Breakspear Medical Group Limited

Breakspear Medical Group

Inspection report

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Overall summary

We carried out an announced comprehensive inspection on 11 May 2018 to ask the service the following key questions; Are services safe, effective, caring, responsive and well-led?

Our findings were:

Are services safe?

We found that this service was 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 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.

This service is registered with CQC under the Health and Social Care Act 2008 in respect of the provision of advice or treatment by, or under the supervision of, a medical practitioner, including the prescribing of medicines for the purposes of allergy treatment and immunisations.

The service manager 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.

41 people provided feedback about the service using CQC comment cards ahead of our inspection. All comments were positive and 39 people noted specific, detailed information about their experiences. Some patients noted they had used the service for over nine years and said their treatment had demonstrably improved their quality of life. Some cards were written by the parents of

Summary of findings

children, who said they felt all the staff had treated their child appropriately with respect. All 41 comment cards referred to the kindness of staff or the dignity with which they were treated.

Our key findings were:

- Care and treatment was delivered by a well-trained team that maintained up to date knowledge of the latest national and international guidance.
- The ethos of the service was demonstrably patient-centred with effective clinical governance processes in place.
- Treatment was evidence-based and a dedicated researcher worked with clinicians to ensure patients had access to outcomes from the latest research to guide safe and effective treatment.
- Staff placed considerable value on engagement with patients and feedback was consistently positive, with a significant track record of care that had positively impacted patient's lives.
- Staff demonstrated passion, motivation and a drive for innovation in meeting individual needs
- The clinical team used the outcomes of international research and internal resources to meet the needs of patients who had exhausted treatment options elsewhere.

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

- Review infection control audit processes to ensure areas of substandard performance are promptly addressed.
- Review fire risk assessments in the building and review day-to-day environment management processes to ensure good fire safety standards.
- Only supply unlicensed medicines against valid special clinical needs of an individual patient where there is no suitable licensed medicine available.

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 providing safe care in accordance with the relevant regulations.

- Safe working practices were in place that meant incidents were reported, investigated ad learned from.
- There was a clear staffing structure in place to monitor patient safety, including through acting on national safety alerts.
- Medicines management policy and practice was in line with national and international guidance on licensed, off-license and 'special' medicine.
- Risks to patients were well managed and staff adapted service delivery to maintain safe treatment and care.
- Safeguarding procedures were embedded in the service and staff were trained to respond to concerns and incidents.

We found areas where improvements should be made relating to the safe provision of treatment.

- Infection control processes, including audit, did not result in consistently good standards. We found several areas in which improvements were needed that audits had not identified or that audits had identified but no action had been taken.
- Day-to-day practice did not always include adherence to good fire safety and prevention practice.
- The most recent fire risk assessment did not accurately reflect the environment.

Are services effective?

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

- Care, treatment, screening and testing were carried out in line with national and international best practice and research outcomes. Where no UK accrediting body existed for a procedure or treatment staff found an international equivalent measure of efficacy and safety.
- Clinical and professional competency were key priorities of the senior team and staff had access to on-going training and specialist development, which was reflected in the service they provided.
- The service delivered treatment based on the latest available clinical research findings, which was monitored by a dedicated in-house researcher. This meant all treatment was evidence-based.
- Staff had a clear understanding of the Mental Capacity Act (2005) and consent processes were consistently used and adapted to specific treatments.

Are services caring?

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

- All patients were asked for feedback and staff had adapted patient satisfaction surveys into common first languages spoken by patients and into a child version.
- The senior team acted on feedback from patients and published a detailed annual report to identify areas of good practice and act on suggestions for improvement.
- Feedback from patients was overwhelmingly positive and we received detailed comments about how treatment had improved quality of life.
- Patients were involved in decision-making about their care and treatment plans and gave the service consistently good feedback in relation to their involvement.
- Staff understood the principles of privacy and dignity and delivered care and treatment in line with best practice.

Summary of findings

Are services responsive to people's needs?

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

- Staff had developed the service based on the needs of the local, national and international patients who presented at the clinic.
- Services were available for patients with complex or multiple needs, including alcohol and drug dependency.
- An internally-accredited laboratory was based on site and agreements were in place with multiple international partners to ensure samples were processed quickly and safely.
- Service and environmental adaptations were in place for children and those with complex or specialist needs.
- The quality manager led a complaints procedure that was embedded in the service and resulted in improvements to care and practice.

Are services well-led?

We found that this service was providing well-led care in accordance with the relevant regulations.

- Governance processes were in place and ensured clinical services were evidence-based and in line with best practice guidance.
- There was a demonstrably positive, cohesive working culture in which each member of staff was valued and listened to.
- Protocols and policies were up to date and updated when national or international research indicated this would benefit patients.
- The leadership team was coherent and well respected and contributed to a feeling of loyalty amongst staff.
- A recent review of the vision and strategy had resulted in a renewed focus on external engagement, which the senior team recognised as important for business continuity.

We found areas where improvements should be made relating to the well-led provision of treatment.

- Although governance and risk management systems were in place, they had not always resulted in consistent standards in infection control or fire safety.

Breakspear Medical Group

Detailed findings

Background to this inspection

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.

Services are provided from:

Breakspear Medical Group

Hertfordshire House

Wood Lane

Paradise Industrial Estate

Hemel Hempstead

Hertfordshire

HP2 4FD

The service is open Monday to Saturday from 9am to 5pm and is closed for bank holidays.

The inspection was led by a CQC inspector and a specialist advisor who:

- Carried out an announced inspection on 11 May 2018.
- Spoke with ten members of staff in a range of clinical and non-clinical roles.
- Reviewed a sample of patient records.
- Looked at the comments made by patients on 41 CQC comment cards.
- Reviewed audits, internal reports and patient satisfaction surveys.

We informed local stakeholders that we were inspecting the service; however, we did not receive any information from them.

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.

Two full time doctors and three-part time doctors lead clinical treatment. This team represents a range of specialties, including in psychiatry, infectious diseases and autonomic neurophysiology. Ten registered nurses, each with training and experience in a clinical specialty, provide care and treatment.

At the time of our inspection the service had 2000 registered patients and provided care on a private basis with some extra-contractual care provided on behalf of the NHS. The service was equipped for children although this was rare and in the previous 12 months the service had provided care or treatment to five children. In the previous year 44% of new patients were seen based on personal recommendation, 40% were seen as a follow-up visit and 8% were referred by an NHS or private consultant.

The service provides environmental medicine treatment for patients experiencing allergies, sensitivities and intolerances in addition to myalgic encephalomyelitis, chronic fatigue syndrome, malnutrition or obesity, smoking cessation and alcohol and drug harm reduction. The service also provides care and investigative treatment for patients living with Lyme disease.

There are four consulting rooms, two main wards with trollies and seats and three individual side rooms. There is a dedicated children's treatment room and a children's play area adjacent to space used for immunisations. There is a

Detailed findings

kitchen on site staffed by dedicated chefs and patients have access to two waiting areas and a dining room. An accredited laboratory is on site and the team maintains agreements with accredited laboratories worldwide that provide timely screening of biological samples.

Are services safe?

Our findings

Safety systems and processes

All staff had training in safeguarding adults to level 2 and senior clinical staff had training to level 3. A safeguarding lead was in post who ensured policies and staff training were up to date and met the latest national guidance. The safeguarding lead ensured clinicians whose primary area of practice was outside of England practiced in line with local regulations.

The service occasionally provided paediatric services including infant immunisations and childhood allergy management. The service had registered children's nurses as part of the team; all doctors had safeguarding children training to level 2 and the nurse manager had safeguarding children training level 3. In addition, the medical director was a paediatrician. Safeguarding children training had included specialist modules on recognised faked or imagined illnesses, female genital mutilation (FGM), spiritual abuse and exploitation and trafficking. Staff said the safeguarding training also prepared them to provide care and treatment to children living with attention deficit hyperactivity disorder (ADHD). Staff had encountered one significant safeguarding concern involving a child and demonstrated appropriate action and liaison with the police and local authority crisis team.

Staff used the visual infusion phlebitis (VIP) score as a safety mechanism to monitor patients for the signs of phlebitis during treatment.

The whole team had a daily safety briefing in the morning before the first patient arrived. This enabled them to plan the day ahead and put in place requirements for patients with specific needs or complex care.

Care and treatment was only delivered when a doctor was on site. This meant if a patient experienced unexpected symptoms or side effects a clinician was available to carry out an assessment. There was no formal protocol for deteriorating patients and staff said they would arrange for the patient to be transferred to hospital or call paramedics in an urgent situation.

There were no fire door or fire exit signs in the corridor on the first floor of the building and we found doors in some areas wedged open when not in use in one part of the building. This presented an increased risk of fire spreading in an emergency. For example, there were three doors wedged open in one office and six items of electrical equipment plugged in and powered up, including an oxygen concentrator.

All staff had up to date fire safety training and the team took part in a simulated evacuation annually. The quality manager had sourced practical fire extinguisher training for staff and this was due to be delivered shortly after our inspection. A trained fire warden was allocated to each department and had a nominated deputy. The senior team managed the rota to ensure each department had a fire warden or deputy on each shift.

The service had undergone a fire risk assessment in December 2017 and found no significant risks. The risk assessment noted that self-closing fire doors were clearly labelled. However, the building had no self-closing fire doors. This meant we were not assured the fire risk assessment had been completed thoroughly or was fit for purpose. We spoke with the senior team about this who said they would review the risk assessment.

Staff were trained as chaperones and posters were displayed around the building to advise patients this service was available. Patients could request a chaperone for each appointment and staff planned for this in advance.

The service had an up to date Legionella certificate for all water outlets in the building. Legionella is a type of bacteria that can live in areas connected to a mains water supply but that is not used regularly. A check for this bacterium means the service manages the risk effectively.

Risks to patients

Emergency pull cords were located in all clinical areas and in bathrooms and waiting areas. A first response team was in place whenever the service was open and responded to all alarm activations and patient emergencies.

Basic life support and cardiopulmonary resuscitation (CPR) training was mandatory for all staff and the whole team completed annual refresher training.

Emergency equipment and guidance for use was maintained in line with Resuscitation Council UK guidelines. We looked at all the emergency equipment on site and the records relating to routine safety checks. We found equipment to be well maintained and regularly checked, including the oxygen cylinder and automatic

electronic defibrillator (AED). Oxygen masks and AED pads were available in a variety of sizes, including for children. A biohazard spill kit was available adjacent to the wards and was in date with documented checks.

Chemicals were stored according to best practice standards in the Control of Substances Hazardous to Health (COSHH) Regulations (2002). This included an up to date register of the materials kept on site and the procedures to follow in the event of a spillage or contact with skin. However, we found a bottle labelled 'unperfumed hand gel' in a patient area that had no ingredient list, manufacturer details or information on the contents. This meant it was not immediately apparent if the gel was antibacterial or if it was indicated for use with all skin types.

A sharps bin was stored at each bedside and between each pair of patient treatment chairs. Staff had labelled and dated each box and all were within the safe storage capacity, which meant the service was compliant with the Health and Safety (Sharp Instruments in Healthcare) Regulations 2013. Processes were in place to ensure waste was disposed of in line with the Hazardous Waste Regulations (2005), including the use of a waste register.

Staff cleaned the environment with non-scented cleaning products and there were signs posted in multiple areas instructing people not to visit if they were wearing scented personal products such as perfume or cologne. This was a risk management strategy to reduce the risk of allergic relations in patients who were attending the clinic for the management of environmental sensitivity.

Most areas were clean and free from dirt or dust. However, we found some areas that required more consistent cleaning and monitoring. Two consulting rooms that were occasionally used for childhood immunisations were carpeted and had fabric chairs and one clinical room had a visibly dirty fabric chair. Fabric chairs present an increased infection control risk because they cannot easily be disinfected. A keyboard used by doctors in one consulting room was visibly dirty with no antibacterial cover on it. We saw an oxygen cylinder kept in a clinical area was heavily rusted and four chairs had footstools with ripped coverings and exposed foam, a chair with a ripped covering, a damaged wall and a printer with thick dust covering it.

The infection control lead carried out unannounced hand-washing observations with staff. All sinks had pictorial guides to effective hand-washing techniques based on World Health Organisation guidance posted above them.

In the 2017 patient satisfaction survey 100% of patients described the ward cleanliness as good or excellent, 99% described the waiting and dining area cleanliness as good or excellent and 95% rated the toilet cleanliness as good or excellent. Overall 98% of patients rated their overall impression of the facilities as good or excellent.

Staff used a low-dose immunotherapy protocol when patients first started a treatment plan for allergy management. This meant they began treatment using a range of antigens at gradually reduced dilutions while monitoring the patient's response, symptoms and vital signs. The clinical team had developed this process over a significant period and identified it as the safest, lowest-risk approach to patients who often presented with little existing medical history on their condition.

Where staff carried out procedures that did not have national clinical guidance or established UK safety standards, they monitored risks in line with research evidence and international guidance. For example, patients who underwent whole-body hypothermic iratherm treatment had an increased risk of artificially-induced pyrexia (fever). To manage this risk the treatment was always supervised by a trained nurse with the use of sauna treatment and continual monitoring of vital signs.

Each doctor maintained professional indemnity insurance and the registered manager kept a record to ensure this was up to date, which we reviewed as part of our inspection.

The service measured how patients perceived the safety of their treatment in satisfaction surveys. In 2017 97% of patients said they felt their care and treatment had been delivered safely.

Information to deliver safe care and treatment

Patient records were electronic and stored securely on an internal IT system. Data was backed up remotely, which meant patient information was protected in the event of a systems failure.

Are services safe?

We looked at a sample of three patient records and found staff entries were detailed, legible and clear to understand. Staff dated each entry and we were able to identify the person who completed each entry.

The nature of the service meant some treatments were provided without a conventional evidence base or large-scale evidence of potential side effects. Staff explained this to patients as part of their treatment plan and consent records included details of these discussions.

Registered nurses led the patient liaison team and reviewed planned treatment after patients' initial consultation with a doctor. This meant patients had time to speak with a clinically trained member of staff who could discuss their treatment plan as well as the cost.

Staff use individual risk assessments for each patient to ensure information was readily available about the action to take in the event of an adverse reaction or incident.

Safe and appropriate use of medicines

At Breakspear Medical Group we found that patients were treated with unlicensed medicines.Treating patients with unlicensed medicines is higher risk than treating patients with licensed medicines, because unlicensed medicines may not have been assessed for safety, quality and efficacy.

Medicines can also be made under a manufacturers specials licence. Medicines made in this way are referred to as 'specials' and are unlicensed.Medicines and Healthcare Products Regulatory Agency (MHRA) guidance states that unlicensed medicines may only be supplied against 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.

Clinicians understood their prescribing responsibilities with regards to medicines used under license and those used off license. Where medicines were licensed in other countries but not in the UK doctors discussed this with patients and explained what this meant.

The service kept a stock of emergency medicines in line with guidance from the British National Formulary (BNF). Medicines were within their expiry date and stored in an area in which staff controlled and monitored the temperature to ensure the medicines remained in the safe range recommended by the manufacturer. However, one emergency anti-allergy medicine was listed on the stock list but was not available on site. We spoke with the nurse manager about this who said they would address it.

Staff documented daily temperature checks of the areas used to store medicines, including refrigerated medicine. We looked at the records for the previous month and found them to be up to date with no missing records. Staff could describe the procedure they would follow if a temperature exceeded the safe maximum issued by the manufacturer.

The medicines management policy was up to date and had been reviewed annually. The prescribing policy was in line with best practice and ensured people received medicine safely. Registered nurses administered intravenous infusions and dispensed medicines after they had been prescribed by a doctor.

The senior team adhered to the requirements of the MHRA Inspectorate in relation to buying unlicensed medicines from outside of the UK. This included in relation to the correct use of a Wholesale Dealer's Authorisation and a Manufacturer's 'Special' License during instances of shortages of specific medicines, such as the mumps vaccine. Staff manufactured vaccines on site with oversight from the MHRA and in line with formularies they had developed.

Track record on safety

The service manager monitored national safety alerts from the National Patient Safety Agency (NPSA) and disseminated these to each member of clinical staff who then checked their patient lists to identify anyone who may be affected. The service manager maintained a record of NPSA alerts and the action taken, if any, for each.

The service had a policy that no patients could leave with a cannula or peripherally inserted central catheter (PICC) line still in place. As a result, the service had no reported safety incidents relating to lines.

All staff were up to date with mandatory training and refresher training and a named individual was responsible for monitoring this in their team.

The service had reported no serious incidents with harm.

Lessons learned and improvements made

The quality assurance manager reviewed incident reports and carried out investigations to identify how

improvements could be made. All staff were encouraged to report incidents in a culture of open communication to ensure everyone could participate in learning. For example, a member of staff had experienced a needlestick injury as a result of improper disposal of a syringe. The quality assurance manager reviewed policies and procedures to ensure they were up to date and fit for purpose and ensured each member of staff understood appropriate waste disposal standards.

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 gave affected people reasonable support, truthful information and a verbal and written apology. They kept written records of verbal interactions as well as written correspondence.

Are services effective?

(for example, treatment is effective)

Our findings

Effective needs assessment, care and treatment

The provider assessed needs and delivered care in line with relevant and current evidence based guidance and standards such as the National Institute for Health and Care Excellence (NICE) best practice guidelines.

Clinical staff carried out ongoing audits into the causes, symptoms and treatment of Lyme disease in recognition of a lack of understanding and available research data nationally and internationally. The most recent audit was focused on quality of clinical care and led the senior team to implement new care and treatment protocols for the condition. One month prior to our inspection NICE issued updated clinical guidance in relation to the treatment and management of Lyme disease. The clinical team were in the process of updating treatment protocols to ensure they adhered to this guidance.

Each patient's named doctor carried out a structured annual review that included medicine and all elements of therapy and treatment. Patients were required to attend the review and their doctor suspended the treatment plan if they missed it. This was to ensure the clinical team maintained an up to date needs assessments of each patient so that treatments could continue to be developed.

There was a laboratory on site that was accredited by the United Kingdom Accreditation Service (UKAS). This meant UKAS had identified the laboratory as working in the public interest with competence and integrity.

Clinicians were experts in their field and accredited by the appropriate bodies in the usual place of residence, such as the American Academy of Environmental Medicine. This was in addition to their registration with the UK General Medical Council.

Some clinical investigations, such as blood tests for nickel allergy, could not be reliably carried out locally or in the UK. To ensure patients received timely and safe laboratory tests, the service had agreements in place for a courier service to carry biological samples out of the UK. Staff tracked samples electronically while they were in transit. Where laboratories in other countries were used for testing, the clinical team ensured they were accredited by the appropriate authorities and could prove up to date certification such as for compliance with the Clinical Laboratory Improvement Amendments (1988) in the US. The service worked with the International Laboratory Accreditation Cooperation to track the accreditation status of the laboratories they worked with.

Monitoring care and treatment

Clinical staff were trained in the Mental Capacity Act (2005) and where they were concerned about a patient's ability to consent to care or believed they lacked capacity, they referred to the patient's GP or a psychologist before beginning treatment. Doctors could carry out a dementia screening test on site if they were concerned about a patient's behaviour or memory and used the outcome to decide whether to make a specialist referral.

Where new research was released that was relevant to the care and treatment offered, the clinical nurse manager and medical director reviewed existing policies and treatment protocols to ensure they reflected the latest available understanding of the condition. The continual review of specialist research meant staff monitored care and treatment in the context of developing knowledge of patient outcomes in addition to the individual outcomes of each patient.

Patients were required to pass a fitness assessment before they could undergo whole-body hypothermia iratherm treatment. During the procedure a registered nurse monitored the patient's condition continually to ensure the treatment was effective and not causing unwanted side effects.

Doctors prescribed basic pain relief when necessary and nurses monitored patients for pain during treatment.

Effective staffing

All doctors were registered with the General Medical Council (GMC) and all nurses carried out revalidation in line with Nursing and Midwifery Council requirements. Three doctors were on the specialist register; one each for psychiatry, infectious disease and autonomic neurophysiology.

A team of 10 registered nurses worked in the service and each individual had expertise in a different clinical area or specialty.

A researcher was based permanently in the service and managed an extensive collection of literature and range of

journal subscriptions. The researcher joined weekly multidisciplinary meetings to coordinate case reviews and patient care planning and ensure clinical staff incorporated the latest available research on their patient's conditions.

A 24-hour, seven-day support phone line was available, staffed by a doctor and accessed through the service's main contact number. Staff gave this information to patients on discharge or between appointments and encouraged them to contact the service if they had questions, concerns or unexpected side effects.

The researcher held a three-monthly meeting with the clinical team to review their understanding of new research outcomes that would help them provide care and treatment. The meeting included a journal club and staff discussed weekly readings the researcher issued to ensure staff maintained up to date understanding of changes in treatment protocols and recommendations. Nurse training was delivered at local hospitals or in house by clinical nurse specialists who assessed everyone for competency.

New nurses underwent a three-month induction period that included mandatory training, one-to-one observations and two weeks of supernumerary shadowing on the two wards.

A phlebotomist worked in the service to provide support for difficult cannulations and had undertaken healthcare assistant training and carried out pulse checks, temperature checks and electrocardiograms (ECGs).

The service had dedicated training and seminar space used for staff development and staff told us they regularly contributed ideas to the senior team for training plans.

Staff were supported to attend specialist training and clinical and professional opportunities and demonstrated a track record of competency development. For example, two nurses had attended specialist training with the Allergy Academy and five staff in various roles had attended a 'masterclass' in allergy management at a children's hospital.

The clinical nurse manager and quality manager carried out supervisions and appraisals for staff. In addition to a review of the quality of their work this included a discussion about their own wishes for progression and development and a discussion of the individual feedback received from patients.

Coordinating patient care and information sharing

The permanent clinical team attended weekly multidisciplinary meetings to review patient progress, referrals and complex care needs. Reviews from clinicians involved with other aspects of the patient's care, such as GPs or consultants, were involved where this would help to plan and deliver effective care. Where patients lived outside of the UK and/or were under the care of a physician based outside of the UK, the clinical team facilitated international communication.

Clinicians prepared detailed care and treatment summaries for GPs and family doctors based outside of the UK if patients gave their consent. The team prepared a summary for each visit or course of treatment.

Processes were in place for staff to provide onward referral information to NHS or other private specialists if clinical treatment indicated this was in the patient's best interest. Staff facilitated this in the most appropriate way for the patient, such as through their GP for UK-based patients and through their family doctor or referring consultant for those based outside of the UK.

Nutritionists, chefs and the clinical team worked together to plan menus and supplements for patients during their treatment and to take away with them.

Where patients presented with a significant risk relating to mental health staff demonstrated good coordination of their care. For example, when one patient disclosed suicidal thoughts the doctor liaised with the psychologist and ensured the patient received appropriate support. Similarly, where patients disclosed past alcohol misuse clinicians liaised with their GP to ensure medicines and treatment were likely to be safe and not contraindicative.

Supporting patients to live healthier lives

A dedicated catering team prepared meals on site for patients. They maintained strict standards for healthy meal preparation and sourced fresh, local produce free from artificial ingredients.

In the 2017 patient satisfaction and first visit satisfaction survey, patients rated the catering service consistently well:

- 97% of patients rated the variety and choice of food as good or excellent.
- 100% of patients rated the temperature of the food as good or excellent.
- 98% of patients rated the overall standard of catering as good or excellent.

Are services effective?

(for example, treatment is effective)

- 97% of patients said they enjoyed their meal.

Some patients noted in the survey they would like more organic options to add to the organic teas and coffee already available. The lead chef and quality team were working together to consider changes based on feedback, including the introduction of a new menu with more variety.

Staff provided specialist care, therapy and treatment for patients with needs relating to wider health or lifestyle issues. This included nutritional therapy for obesity, a smoking cessation programme and support for alcohol misuse. Staff had prepared printed information for each of these conditions with guidance on how they could help.

The service provided a dedicated weight loss programme based on evidence from the Obesity Management Association. This was a programme led by clinicians and included clinical tests to identify risks associated with obesity, nutritional supplements and psychological help with food cravings. This programme was part of a comprehensive range of nutritional guidance and services provided by the service, including a weight enhancement programme and specialist meal plans.

Staff had developed a treatment protocol for patients living with diabetes to improve their diet and reduce restrictions placed on them by their usual doctor.

Staff had prepared information leaflets for patients to help them assess their environment for allergens or other issues that caused a reaction.

Consent to care and treatment

A thorough consent process was in place and staff did not begin treatment until they had completed discussions with patients about their treatment plan, its likely success and the estimated cost. Patients completed consent forms with a witness and staff gave them time to ask questions and encouraged a cooling off period to allow them time to think about their options.

Consent documentation reflected specific procedures, which meant patients and staff had a documented record of exactly what had been consented to. For example, consent forms were in place for the use of medicines under special license for low-dose immunology, the use of antibiotics and the use of whole-body hypothermia iratherm and sauna treatment. Staff gave patients a copy of their signed consent documentation to take with them and encouraged them to ask questions about it. The consent documentation for each procedure included the known benefits and risks as well as details of what was not known about it. Consent forms were available in German, Italian and French to ensure patients who spoke one of these languages more fluently than English could fully understand their planned treatment.

In the 2017 patient satisfaction and first visit satisfaction surveys 99% of patients said they consented to all care and treatment they received. The quality assurance manager had reviewed all patient documentation from this period and found no evidence any clinical treatment had been delivered without the patient's signature to confirm they understood and approved the procedure.

Clinical staff had carried out a three-cycle audit of consent and record-keeping between January 2017 and May 2018 and found consistent practice in line with standard operating procedures.

Are services caring?

Our findings

Kindness, respect and compassion

The senior team monitored patient satisfaction through a rolling patient satisfaction survey and a first visit satisfaction survey. In 2017:

- 100% of patients rated their greeting on arrival from the reception team as good or excellent.
- 98% of patients rated their overall impression as good or excellent.
- 100% of patients rated their overall standard of medical care as good or excellent.
- 100% of patients rated their overall standard of nursing care as good or excellent.
- 100% of patients rated the friendliness and helpfulness of the catering team as good or excellent.
- 100% of patients said they were recommend the service fully or for specific treatments.

Ahead of our inspection we asked the service to make CQC comment cards available for patients, or the parents of young patients, to provide feedback. The service did not have access to the completed comment cards. We received 41 completed cards, all of which referred to the kindness, compassion and respect of staff. Some people noted they had used the service for several years and found the way in which staff treated them to have been consistently positive. Where parents completed feedback on behalf of their child, they noted in each case how happy they were with the friendliness of staff towards them. This included where a child was afraid of needles and nurses always took the time to make them feel safe and less vulnerable.

Involvement in decisions about care and treatment

Of the 41 patient comment cards we received, each patient that mentioned interactions with the medical team (27 in total), noted they always included them in discussions about treatment plans. Patients said doctors provided a clear rationale for their treatment as well as outlining expectations and potential side-effects. Where patients had received long-term treatment, they said staff kept them up to date continually with regards to progress or potential changes.

In the 2017 patient satisfaction survey and first visit satisfaction survey:

- 96% of patients rated the explanation of procedures they received from staff as good or excellent.
- 99% of patients rated the way their course of treatment was explained as good or excellent.
- 94% of patients rated the way the expected outcome was explained as good or excellent.
- 98% of patients rated the way their questions were answered as good or excellent.
- 93% of patients felt they were provided with sufficient and appropriate information to make informed choices about their care and treatment.
- 98% of patients said clinical staff were good at keeping them informed.
- 97% of patients felt they were given individual attention, including when asking questions.
- 98% of patients rated the information given for their aftercare as good or excellent.
- 88% of patients said they felt appropriately involved in decisions about their care and treatment and a further 9% said this was true to some extent.
- 94% of patients said the purposes of their medicines to take home were explained in a way they could understand.
- 93% of patients said they were told who to contact if they had questions about their aftercare.

It was evident from our observations of care and discussions with staff that patients were given time to ask questions and opportunities to discuss their concerns.

Patient satisfaction surveys were printed in Italian, German and French to ensure all patients who used the service had the opportunity to provide feedback. The service had also prepared a satisfaction survey adapted for children with pictures to help them provide information on how they felt.

Privacy and Dignity

A significant theme in the comment cards we received related to positive comments about privacy and dignity. 37 patients noted they always felt treated with dignity and that all the staff they interacted with demonstrated a clear understanding of privacy.

In the 2017 patient satisfaction survey and first visit satisfaction survey 99% of patients said they were treated with dignity and respect.

Are services caring?

An up to date privacy, dignity, sex and sexuality policy was in place that enabled patients to choose if they preferred a female or male doctor and nurse and enabled to request a side room for treatment instead of the main wards.

Are services responsive to people's needs?

(for example, to feedback?)

Our findings

Responding to and meeting people's needs

Posters in waiting and dining areas provided an introduction to the role of each team and department, including photographs and role descriptions

In the 2017 patient satisfaction and first visitor satisfaction surveys 92% of patients said their needs and preferences were fully met and 8% said their needs were almost fully met.

Patients were responsible for paying for their own interpreter or translation services and staff could arrange this on request. Where clinicians felt a patient could not fully understand their planned treatment due to a language barrier, they ensured an interpreter was booked before proceeding further with the treatment plan.

The clinical team had a demonstrable interest in research and the latest health population and epidemiological data available. They maintained an international context and incorporated clinical research outcomes from specialist centres globally to ensure patients were offered the latest available treatments. The service provided reviews and treatment for patients who had often exhausted treatment plans elsewhere, including with their GP or NHS consultant. This meant clinicians worked with the in-house researcher to identify potential new strategies for the service's population. For example, the clinical team recognised a lack of understanding in the signs, symptoms and treatment of Lyme disease and had completed two papers for publication that provided new insight into effective condition management.

Staff prepared printed information for patients on care and treatment bundles they provided, including for health promotion purposes such as smoking cessation. Information was detailed and easy to follow and included specific guidance to help people get the most out of their plan. For example, the weight enhancement programme included specific diet advice such as the best type of cooking oil to use and the temperature at which it should be used for maximum effect.

The service had a nearby guest house for patients who travelled long distances. This meant patients could stay locally during lengthy courses of treatment to reduce the pressure and stress of daily travel.

Staff maintained a website that included clinical and medical guidance for patients. However, it was not evident this information was always evidence-based. For example, the website made specific claims about the causes of conditions such as migraine and osteoporosis without references to the source of the claims. Staff told us the in-house researcher was not involved in preparing the information posted on the website, which meant we were not assured the information was accurate nor that it offered patients the ability to consider alternatives.

The clinical team used the low-dose immunotherapy protocol to develop highly specialised antigens for each patient's specific allergy or sensitivity. Each antigen strength was individualised for the specific patient and staff ensured there were no indications of side effects or unwanted symptoms before patients were discharged with the medicine. Nurses ensured patients understood how to self-administer the medicine before discharge, including by observing the patient administer to ensure they understood.

All clinical areas and toilets were accessible by wheelchair or by patients with reduced mobility and there were baby-changing facilities on site.

A children's play area with wipe-clean toys was available in the waiting area for the childhood immunisation service and staff used this as a distraction technique for children nervous about treatment.

The service provided whole-body hypothermic iratherm treatment for chronic fatigue syndrome. This was a unique service in the UK and the service had the only equipment in the country used for this purpose. Registered nurses with up to date competency assessments carried out this treatment in line with guidance resulting from research on this treatment.

Staff planned all elements of the service to avoid allergic or sensitivity reactions for patients. For example, the service treated some patients who were allergic to plastic. As a result, staff reduced the use of plastic in the environment, such as by importing glass intravenous bottles to avoid the use of standard plastic bottles used in the UK.

The service was equipped to provide services to patients living with a learning disability included resources to help with communication. This included where children or young people with a learning disability attended for immunization or allergy screening.

Are services responsive to people's needs?

(for example, to feedback?)

Staff demonstrated an understanding of the needs of the local population and how this might affect clinical presentation and individual need. For example, there was a significant public health concern with recreational drug use and dependency in the local area. Where staff were aware of these issues they managed prescriptions and treatment plans appropriately, such as if a patient needed weaning from multiple medicines used for pain management.

Nutritionists maintained a patient information display board in the dining room and waiting area. This included newspaper articles on nutrition-related conditions, research articles in easy-read format and guidance on the nutritional content of common food.

The dining room was equipped with a reverse osmosis filtration water tap and a ceramic filter water tap. Both were clearly signed with information about the specific benefits of using them.

Timely access to the service

The senior team monitored patient satisfaction with access through an on-going patient satisfaction and first visit satisfaction survey. In 2017 96% of patients rated the promptness of their appointment as good or excellent and 4% rated this as fair. In the same period 90% of patients said their most recent phone call to the service had been answered in a timely fashion and 91% of patients said the same for their most recent e-mail. 95% of patients said their treatments were performed on time. 88% of patients said they were advised when and how to book their next appointment.

The patient liaison team led a system to ensure a named member of staff was responsible for acting on pathology results on the day they were received, including when the doctor who ordered the tests was not on site. This meant doctor's instructions were acted on and patients informed as soon as test results were available.

Each clinician scheduled their services based on demand and patient need, which meant some clinicians were in the clinic only on occasion. A system was in place to ensure patients received continuity of care whenever they visited the clinic. This meant doctors could refer patients to each other based on their own specialties and patients could be seen without delay if other clinicians could safely treat them.

The service had a dedicated room for digital video conferences and patient consultations. This enabled patients who lived outside of the local area, including those outside of the UK, to virtually attend reviews and meetings. This reduced the need for patients to travel long distances when they were not due to undergo treatment.

Listening and learning from concerns and complaints

There was a formal complaints policy in place and this was displayed in the clinic and available on the website.

The quality assurance manager was responsible for investigating and resolving complaints and the patient liaison team identified areas for improvement as a result of patient feedback. As part of the service's ethos of positivity the senior team referred to complaints as feedback and the quality manager liaised with each complainant individually to resolve the issue.

The quality manager had acted on feedback given as part of complaints by introducing additional staff training and reviewing policies. For example, one patient provided negative feedback about the style of communication from a specific doctor. The manager worked with the doctor who undertook a communications skills training course.

Staff understood patients had high expectations of the treatment and service as a result of paying themselves. The quality manager was responsible for liaising with patients and clinical teams to manage the service in line with expectations.

Are services well-led?

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

Our findings

Leadership capacity and capability

The medical director and chief operating officer maintained overall responsibility for the service with support from the service manager and quality manager. A nurse manager led the nursing team and a clinical nurse manager led the maintenance of policies, procedures and documentation. All the staff we spoke with said they felt the hierarchy of the organisation was 'flat', which meant they felt they could work free from the influence of internal politics.

The senior team demonstrated a leadership approach that prioritised patient care, experience and outcomes as part of the overriding ethics of the business. For example, where staff became concerned one patient was vulnerable and unable to afford treatment, they contacted the patient's GP and made joint decisions in their best interest.

Vision and strategy

A new vision and strategy had recently been implemented and staff told us they had all contributed to this to ensure it reflected their ethos and approach of patient-centred, research-driven unique care. The key priorities in the new strategy were quality and sustainability and each member of staff we spoke with spoke confidently about their role in this. Increased dissemination of the specialist work the service provided a was a key element of the new strategy and the senior team planned to increase medical professional training and social media engagement to achieve this.

The service was demonstrably structured to provide high quality care and treatment to patients with a special focus on those who had exhausted options with other providers. The quality manager said their role was to make sure every patient felt looked after and listened to and this was a core element of the service.

Culture

The senior team actively promoted a culture of openness and honesty, including in line with the Duty of Candour. This meant patients were treated by a team of staff who valued and promoted learning from mistakes or unpredictable events and shared outcomes and learning.

The culture of the organisation was driven by a staff team who said they found the work very rewarding. For example, some patients had moved home to live closer to the clinic when they had experienced a significant improvement in their quality of life with on-going treatment. Staff said patients often presented to the service feeling despondent after long periods of no improvement in their condition after treatment plans in more traditional medical services.

Staff told us they felt part of the organisation and respected by the senior team. They said they were able to offer feedback, ideas for improvement and requests for future development. For example, the senior team had arranged training on the management of allergies to mould as a result of feedback from staff.

There was a clear safety culture in place that staff adhered to as a priority. Staff told us patients often requested care or treatment that would breach safety or ethical rules but they always declined this and offered safer alternatives.

Governance arrangements

Policies and procedures were kept in the clinic in hard copy and online with electronic access. We looked at a sample of policies in both hard copy and electronic form and found they were up to date with trackable review dates for auditing

The service no longer provided credit accounts to patients for treatment. This change of policy was implemented to protect the service financially and to reduce the risk of patients experiencing negative health outcomes from financial stress and pressure. This was a governance-led decision based on previous incidents whereby patients experienced significant levels of debt by relying on the service's credit.

Staff who participated in research were required to demonstrate ethics approval from an appropriate organisation and were required to obtain documented consent from patients before using their information for research purposes.

Staff adhered to a data management policy that meant patient records were securely destroyed 10 years after the last patient contact.

The clinical care manager held three-monthly infection control meetings with the infection control lead and a member of staff from each department.

Are services well-led?

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

Regular infection control audits were in place but it was not evident that they reflected good clinical governance. For example, in one audit staff had scored clinical areas as completely free from dust and then noted in the comments section they found one bedframe with dust on it. Two audits noted that a bin in a consultation room had no hands-free opening mechanism but the action plan was blank for both. In addition, an audit from March 2017 noted a chair needed to be repaired. The audit did not identify the chair or where it was located and there was no documented evidence that it had been repaired.

Managing risks, issues and performance

The senior team tracked the annual performance of the service as reported in patient satisfaction surveys from year to year and used the results to identify improvements over time. For example, patient-rated communication with staff improved by 66% between 2014 and 2017 for measures relating to staff coordination and responsiveness to e-mails and letters. There was a 21% increase in the percentage of patients noting their needs and preferences had been fully met between 2016 and 2017. In the same period there was a 23% improvement in the percentage of patients who said they were told who to contact if they had questions about their aftercare. As part of the performance and quality monitoring processes staff monitored patient perception of changes over time in the satisfaction surveys. In 2017 amongst patients who had visited the clinic at least once before, 47% said the service was getting better and 52% said it had stayed the same.

Hard copy medical records were stored in a locked area with restricted access. However, records were not stored in fire-proof cabinets, which meant there was a significant risk of loss in the event of a fire. This meant the service did not fully meet the records storage standards set by the General Medical Council.

Appropriate and accurate information

Clinical staff were not involved in pricing or estimating treatment plans, which the patient liaison team prepared. This ensured there was no conflict of interest between medical need and the financial operation of the service. Where patients queried costs the patient liaison team worked with the clinical team to identify the procedures, tests or investigations they considered to be the highest priority. This meant patients with financial constraints or concerns could make the best decisions about their care based on a balance of accurate clinical and pricing information.

The senior team monitored how patients felt about the information given to them and communication with them in the patient satisfaction and first visitor satisfaction surveys. In the 2017 survey 95% of patients said the explanation and presentation of costs was good or excellent and 96% of patients said staff were good or excellent at answering their questions. 84% of patients felt staff had communicated with each other effectively about their tests and treatment.

Prior to discharge staff provided each patient with a summary of the treatment they had received along with details of what is was for and what they could expect next.

Engagement with patients, the public, staff and external partners

The senior team monitored patient satisfaction through a rolling patient satisfaction survey and a first visit satisfaction survey. The team carried out a full analysis of the results on an annual basis and published their findings for reference by current patients, those considering treatment in the clinic and for staff reference and training purposes.

Staff were engaging with external partners to increase local knowledge of their services and to identify future professionals to train in environmental medicine. This was part of the services' future sustainability strategy and included liaising with training professionals in medical schools.

The quality manager had a professional background in customer service and was dedicated to ensuring patients had a positive experience in the service. They worked with all departments to embed patient-centred approach to care, which we saw evidence of through our observations and comments made by patients.

Continuous improvement and innovation

A full-time researcher and librarian, who had previous experience with the British Medical Library, worked in the service and maintained a comprehensive research library.

The service provided opportunities for trainee nutritionists to spend time shadowing permanent staff and to develop

Are services well-led?

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

their skills and career plans. This had resulted in permanent recruitment to a nutritionist post, which demonstrated the team's approach to sustainability and opportunities for trainees.

Staff recognised several patients who had experienced a significantly improved quality of life following innovative treatment they had delivered after the patient was discharged from their main service. For example, they had treated one patient for a severe allergy that had paralysed them and rendered them unable to compete in sports important to them. The service's approach to treatment resulted in improved mobility to the extent the patient recovered their physical ability and secured a job in a sports-related field.

The senior team maintained continual targeted surveillance of media coverage of conditions such as chronic fatigue and Lyme disease. This helped them to predict when queries for treatment would increase and enabled them to prepare evidence-based treatment plans that addressed the key points made by the media.