

Miscarriage Clinic Limited

The Centre for Reproductive Immunology and Pregnancy

Inspection report

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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?	Good	
Are services effective?	Inspected but not rated	
Are services caring?	Good	
Are services responsive to people's needs?	Good	
Are services well-led?	Good	

Summary of findings

Overall summary

We rated it as good because:

- The service had enough staff to care for patients and keep them safe. Staff assessed risks to patients, acted on them and kept good care records. The service managed safety incidents well and learned lessons from them.
- Staff followed COVID-19 guidelines and there was alcohol hand gel available for staff and patients throughout the clinic. On entry all visitors were asked questions relating to their current health and had their temperature taken to detect any signs of infection. All visitors were asked to use the alcohol hand gel.
- The clinic had a service level agreement with an infection prevention and control lead nurse from a local NHS trust to complete a yearly audit, and to provide staff with training specific to the clinic.
- Staff provided good care and treatment and gave patients pain relief when they needed it.
- Staff worked well together for the benefit of patients, advised them on how to lead healthier lives, supported them to make decisions about their care, and made sure patients had access to good information.
- Staff treated patients with compassion and kindness, respected their privacy and dignity, took account of their individual needs, and helped them understand their conditions. They provided emotional support to patients, families and carers.
- The service's website had a wealth of resources and signposted patients to information about fertility treatment and how to best support their health and wellbeing whilst undergoing treatment.
- Staff monitored waiting times and made sure patients could access emergency services when needed. In the unfortunate instance of a miscarriage being diagnosed, staff offered a quiet place for patients to have some time with a midwife to discuss their options. This included an offer of surgery, if chosen as treatment, within 48 hours from diagnosis to procedure with results and a follow up appointment within four weeks.
- Staff made sure patients with mental health issues received the necessary care to meet all their needs. All patients were reviewed by their consultant during the initial appointment and if identified as necessary, they were referred for counselling or to their GP before progressing with treatment.
- The service planned care to meet the needs of local people, took account of patients' individual needs, and made it easy for people to give feedback. People could access the service when they needed it and did not have to wait long for treatment.
- Leaders ran services well using reliable information systems and supported staff to develop their skills. Staff understood the service's vision and values, and how to apply them in their work. Staff felt respected, supported and valued. They were focused on the needs of patients receiving care. Staff were clear about their roles and accountabilities. The service engaged well with patients and staff to plan and manage services and all staff were committed to improving services continually.
- All members of the leadership team had extensive experience in their area of interest and had previously worked, or continued to work, within the NHS as well as at the clinic.
- There was a strong emphasis on staff wellbeing. Staff had access to wellbeing support and the leadership team arranged two virtual mental health and wellbeing sessions with an external provider during the COVID-19 pandemic. Staff reported this had been helpful to manage their work and personal lives.

However:

- The clinic did not routinely audit the effectiveness of care and treatment provided.
- The clinic did not formally audit the quality of the ultrasound images and reports undertaken.

Summary of findings

Our judgements about each of the main services

Service Rating Summary of each main service

Diagnostic and screening services

Good



We rated this department as good because it provided a safe, caring, responsive and well led service. We do not rate effective.

Summary of findings

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Summary of this inspection

Background to The Centre for Reproductive Immunology and Pregnancy

The Centre for Reproductive Immunology and Pregnancy located in Epsom, is an independent service operated by Miscarriage Clinic Limited. The service offers women's health support such as pregnancy care and delivery, prenatal testing and baby scans, management of hyperemesis gravidarum (excessive nausea and vomiting), general gynaecology and complimentary therapies. The service provides these services to people over 18-years-old.

The Centre for Reproductive Immunology and Pregnancy has been registered with CQC since July 2015 but has never been inspected previously. The service has had a CQC registered manager since registration and the current manager has been in post since 2016.

The service is registered to provide the following regulated activities:

- Diagnostics and screening procedures.
- Surgical procedures
- Treatment of disease, disorder or injury

Track record on safety (February 2021 to January 2022):

- No never events
- No serious incidents
- No incidences of healthcare acquired infection

How we carried out this inspection

We inspected this service using our comprehensive inspection methodology. We carried out the inspection on 19 January 2022. We spoke with two patients and seven staff. We reviewed seven patient's records. We reviewed patient feedback from the previous 12 months.

You can find information about how we carry out our inspections on our website: https://www.cqc.org.uk/what-we-do/how-we-do-our-job/what-we-do-inspection.

Outstanding practice

We found the following outstanding practice:

• There was a clear pathway for fetal defects identified during patient scans. Information regarding treatment and a management plan were discussed with patients. The clinic would ascertain the patient's NHS provider and a copy of the report was sent to the fetal medicines team for awareness, support and further management of the patient during the pregnancy.

Summary of this inspection

- The clinic offered an inclusive service focussing on providing all aspects of care for patients such as consultations, scans, blood tests, treatment infusions, theatre procedures, recovery care and follow up. This meant patients received continuity of care while under the care of the clinic.
- The clinic, with consent, arranged for patients who had been with the clinic for some time to support other patients. Patients who were about to experience the same treatment or procedures shared their experiences and gained support from each other.
- The medical director had designed a mobile application to improve the overall patient experience and give patients the ability to view their treatment plan, track progress, receive reminders of medication to take and when to take it, as well as being able to book appointments with the clinic.
- Education was an integral part of the culture at the clinic. The medical director had made significant contributions to research into the diagnosis and treatment of miscarriages in national papers and international publications.
- The clinic was one of a few miscarriage services applying hyaluronic acid gel in the uterus following a surgical procedure to reduce the risk of scar tissue build-up which can have a further impact on fertility.

Areas for improvement

Action the service MUST take is necessary to comply with its legal obligations. Action a service SHOULD take is because it was not doing something required by a regulation, but it would be disproportionate to find a breach of the regulation overall, to prevent it failing to comply with legal requirements in future, or to improve services.

Action the service SHOULD take to improve:

Diagnostic imaging

- The clinic should ensure that they develop patient outcome auditing to review the effectiveness of care and treatment Regulation 17(3).
- The clinic should consider formally auditing the quality of the images and reports completed in line with national guidance.

Our findings

Overview of ratings

Our ratings for this location are:

D'	1	
Diagnostic	and	screening
services		

Overall

Safe	Effective	Caring	Responsive	Well-led	Overall
Good	Inspected but not rated	Good	Good	Good	Good
Good	Inspected but not rated	Good	Good	Good	Good



Are Diagnostic and screening services safe?

Good



We rated it as good.

Mandatory training

The service provided mandatory training in key skills to all staff and made sure everyone completed it.

Staff received and kept up to date with their mandatory training. The mandatory training was comprehensive and included health and safety, infection, prevention and control (IPC), information governance, fire safety, equality and diversity, manual handling and basic life support. All staff had completed a one-day training session conducted externally by a third-party service.

Managers monitored mandatory training through a training matrix and alerted staff when they needed to update their training.

Medical staff with practising privileges received, and kept up to date with, mandatory training. The training was provided by the NHS and was monitored by the clinic.

Clinical staff completed training on recognising and responding to patients with mental health needs, learning disabilities, autism and dementia. Specific training was incorporated within safeguarding training.

Safeguarding

Staff understood how to protect patients from abuse and the service worked well with other agencies to do so. Staff had training on how to recognise and report abuse and they knew how to apply it.

All clinical staff received training specific for their role on how to recognise and report abuse. Staff had completed children and adult safeguarding to level 2, while medical staff were trained to level 3 in both adult and children's safeguarding.



Staff knew how to make a safeguarding referral and who to inform if they had concerns. The resident doctor was the safeguarding lead and had safeguarding adults and children level 3 training. This was in line with the intercollegiate guidance. There was an up to date adults at risk policy as well as a safeguarding flow chart which showed what process to follow when making a safeguarding referral. All staff knew how to access the information.

Female genital mutilation (FGM) and sexual exploitation were provided as part of the service's all-in-one day mandatory training under safeguarding. Staff felt confident to speak with patients about FGM and knew how to report it.

In addition, the medical director had developed an FGM advocacy training toolkit for the Royal College of Obstetricians and Gynaecologists.

Staff could give examples of how to protect patients from harassment and discrimination, including those with protected characteristics under the Equality Act.

Staff knew how to identify adults and children at risk of, or suffering, significant harm and worked with other agencies to protect them. Children and babies were not able to attend the clinic with patients since the COVID-19 pandemic.

Cleanliness, infection control and hygiene

The service-controlled infection risk well. Staff used equipment and control measures to protect patients, themselves and others from infection. They kept equipment and the premises visibly clean.

Clinical areas were clean and had suitable furnishings which were clean and well-maintained.

The clinic employed a cleaning company who attended daily to manage general cleaning. Cleaning records were maintained daily, were up-to-date and demonstrated that all areas were cleaned regularly.

An audit of clinical areas was carried-out every two weeks and an environmental cleaning audit was completed monthly to ensure continued compliance.

Staff followed COVID-19 guidelines and there was alcohol hand gel available for staff and patients throughout the clinic. On entry all visitors were asked questions relating to their current health and had their temperature taken to detect any signs of infection. All visitors were asked to use the alcohol hand gel.

Staff followed infection control principles including the use of personal protective equipment. Clinical staff wore scrubs and were bare below the elbows. Staff wore face masks at all times, and we saw regular cleaning of hands and applying of alcohol hand gel.

Clinical rooms were equipped with different sized gloves as well as aprons and masks. Staff followed the recommended hand washing technique and we saw hand washing posters displayed on the walls.

Clinical staff completed yearly infection, prevention and control training. The clinic had a service level agreement with an IPC lead nurse from a local NHS trust to complete a yearly audit and to provide staff with training specific to the clinic. The last audit had been carried out in March 2021 and the service had achieved an overall score of 94%.



Staff cleaned equipment after patient contact and labelled equipment to show when it was last cleaned. The clinic had two hysteroscopes for procedures. Transvaginal probes were cleaned with the appropriate wipes following each procedure. We saw staff attach the hysteroscope sterilisation label in the procedure book identifying which scope was used.

Environment and equipment

The design, maintenance and use of facilities, premises and equipment kept people safe. Staff were trained to use them. Staff managed clinical waste well.

The service had suitable facilities to meet the needs of patients' families. Patients accessed the clinic via an intercom system at the front door. For security reasons, closed-circuit television was located in communal and outside areas.

The reception was located on the first floor along with two consulting rooms, a procedure room, a patient suite, a reception area and a patient waiting room. On the top floor was the toilet and sluice room, a clinical staff office, the registered manager's office and an administration team room.

As patients entered the building there were steps up to the main clinic. A lift and ramp were available for wheelchair users to access the main clinic. A disabled toilet was near to the lift with a curtain which provided privacy.

The waiting room was spacious, and the seating arrangement allowed for social distancing. The rooms were easily accessible with clear signage on doors. Each consultation room had a computer and was able to provide remote patient consultations.

Hand-sanitising gel was available throughout the service. The sinks had elbow operated taps. This was in accordance with the *Health Building Note 00-09: Infection control in the built environment.*

Patients completed a COVID-19 questionnaire and reception staff took patients' temperatures before guiding them into the waiting room next door.

Emergency equipment was available in the treatment area and an additional emergency grab bag locked away in a cupboard in reception. We checked the resuscitation trolley and found all equipment and emergency medicines were in date. The records we viewed identified that checks were carried out daily by the nursing staff.

An emergency grab bag and defibrillator were kept in an accessible cupboard in the reception area. This was checked daily.

The service had enough suitable equipment to help staff safely care for patients. Staff carried out daily safety checks of specialist equipment. The ultrasound machines and hysteroscopes were checked daily, which included portable equipment testing.

Staff disposed of clinical waste safely. Clinical and waste bins were labelled, and we saw they were used correctly. Sharps bins were dated, signed and changed every three months in line with national guidance. Large clinical waste storage bins were housed at the back of the building and this storage area was not accessible to the public.

The service had a clinical waste removal contract with an external company. The contractor collected the clinical waste weekly.



Staff took bloods in clinical areas and labelled the bottle with the patient details. A courier collected the bloods and sent them to the laboratory for testing. Urgent blood results were immediately given to the consultant for review.

Assessing and responding to patient risk

Staff completed and updated risk assessments for each patient and removed or minimised risks. Staff identified and quickly acted upon patients at risk of deterioration.

Staff completed risk assessments for each patient on arrival, using a recognised tool. They reviewed this regularly and after any incident.

Patients received a comprehensive assessment including a COVID-19 risk assessment during the initial patient consultation. Individual risks were assessed, and advice given. Staff shared key information to keep patients safe.

Staff communicated information clearly to each other and followed the World Health Organisation surgical safety checklist in the treatment area.

All staff completed a COVID-19 risk assessment. The assessment included health and psychological factors as well as a section for discussion on how the clinic could support them.

Staff knew about and dealt with any specific risk issues. All patients who began a treatment plan of steroids were given a steroid care card to alert medical staff in the event of an emergency, as per NHS guidance.

Staff responded promptly to any sudden deterioration in a patient's health. We looked at three incident reports. We saw one incident where a patient felt faint and unwell during a procedure. A consultant was present and further staff were called to support immediately. The right treatment was provided, and paramedics were called and attended the clinic. Regular observations commenced and the patient was regularly monitored until they felt well.

Patients were advised to continue their antenatal care at 16 weeks of pregnancy with their NHS midwifery teams. Patients received copies of all reports, scans and treatment so this information could be shared at their NHS hospital appointments or with their GP.

There was a clear pathway for fetal defects identified during patient scans. Information regarding treatment and management plans would be discussed with patients. The clinic would identify the patients local NHS provider and a copy of the report was sent to the fetal medicines team for awareness, support and further management of the patient during the pregnancy. If there were further major concerns identified during the patient's examination, the clinic would contact the fetal medicine consultant and complete a handover of findings.

Staffing

The service had enough staff with the right qualifications, skills, training and experience to keep patients safe from avoidable harm and to provide the right care and treatment. Managers regularly reviewed and adjusted staffing levels and skill mix and gave staff a full induction.

The service had enough nursing and support staff to keep patients safe. The service was fully staffed, and the registered manager could adjust staffing levels according to the needs of the clinic. On the day of the inspection, there were sufficient staff to manage the planned activities.



The service had a low staff turnover rate, with most staff having worked at the service for several years. Annual leave and sickness were covered in-house by permanent staff and the service did not employ agency clinical staff.

Medical staffing

The service had enough medical staff with the right qualifications, skills, training and experience to keep patients safe from avoidable harm and to provide the right care and treatment. Managers regularly reviewed and adjusted staffing levels and skill mix and gave staff a full induction.

The service had enough medical staff to keep patients safe. The medical team consisted of consultants who held the appropriate qualifications and experience within gynaecology, obstetrics, urology, radiology and anaesthetics. On the day of inspection, there were two clinics, one in the morning and the other in the afternoon. One employed gynaecologist specialist doctor ran the morning clinic and the afternoon clinic was led by the medical director. The clinic had appointed a clinic resident doctor with extensive miscarriage experience to support patients during their patient journey

All consultants had current practising privileges and held clinics within the NHS.

The service had low turnover rates for medical staff and did not use locums.

Records

Staff kept detailed records of patients' care and treatment. Records were clear, up to date, stored securely and easily available to all staff providing care.

Patient notes were comprehensive, and all staff could access them easily. All records were paper records and were stored securely in locked cupboards. All staff had completed information governance and data protection training as part of their mandatory training.

Computers were password protected and staff signed out when they were away from their desk.

We viewed seven sets of patient records all of which followed the same comprehensive format. Completed records included a medical history sheet, health screening, a treatment plan and consent forms. We saw evidence of hospital and clinic reports being received. There was also a section for consent forms and treatment plans for a patient's partner if required.

All communication with patients whether telephone calls, examinations or consultations were documented clearly in the records.

Information we reviewed within the records showed a clear timeline of treatment and communication, as well as a clear discharge plan.

Medicines

The service used systems and processes to safely prescribe, administer, record and store medicines.

Staff followed systems and processes to prescribe and administer medicines safely. The clinic had a comprehensive medicines policy which staff knew how to access.



Staff completed medicines records accurately and kept them up to date. Staff were aware of their professional responsibilities of safe management of medicines and clear documentation.

Medicines prescribed or given during procedures were clearly documented on a paper administration record and signed by a clinician.

A medicines management audit was completed every three months. The most recent audit showed the clinic was 100% compliant in the storage and management of medicines.

The clinic had a service level agreement with a pharmacist within a local independent hospital which included an advisory service with the pharmacist. The advisory service included guidance on issues relating to updates and advice on medicines storage as well as completing the medicines management audit. The pharmacist was also responsible for providing the quality control of medicines.

The controlled drugs medicines license was displayed in the clinic but had expired in August 2021. The registered manager told us a renewal application had been completed prior to the license expiring. However, there was a current delay in the drug licensing agency processing applications. We were given emails from the drug licensing agency which confirmed the information and had advised the clinic they could continue to undertake activities under the previous issued drug license.

Staff stored and managed all medicines and prescribing documents safely. The service had a system to check medicines cupboards and the fridge. We viewed the records and found they were completed correctly, and all medicines were in date. The medicines fridge had an integrated lock and was kept in the reception area. Fridge temperature checklists were checked daily and monitoring systems provided assurance that fridge temperatures were within the recommended temperature ranges.

The senior staff in charge for that day were responsible for the keys to the controlled drugs cupboard, medicines cupboards and fridge.

Staff followed national practice to check patients had the correct medicines when they were receiving treatment within the clinic or for any medications to be taken home.

Staff learned from safety alerts and incidents to improve practice. Staff we spoke with confirmed that they received medical safety alerts and learning from medicine incidents.

Incidents

The service managed patient safety incidents well. Staff recognised incidents and near misses and reported them as required. Managers investigated incidents and shared lessons learned with the whole team and the wider service. When things went wrong, staff apologised and gave patients honest information and suitable support.

Staff knew what incidents to report and how to report them. Staff raised concerns and reported incidents and near misses in line with provider policy. Incidents were reported on the incident log which all staff had access to. The incident log was reviewed as part of the quality assurance audits, was discussed at the clinical governance meetings and reported in the bi-annual exception report.

There were 17 incidents reported from January 2021 to November 2021 and these were reported in the incident log.



Staff understood duty of candour and were open and transparent. The incidents we reviewed showed that information and a full explanation were given to patients. For example, a patient attended a clinic for bloods on three separate occasions and on each occasion either the bloods had not been processed or the wrong bottle had been used. Guidance was followed and information was shared with the patient. The provider also changed the time of day patients were seen to have bloods taken to stop these incidents from occurring again.

Managers debriefed and supported staff after any incident. Staff received feedback around key issues of risks and outcomes of investigations during team meetings.

Incidents were reviewed to identify any gaps in staff learning. The clinic had recently appointed a clinical services manager who had oversight and management of the clinical team. The clinical services manager shared key learning from incidents so that continual learning could be incorporated into practice. For example, specific learning from an incident around a collapsed patient was incorporated into advanced life-support training to all clinical and medical staff.

Are Diagnostic and screening services effective?

Inspected but not rated



We do not rate effective for diagnostic imaging services.

Evidence-based care and treatment

The service provided care and treatment based on national guidance and evidence-based practice. Managers checked to make sure staff followed guidance.

Staff followed up-to-date policies to plan and deliver high quality care according to best practice and national guidance. Policies were available electronically to support good practice.

We saw examples of policies and procedures staff used to support their work; these referenced national guidance from institutes such as the British Thoracic Society, The Academy of Medical Royal Colleges and Royal College of Obstetricians and Gynaecologists.

Changes in national guidance was communicated to staff through the regular staff huddles and by email. All staff were involved in reviewing policies and procedures due for review however, the clinical manager and registered manager were responsible for overseeing any changes or updates of policies to ensure they were in line with national guidance and embedded into practice effectively.

Nutrition and hydration

Staff offered refreshments to patients following their procedures if it was safe to do so. Patients and visitors had access to drinking water in the waiting room.

The clinic managed patients with hyperemesis gravidarum. Staff closely monitored patients diagnosed with this condition and prescribed anti-sickness medication and steroids as necessary.



Pain relief

Staff assessed and monitored patients regularly to see if they were in pain and gave pain relief in a timely way.

Pain relief was discussed with patients as part of their pre-operative assessment and following a surgical procedure. Staff prescribed, administered and recorded pain relief accurately. We saw pain relief was documented in the patient records.

All patients undergoing manual vacuum aspiration and hysteroscopy procedures were offered intravenous sedation. When intravenous sedation was used an anaesthetist was always present and responsible for its administration and the monitoring of patients under conscious sedation throughout the procedure.

Patients were advised verbally, and provided with written information, to contact the clinic immediately if they experienced excessive pain.

Patient outcomes

Staff used the findings to make improvements for patients.

Managers and staff carried out a programme of audits to check improvement over time. There was an audit schedule that detailed routine audits the service undertook throughout the year. Audits undertaken included the World Health Organisation surgical safety checklist, infection control and medicines management.

Managers used information from audits to improve care and treatment. Managers shared results and made sure staff understood information from the audits. The manager explained staff were involved in drawing up action plans if improvement was required.

Managers and staff used the results to improve patient' outcomes. The registered manager told us that the quality of the service was demonstrated by the number of re-visits, patient reviews and word of mouth recommendations that were made about the service. The resident doctor and data analyst collected data on the number of successful pregnancies for example, but detailed analysis of data on patient outcomes was in its infancy. The clinic's leaders had recently appointed a data analyst to turn this data into meaningful information that could be routinely monitored for its effectiveness and drive improvements.

The service did not participate in any national audits as there were no audits relevant to the services provided. Furthermore, the service did not routinely monitor the quality of images and reports produced in line with national guidance. The British Medical Ultrasound Society and Royal College of Radiologists recommended that services should aim to review five percent of all examinations and reports. This meant that there were limited opportunities to identify poor ultrasound scanning, reporting and the sharing of learning from any discrepancies.

The clinic had not engaged with the Private Healthcare Information Network (PHIN). PHIN is intended to improve the availability of information to patients for private healthcare services, making the information comparable with that which is already available for the NHS.

Competent staff

The service made sure staff were competent for their roles. Managers appraised staff's work performance to provide support and development.



Managers gave all new staff including bank staff a full induction tailored to their role when they started working for the service. This included mandatory, on the job and developmental training.

Staff were experienced, qualified and had the right skills and knowledge to meet the needs of patients. Pre-employment checks of all staff employed by the service were undertaken to ensure they were competent for the role they would undertake. We reviewed seven staff files including those of administrative, nursing and medical staff. Staff files included photographic identification, training records, immunisation status, a disclosure and barring service check, professional references, insurance, evidence of revalidation and professional registration.

Clinical staff had undertaken higher educational training to undertake their role. These staff were registered with the Nursing and Midwifery Council and the General Medical Council which required them to agree to a code of professional conduct to maintain registration. Records of these were up to date with the date of revalidation recorded.

Managers supported staff to develop through annual, constructive appraisals of their work. All staff had received an appraisal within the last 12 months. Staff told us that there were opportunities for further training and that they were given time to enhance their skills. They were encouraged to seek out courses and gain qualifications and saw some staff had taken this up to assist them in their roles and careers.

Multidisciplinary working

Doctors, nurses and other healthcare professionals worked together as a team to benefit patients. They supported each other to provide good care.

Administrative and clinical staff spoke positively about their working relationships. Staff felt there were no barriers between professionals. Nurses told us they were able to contact medical staff easily and administrative staff said during busy periods they could seek help from clinical staff.

Staff held regular and effective multidisciplinary meetings to discuss patients and ensure they had a positive patient experience.

Staff worked together with other providers, when required. For example, the clinic had close working connections with other NHS services and referred patients upon discharge or if patients wished to have other treatments or procedures elsewhere. Staff ensured there was effective communication when handing over care to other providers and shared any records of care provided while under the care of the clinic.

Staff supported patients when they were referred or transferred between services. Staff told us that when advice was sought from other professionals, patients would be given the relevant contact details to make further appointments.

Patients saw all the health professionals involved in their care at one-stop clinics. For example, patients attending could see a consultant as part of their scheduled reviews, a midwife for intralipid infusion and a complementary therapist in one visit.

Seven-day services

Key services were available to support timely patient care.

The service was open Monday to Friday, from 8am to 6pm. Outside of these hours an on-call registered midwife was available to support patients between 6am and 9pm and between the same hours on Saturday and Sunday. Staff could call for support from doctors and other disciplines, including mental health services and diagnostic tests.



Health promotion

Staff gave patients practical support and advice to lead healthier lives.

Staff assessed each patient's health prior to starting treatment and provided support for any individual needs to live a healthier lifestyle. Each patient was asked to complete a pre-appointment history sheet giving in-depth details of their health status, gynaecological, medical and family histories as part of their pre assessment. This was to ensure patients were placed on the most suitable patient pathway and offered the appropriate support.

Staff assessed each patient's health at every appointment and provided support for any individual needs to live a healthier lifestyle.

The service had relevant information promoting healthy lifestyles and support in patient areas. These were accessed through QR (a type of matrix barcode with information about the item to which it's attached) codes and covered topics such as acupuncture, stress relief and advice on pregnancy.

The clinic offered patients a holistic approach to having care by referring patients to a GP who specialised in optimising lifestyle choices and health screening and dietary/weight control advice. In addition, they offered acupuncture and counselling services where it was identified that it may improve or compliment other treatments the patient was currently on.

Consent, Mental Capacity Act and Deprivation of Liberty Safeguards

Staff supported patients to make informed decisions about their care and treatment. They followed national guidance to gain patients' consent. They knew how to support patients who lack capacity to make their own decisions or were experiencing mental ill health.

The clinic had a consent policy which was in date and was compliant with the Mental Capacity Act and Deprivation of Liberty Safeguards legislation. The policy set out staff responsibilities for seeking and obtaining informed consent, including the type of consent (verbal or written) needed for procedures undertaken at the centre.

Staff made sure patients consented to treatment based on all the information available. We saw the consent process started when a patient first contacted the clinic. Specific procedure consent forms were sent to the patient, this gave patients time to thoroughly read and understand the benefits and risks of the procedure or treatment. Each consent form contained comprehensive information specific to the procedure.

Staff gained consent from patients for their care and treatment in line with legislation and guidance. Patients were required to sign the consent form to confirm they had read and understood the information it contained. Patients also had to sign to confirm they had been provided with all the relevant information.

Staff understood how and when to assess whether a patient had the capacity to make decisions about their care. The initial patient consultation provided staff with an insight into the patient's capacity and understanding.

Staff received and kept up to date with training in the Mental Capacity Act and Deprivation of Liberty Safeguards. Staff understood the importance of informed consent and told us they had received training on the approach to take to ensure patients were fully informed before completing the consent form.



Staff clearly recorded consent in the patients' records. The service audited consent forms yearly as part of their audit schedule to ensure that consent was obtained in line with national guidance before all procedures. The clinic had performed well in the audit and had achieved a compliance rate of 97%.

The clinic had never had cause to seek a deprivation of liberty authorisation.

Are Diagnostic and screening services caring?		
	Good	

We rated it as good.

Compassionate care

Staff treated patients with compassion and kindness, respected their privacy and dignity, and took account of their individual needs.

Staff were discreet and responsive when caring for patients. Staff took time to interact with patients and those close to them in a respectful and considerate way. We observed staff communicating with patients and giving them time to ask questions and talk.

Patients told us they were well informed, supported and reassured. They felt safe with staff and patients said staff treated them well and with kindness. Patients told us their privacy and dignity were respected. Patients felt comfortable and staff made them feel at ease.

Patients told us they felt well supported and were able to contact the clinic if they had any concerns or questions. Patients had direct access to midwives and were able to ask questions or gain reassurance.

Only one patient and their companion were seen in the reception at any time. The reception area was spacious and enabled receptionists to speak to the patient without being overheard.

Staff followed policy to keep patient care and treatment confidential. Trained staff chaperoned patients during each consultation and procedure.

There was a strong visible person-centred culture. Patients completed a comprehensive pre- appointment history sheet prior to their first consultation. This enabled staff to tailor their treatment and care to each patient. This was evident in all patient records we reviewed.

Staff were highly motivated and inspired to offer care that was kind and promoted people's dignity. Staff understood and respected the individual needs of each patient and showed understanding and non-judgmental attitude when caring for or discussing patients with mental health needs. We observed staff interacting with patients with a compassion. Staff told us they were aware of the emotional feelings patients had and the effects miscarriage and treatment might have on their mental health. Therefore, they encouraged patients to contact the clinic with any questions or worries in order to provide support and offer reassurance.



The clinic provided each patient who had reached 16 weeks of pregnancy and was discharged to NHS services a gift box containing, hand gel, hand cream, candle and a chocolate as well as a card wishing them well on their onward pregnancy journey. Staff felt this was a way of acknowledging that the patient had reached their goal of becoming pregnant.

Emotional support

Staff provided emotional support to patients, families and carers to minimise their distress. They understood patients' personal, cultural and religious needs.

Patients were always treated with dignity by all those involved in their care, treatment and support. Staff understood the emotional and social impact that a person's care, treatment or condition had on their wellbeing and on those close to them.

Staff undertook training on breaking bad news and demonstrated empathy when having difficult conversations. Staff told us they felt confident to support patients and their families through any difficult decisions or unfavourable outcomes.

Staff told us they provided a holistic approach to patients focusing on the wellness of patients and providing lifestyle care and preconceptual advice. The clinic focused on providing all aspects of care for patients such as consultation, scans, bloods tests, treatment infusions, theatre procedures, recovery care and follow up. This meant patients received continuity of care while under the care of the clinic.

All patients were followed up after any procedure to check they were recovering and were well.

Patients valued their relationships with the staff and felt they often went the extra mile for them when providing care and support. The clinic, with consent, arranged for patients who had been with the clinic for some time to support other patients. Patients who were about to experience the same treatment or procedures shared their experiences and gained support from each other.

The clinic organised and could refer patients for external counselling support.

Understanding and involvement of patients and those close to them Staff supported patients to understand their infertility and make decisions about their care and treatment. Staff talked with patients and families in a way they could understand.

Patients and their families could give feedback on the service and their treatment and staff supported them to do this. Staff supported patients to make informed decisions about their care. Patient feedback was overwhelmingly positive and included comments such as, "You have all been fantastic with your knowledge, care and compassion". "Every step of the way I was cared for, informed and encouraged". "Thank you to each one of you, for sticking by us, supporting us and letting us cry on you. I don't forget good kind people, so I won't forget you".

Staff made sure patients and those close to them understood their care and treatment. Administrative staff sent patients letters with the relevant information depending on the stage of their enquiry. For example, the initial letter included an overview of what to expect including an approximate indication of the total cost. Once patients had had a consultation and an agreed treatment plan, this information was provided in written form further explaining the process and cost. Staff checked the patient's understanding of this information before starting any aspect of the treatment and patients told us they were given time to reflect on the information they had been given.

The service was sensitive to patients going through difficult times. They offered patients who had suffered a miscarriage on the day of their appointment, a grace period for payment as they understood the difficult nature of taking money at a very stressful time.

Are Diagnostic and screening services responsive?		
	Good	

We rated it as good.

Service delivery to meet the needs of local people

The service planned and provided care in a way that met the needs of local people and the communities served.

Patients who attended the clinic were privately funded or insured patients. This was explained to the patients during the initial contact with the clinic before proceeding with any consultation or treatments.

Facilities and premises were appropriate for the services being delivered. The layout of the building was suitable with enough consultation rooms, inhouse operating theatre and recovery area and two separate ultrasound scanning rooms.

WIFI was available throughout the clinic and was free to use for all people on the premises. This allowed patients to access all leaflets without the need for paper leaflets, although these were also available in limited quantities.

The service had systems to help care for patients in need of additional support or specialist intervention. The clinic provided a range of services including, a range of pregnancy scans, diagnostic and screening and treatment of recurrent miscarriage, complimentary therapies, manual vacuum aspiration and hysteroscopy. Services were offered to local, national and international patients.

Managers planned and organised services, so they met the changing needs of not only the local population but for those patients across the country and internationally. Through the COVID-19 pandemic, the service had embraced the use of technology, introducing virtual clinics so patients could continue with their treatments while complying with COVID-19 guidelines. The service had also introduced a postal service for the delivery of medication and patients commented that this had been cost-effective as it eliminated the need to travel to travel and collect medication. They stated this had made the service more convenient for them to access

The service's website had a wealth of resources and signposting that patients could access to inform themselves about fertility treatment and how to best support their health and wellbeing whilst undergoing treatment.

The clinic had begun quarterly antenatal classes and baby drop-in clinics for parents to meet other parents whose babies had been conceived with the help of the clinic. However, these had been stopped to comply with COVID-19 guidance at the time. The clinic planned to restart the sessions.

The clinic was declared as a green zone during the peak of the COVID-19 pandemic therefore offered patients in Surrey, the southwest and surrounding areas the option to have surgical intervention at the clinic. This option was available to non- Centre for Reproductive Immunology and Pregnancy patients who may not necessarily have sought treatment for their miscarriages.



Meeting people's individual needs

The service was inclusive and took account of patients' individual needs and preferences. Staff made reasonable adjustments to help patients access services. They coordinated care with other services and providers.

The service had information leaflets available in languages spoken by the patients and local community. When the person required information in their preferred language, the clinic provided translated information although we were told this was rare.

Managers made sure staff, and patients, loved ones and carers could get help from interpreters or signers when needed. Staff had access to translation service through a third-party provider. Staff could request face to face and telephone translators for patients whose first language was not English or for British sign language.

Reasonable adjustments were made so that patients with disabilities could access and use services on an equal basis to others. Facilities and premises were appropriate for the services being delivered. The layout of the building was suitable and fully accessible to those with physical disabilities. There were enough consultation rooms with ultrasound scanning facilities, a procedure room and a recovery room. All this provided an inclusive service without the need for patients to be referred elsewhere.

The service took account of patients with sensory loss, mobility and communication difficulties and adjusted the service to meet their needs. These patients were given longer appointments to ensure the care they were given was unrushed, appropriate and safe. Family members or their carer were able to stay for their appointment if needed by patients.

Women with rhesus negative blood which if left untreated could result in birth defects or stillbirth, were given a treatment of anti-d injections following a manual vacuum aspiration procedure (MVA). The clinic had a service level agreement with the local hospital. The agreement provided a dual element from a patient and safety perspective which allowed the clinic to offer women anti-d at the time of their MVA procedure without the need to return to their GP or local hospital. In the event of an emergency, the clinic would transfer the patient to the local hospital in line with the agreement.

Staff made sure patients living with mental health issues received the necessary care to meet all their needs. All patients were reviewed by their consultant during the initial appointment. The medical director explained that medication used for fertility treatments had an impact on mental health therefore when patients were identified as needing psychological support, they were referred for counselling or to their GP before progressing with treatment. The clinic gave us a recent example where a patient was referred back to their GP resulting in a delay in treatment However, we saw feedback from the patient, who expressed their gratitude for the support they had received from the service, ensuring they were in a good mental state before beginning their fertility journey.

There was always a doctor on site to support clinic, Monday to Friday. Staff recognised the importance of having a doctor on site, so women readily had access to a doctor for advice and prescription queries. Similarly, the clinic offered clinical midwifery support and had a senior patient advisor covering the service five days a week. This provided a continuity of support to the patients.

Staff at the clinic believed patients should have access to their medical reports and be actively involved with their care and treatment. Each patient was supplied with a USB device where their scan images were saved and printed reports after each consultation were given to them for their own record at no extra charge. The clinic also gave patient's a copy of their blood results and a typed letter following each consultation summarising their plan of care.



Following discharge, patients were advised to contact the clinic should they have any worries or concerns following their procedure. We saw this information was given to patients as part of the discharge arrangements.

The clinic supported charity events. During baby loss awareness week, the service had offered a number of free consultations in support of the event.

Access and flow

People could access the service when they needed it and received the right care promptly.

In the 12 months before our inspection, the clinic had undertaken 1700 ultrasound scans, 1480 consultations, 351 fetal medicine appointments, 22 manual vacuum aspirations and 21 hysteroscopies.

Managers monitored waiting times and made sure patients could access services when needed and received treatment within agreed time frames. All patients who accessed the service, did so within the expected time. This was scheduled according to their treatment plan and booked in advance. The provider had a second clinic in Harley Street to accommodate some patients who worked in London or international patients to make the service easier to access.

When patients had their appointments cancelled at the last minute, managers made sure they were rearranged as soon as possible. Staff told us appointments were rarely cancelled and that this would only be if there was not enough staff to carry out the procedure safely or if there was equipment failure. This had not happened in the last 12 months. If procedures were cancelled, staff sought to re-book them as quickly as possible to fit around the patients' availability as far as possible.

The clinic did not actively monitor 'did not attend' appointments and told us they had not had any missed appointments in the last 12 months. They explained that due to appointments being highly sought after, patients did not miss the appointments. However, to minimise the rate of 'did not attend' appointments the clinic sent text reminders to patients, notifying them of their upcoming appointment. Staff told us if a patient missed an appointment, they followed the same process as they would if the appointment was cancelled and this was done at no extra cost to the patient.

Managers and staff worked to make sure patients did not stay longer than they needed to. Appointments were scheduled to minimise waiting times when patients arrived for their procedure. During the inspection, we observed staff attending to patients promptly when they arrived for their appointment.

Staff monitored waiting times and made sure patients could access emergency services when needed and received treatment within agreed timeframes. In the unfortunate occasion of a miscarriage being diagnosed, staff offered a quiet place for the clients to have some time with a midwife to discuss the next steps. This included an offer of surgery if chosen as treatment within 48 hours from diagnosis to procedure with results and follow up within four weeks.

Patients had access to a telephone aftercare call with the same midwife that was present during the patient's procedure and or recovery. Staff were with these patients at every step of the way throughout their journey through the clinic.

The administrative team responded to calls and emails within 48 hours. Where possible clinic appointments for patients in treatment were offered in support of patients' availability. The clinic offered timely appointments to support early reassurance scans at short notice.



Most medicines were available onsite allowing patients to start their treatment without delay. The postal medicines service was started to streamline the delivery medicines during the pandemic and provided reassurance for patients that if they ran out of their medicines prior to their next appointment or lived far away, this was still accommodated.

There was a documented approach to the management of laboratory results, and this was managed in a timely manner. Blood test results were often communicated to the patient at their next scheduled appointment which typically was booked two weeks later.

Learning from complaints and concerns

It was easy for people to give feedback and raise concerns about care received. The service treated concerns and complaints seriously, investigated them and shared lessons learned with all staff. The service included patients in the investigation of their complaint.

Patients, relatives and carers knew how to complain or raise concerns. The service clearly displayed information about how to raise a concern in patient areas. The clinic had an in-date complaints policy which set out the responsibilities of staff and the complaints process. The clinic manager was responsible for overseeing the management of complaints.

Staff understood the policy on complaints and knew how to handle them. The service accepted complaints and concerns in person, through telephone or email. Staff said they addressed all complaints at the earliest opportunity if the complainant wished to discuss the matter whilst on site. If this was not possible, the service planned to either speak to the complainant through telephone or in person when it was convenient to the complainant.

Staff knew how to acknowledge complaints and patients received feedback from managers after the investigation into their complaint. In the 12 months before our inspection, the clinic had received three complaints. We reviewed all complaints and saw they were managed in line with the complaints policy. The manager sent a letter acknowledging the complaint within three days and a full response within 20 working days of receiving the complaint. The clinic informed patients of any further action that may be available to them should they not be satisfied with the response to their complaint.

Staff could give examples of how they used patient feedback to improve daily practice. Staff at the clinic strived for excellence and despite having limited patient complaints, they took any patient feedback seriously so that they could ensure patients trusted them to take on board any improvements that might benefit the whole service. For example, as a result of a patient complaint, the service was now carrying out all biopsies in the theatre as patients felt the environment was more comfortable for them.

Managers shared feedback from complaints with staff and learning was used to improve the service. Staff treated patients who made complaints compassionately and took immediate steps to make the necessary changes. We saw feedback from complainants, acknowledging the improvements that had been made since they had made the complaint and praised the staff for their responsiveness.

The outcomes and associated learning points were communicated through huddles and presented at clinical governance meetings. Any trends were identified through the complaints log.

Are Diagnostic and screening services well-led?



We rated it as good.

Leadership

Leaders had the skills and abilities to run the service. They understood and managed the priorities and issues the service faced. They were visible and approachable in the service for patients and staff. They supported staff to develop their skills and take on more senior roles.

The clinic had a clear leadership structure. The leadership team included a medical director, the registered manager and a clinical service manager. All members of the leadership team had extensive experience in their area of interest and had previously worked or continued to work within the NHS as well as at the clinic.

Staff feedback was very positive about the management of the clinic. They felt the leadership team valued their opinions and were readily available to listen to staff. The staff said there was a good sense of teamwork and this was the reason that the majority had worked there for several years.

We saw evidence of good communication between leaders and staff. There were mechanisms for staff to communicate with leaders including formal and informal one to one meetings, daily huddles and through staff surveys. Staff wellbeing was high on the agenda and examples of how this was maintained were seen during the inspection.

Leaders were able to identify the priorities and verbalise risks to the service. Priorities at the time of the inspection included recruitment as the service had seen a growth in demand since the pandemic had begun, adopting technology to improve the efficiency of the service and succession planning.

Vision and Strategy

The service had a vision for what it wanted to achieve.

There was a clear mission and set values. These were displayed in the clinic and staff knew the values. Staff worked in a way that demonstrated their commitment to providing high-quality care in line with this vision.

The clinic's philosophy was to promote cutting edge scientific medical approach and alternative therapy. It was dedicated to diagnosing and treating miscarriages and providing women with the chance of having a successful pregnancy outcome.

Culture

Staff felt respected, supported and valued. They were focused on the needs of patients receiving care. The service promoted equality and diversity in daily work and provided opportunities for career development. The service had an open culture where patients, their families and staff could raise concerns without fear.

The service promoted an open culture. Staff told us they felt supported by the managers and confident to approach them with any concerns. Staff told us they felt respected and valued by their managers and colleagues. They commented on how the clinic was a lovely place to work and the environment allowed them to be productive. Staff stated they worked well as a team and that their opinions were listened to.



Staff demonstrated pride and positivity in their work and the service they delivered to patients. Staff were happy with the amount of time they had to support patients and that was one of the things they enjoyed about their role.

There was a strong emphasis on staff wellbeing. Staff had access to wellbeing support and the leadership team arranged two virtual mental health and wellbeing sessions with an external provider during the COVID-19 pandemic. Staff reported this had been helpful to manage their work and personal matters.

Staff spoke positively about the training, and they told us they had been supported with courses and opportunities to improve their skills. Staff gave examples of how they had been supported to gain additional healthcare qualifications, maintain skills when their main role had changed and about career development.

Governance

Leaders operated effective governance processes, throughout the service. Staff at all levels were clear about their roles and accountabilities and had regular opportunities to meet, discuss and learn from the performance of the service.

The service had an effective governance framework and staff told us it functioned well. The governance arrangements were appropriate for the range of services provided and the small team delivering these services.

The governance framework was supported by a clinical governance policy. The policy set out the key systems and processes that underpinned the clinic's approach to clinical governance. Systems for monitoring clinical governance included clinical audits, education, evidence based clinical practice and risk management.

The clinical governance structure included twice yearly meetings with the multidisciplinary team and an exception report which showed how well the clinic was performing. The report was shared with staff and discussion points raised in the team huddles.

There were monthly team meetings to disseminate information or discuss clinical or non-clinical issues, such as incidents or complaints. Information was shared through the huddles and emails.

Minutes of meetings were stored electronically and accessible to all staff. We reviewed meeting minutes from the bi-annual exception report, clinical governance committee and staffing meetings.

The clinic had several service level agreements (SLA) which provided services, and these were routinely monitored. For example, pharmacy services, laundry, cleaning, and waste management. We reviewed two SLA's which were in date and defined the type of service provided, required performance level, steps on how to report matters affecting performance and a review date of the SLA.

The medical advisory committee was responsible for ensuring that all staff working under practicing privileges had provided evidence that they had the appropriate level of indemnity insurance, qualifications, appraisal and revalidation. All files we reviewed for consultants were up to date and contained the necessary documentation.

The clinic had established policies, procedures and activities to ensure safety and assured themselves that they were operating as intended. Staff we spoke with knew how to access policies and procedures. Policies were evidence based, version controlled, dated and identified a review date. Policies we reviewed were in date.



Management of risk, issues and performance

Leaders and teams used systems to manage performance effectively. They identified and escalated relevant risks and issues and identified actions to reduce their impact.

There were robust arrangements for identifying, recording and managing risks, issues and mitigating actions. This was done through a risk register which the service shared with us for review. Risks were formally reviewed yearly and as and when significant concerns were identified at the clinical governance meeting.

Staff carried out risk assessments including individual risk assessments relating to COVID-19. The staff were actively encouraged to participate in clinical risk meetings so that they felt involved and engaged in risk reviews and service improvements. The ethos was for continual learning to take place not just through mandatory yearly training but in responses to incidents, complaints, and audit reviews. Staff were aware of the current risks and said they escalated any risks to their line manager.

The service took potential risks into account when planning services. They had a business continuity plan that could operate in the event of an unexpected disruption to the service. Staff told us these plans included an adverse weather plan resulting in staff being unable to attend the service. Staff were clear on their responsibilities during these events and who to contact for support.

Information Management

The service collected reliable data and analysed it. Staff could find the data they needed, in easily accessible formats, to understand performance, make decisions and improvements. The information systems were integrated and secure. Data or notifications were consistently submitted to external organisations as required.

Patient records were paper based. All staff had access to full details of a patient's past medical history, medicines, allergies, referral letters, consent information, clinic notes, pre-assessment notes, and consultants' notes.

We reviewed seven sets of patients notes. All contained enough information to enable staff to provide appropriate patient care. This included diagnostic test results and treatment plans.

Information was available on the clinic's website. This was up to date and reviewed weekly. Information included the services provided, contact information, key alerts from Public Health England regarding COVID-19 and other guidance from the Royal College of Obstetricians and Gynaecologists and Royal College of Midwives.

Information governance formed part of the mandatory training programme. All staff had completed the training. They understood their responsibilities to comply with data security standards including maintaining the integrity and confidentiality of patient identifiable records, data management systems and the reporting of incidents relating to security breaches. This was demonstrated during the inspection with all staff having secure, personal log in details and access to e-mail and clinic systems. We observed that no computer terminals or patient records were left unattended displaying confidential information.

The clinic stored medical records for 10 years after treatment was finished with a minimum of four years on site and the remainder at a secure storage facility off site. Records kept on site were stored in a locked cupboard in the nurse's office. The key to the cupboard was kept in a locked key box.



Engagement

Leaders and staff actively and openly engaged with patients and staff to plan and manage services.

Managers sought the views of staff through yearly staff satisfaction surveys with the aim to make changes in order to improve staff experience. The survey carried out in March 2021 was completed by 70% of staff and responses were generally positive particularly to questions such as being involved in decision making and feeling supported by the management team.

Patients were encouraged to leave feedback about their experience by sending feedback through the website or completing a review of the clinic on a search engine. The clinic displayed its QR code in the waiting room to encourage patients to send in feedback. The clinic had noted a decrease in feedback since the COVID-19 pandemic and were looking to develop a feature on the clinic's soon to be launched application to enable patients to feedback when convenient to them.

The service's website provided advice regarding types of procedures the clinic was able to perform and there were many letters of thanks as testimonials from previous patients.

Learning, continuous improvement and innovation

All staff were committed to continually learning and improving services. They had a good understanding of quality improvement methods and the skills to use them. Leaders encouraged innovation and participation in research.

The clinic was focused on innovation and the development of new techniques. The medical director had designed a mobile application which was due to be launched shortly after our inspection. The medical director recognised the importance of improving patient experience and the application aimed to give patients the ability to view their treatment plan, track their progress, medication intake and book appointments. The goal was to give patients more control over their care. We were given a demo of the application and saw there were handy reminders for what medication needed to be take every day, what appointments were scheduled and the purpose of the appointments.

The clinic was currently discussing with another provider about offering patients at home blood pressure machines to use alongside the application without the need to attend the clinic or visit their GP. This was to enable patients with busy lives or lived far from the clinic to have their blood pressure routinely monitored remotely and only attend the clinic as and when necessary.

Education was an integral part of the culture at the clinic and an important contributor to fertility research. We saw evidence of extensive research into the diagnosis and treatment of miscarriage in international and national papers written by the medical director which were all accessible through the clinic's website.

The medical director conducted regular podcasts relating to fertility and miscarriage with the emphasis on current research and dispelling myths on the historic causes of miscarriage.

The clinic had an international relationship with a fertility provider in Alicante Spain, and all staff could attend an all-expense paid conference to further develop their skills and career.



The clinic was one of a few miscarriage services applying hyaluronic acid (a natural substance which acts as a cushion and lubricant in the joints and other tissues) gel in the uterus following a surgical procedure to reduce the risk of Asherman's syndrome (build-up of scar tissue caused by uterine surgery) which can impact further on future fertility, an important factor in a patient cohort of patient the clinic saw. This practice had been adopted for hysteroscopy procedures.