p data-bbox="815 663 1485 730">Regulation 12 HSCA (RA) Regulations 2014 Safe care and treatment</p> <p data-bbox="815 757 1485 824">The provider did not have an effective system to ensure that medicines were safe to use. In particular:</p> <ul data-bbox="815 851 1485 954" style="list-style-type: none"><li data-bbox="815 851 1485 954">• The provider had not adhered to specialist advice relating to a maximum expiry date of six years for products manufactured at this location.