

Early Life Ultrasound Centre Ltd

Early Life Ultrasound Centre

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?

Good



Are services caring?

Good



Are services responsive to people's needs?

Good



Are services well-led?

Good



Summary of findings

Overall summary

At our last inspection we rated the service good. At this inspection, the rating stayed the same. We rated it as good because:

- The service had enough staff to care for women and keep them safe. Staff had training in key skills, understood how to protect women from abuse, and managed safety well. The service controlled infection risk well. Staff assessed risks to women, acted on them and kept good care records. The service managed safety incidents well and learned lessons from them. Staff collected safety information and used it to improve the service.
- Staff provided good care and treatment. Staff worked well together for the benefit of women, advised them on how to lead healthier lives, supported them to make decisions about their care, and had access to good information.
- Staff treated women 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 women, families and carers.
- The service planned care to meet the needs of local people, took account of women's individual needs, and made it easy for people to give feedback. People told us they could access the service when they needed it, although this was dependent on the availability of the sonographer and did not have to wait too long for their results.
- 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 women receiving care. Staff were clear about their roles and accountabilities. The service engaged well with women and the community to plan and manage services and all staff were committed to improving services continually.

Summary of findings

Our judgements about each of the main services

Service

Community health services for adults

Rating

Good



Summary of each main service

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- Staff provided good care and treatment. Staff worked well together for the benefit of women, advised them on how to lead healthier lives, supported them to make decisions about their care, and had access to good information.
- Staff treated women 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 women, families and carers.
- The service planned care to meet the needs of local people, took account of women's individual needs, and made it easy for people to give feedback. People told us they could access the service when they needed it, although this was dependent on the availability of the sonographer and did not have to wait too long for their results.
- 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 women receiving care. Staff were clear about their roles and accountabilities. The service engaged well with women and the community to plan and manage services and all staff were committed to improving services continually.

Summary of findings

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Summary of this inspection

Background to Early Life Ultrasound Centre

Early Life Ultrasound Centre in Cheltenham is operated by Early Life Ultrasound Centre Limited. Scans are provided for pregnant women from 18 years of age. The service provides a range of scans for pregnant women with scans taking place from seven weeks to full term. The service is provided to self-funding women across Cheltenham. These include 3D/4D ultrasound imaging, early pregnancy/reassurance scans, endometrial lining scans and well-being scans. The service employed four staff plus the registered manager, and a total of 1216 scans were performed since January 2022.

The service also provides non-invasive prenatal testing (NIPTs) for pregnant women and caters for pregnant women who choose obstetric ultrasound services, in addition to routine antenatal ultrasound services or those who are undergoing fertility treatment abroad. The service had provided 44 non-invasive prenatal tests since January 2022.

All women accessing the service are private (self-funding) patients.

The service provides the single specialty core service diagnostic imaging. We inspected this service using our comprehensive inspection methodology. We carried out a short notice announced inspection on 01 August 2022.

To get to the heart of patients' experiences of care and treatment, we ask the same five questions of all services: are they safe, effective, caring, responsive to people's needs, and well-led? Where we have a legal duty to do so we rate services' performance against each key question as outstanding, good, requires improvement or inadequate.

Throughout the inspection, we took account of what people told us and how the provider understood and complied with the Mental Capacity Act 2005.

How we carried out this inspection

We carried out a comprehensive inspection of the service under our regulatory duties. The inspection team comprised of a lead CQC inspector and an offsite CQC inspection manager. We gave the service short notice of the inspection because we needed to be sure it would be in operation at the time we planned to visit.

We undertook this inspection as part of a random selection of services which have had a recent Direct Monitoring Approach (DMA) assessment where no further action was needed to seek assurance about this decision and to identify learning about the DMA process.

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>.






Our findings

Overview of ratings

Our ratings for this location are:

	Safe	Effective	Caring	Responsive	Well-led	Overall
Community health services for adults	Good	Inspected but not rated	Good	Good	Good	Good
Overall	Good	Good	Good	Good	Good	Good

Community health services for adults

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

Are Community health services for adults safe?

Good 

Our rating for this service stayed the same. We rated safe 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 met the needs of women and staff. The registered manager ensured staff completed their mandatory training; for example, staff had completed basic life support, infection control, safeguarding, health and safety, mental capacity act, equality and diversity and information governance. All staff had completed the training the registered manager identified as necessary for their role.

Staff also completed role specific mandatory training. For example, sonographers had also completed ultrasound safety and breaking bad news training.

The registered manager monitored compliance with mandatory training and alerted staff when they needed to update their training. Staff confirmed they were given enough time to do training. The registered manager provided protected training days for staff.

The registered manager ensured staff could access online training appropriate for the service. Staff told us they were able to request additional training, and this would be provided for them.

Safeguarding

Staff understood how to protect women 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.

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Staff received training specific for their role on how to recognise and report abuse. The service had clear safeguarding processes and procedures. The safeguarding policy was up to date, last reviewed in January 2022. All staff were trained to at least safeguarding level two for both vulnerable adults and children; for example, the registered manager and the sonographer had received safeguarding adults' level three training. The registered manager was the safeguarding lead.

Staff had not made a safeguarding referral, but they knew how to and who to inform if they had concerns. Staff were able to clearly articulate signs of different types of abuse, and the types of concerns they would report or escalate to the registered manager.

The safeguarding policy also covered female genital mutilation (FGM) and child sexual exploitation (CSE) and provided staff with clear guidance on how to identify and report FGM and CSE. Safeguarding training also covered FGM and CSE.

Cleanliness, infection control and hygiene

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

Clinical areas were visibly clean and had suitable furnishings which were visibly clean and well-maintained. The clinic rooms, toilets, reception and waiting areas were all visibly clean. The registered manager had developed policies during COVID-19 which ensured a higher standard of infection prevention. For example, there were machines which filter and clean the air in reception and the scan room and automatic dispensers were used for soap and hand sanitiser. Cleaning schedules were available. Staff cleaned equipment and waiting areas after every customer contact. For example, the couch in the treatment room used by women was wiped down and covered with a disposable cloth which was changed between patients.

Cleaning records were up-to-date and demonstrated that all areas were cleaned regularly. Staff completed daily and weekly cleaning logs and undertook cleanliness visibility checks of toilet areas throughout their shifts. Staff documented and rectified any areas of concern as necessary. The registered manager had introduced more detailed cleaning logs in response to COVID-19 which prompted staff to clean every surface in the room they were cleaning.

Staff followed infection control principles including the use of personal protective equipment (PPE). There were appropriate hand washing facilities and sanitising hand gel was available. Staff had their arms bare below their elbows and washed their hands before and after each scan. Personal and protective equipment such as latex-free gloves and antiseptic wipes were readily available for staff to use at the service.

In the twelve months before the inspection, there had been no incidences of healthcare acquired infections at the location.

The registered manager had updated the COVID-19 policy to provide guidance for staff to help reduce the spread of infection. Staff were following this policy.

The sonographer followed the manufacturer's and infection prevention and control (IPC) guidance for routine disinfection of equipment. The sonographer wore gloves when carrying out scans in line with infection prevention and control (IPC) compliance.

The service offered non-invasive pre-natal testing (NIPT) services and had a contract with an accredited laboratory. Non-invasive pre-natal testing means the baby's DNA circulating in the mother's blood can be checked for certain

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chromosomes. An abnormal number of these chromosomes could indicate the presence of certain inherited conditions, such as Down's Syndrome, Edward's Syndrome and Patau's Syndrome. Down's Syndrome is a condition where a person has an extra chromosome. Babies with Edwards' syndrome have an extra copy of chromosome 18 in all or some cells. Babies with Patau's syndrome have an extra copy of chromosome 13 in all or some cells. The tests can be done as early as ten weeks into the pregnancy. The registered manager monitored the time it took to receive results.

The service had a non-invasive pre-natal testing procedure outlining the steps to take when obtaining blood samples. The guidance cross-referred to the service's infection prevention and control policy, outlining hand hygiene steps and the safe disposal of sharps and clinical waste to prevent and control the spread of infection.

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 and had enough suitable equipment to meet the needs of women. The clinic's environment was fit for the purpose of service provided. The premises were in the basement of a building in the centre of Cheltenham, with car parking nearby. The building comprised external steps down to access the front entrance, into the reception area. There was a back door into the premises which had a ramp for people who were disabled. There was one, separate scan room. The scan room had a modern couch which could be adjusted for comfort. Pictures from the scan were projected onto a wall. There was a couch for people accompanying the woman. The layout of the building meant the member of staff in reception had direct view of clients in the waiting area and the service could operate a one-way system between the waiting area, the scan room and back to the reception area. The doorway into the scan room was shielded with a portable screen. The waiting area was light and comfortable, with merchandise available to purchase on display.

There was also a small kitchenette for staff use only.

Staff completed regular checks of stock, first aid kit and equipment.

The service did not require a resuscitation trolley. There was a first aid box which was within expiration date. Staff were up-to-date with adult and children first aid training. Staff told us in case of an emergency they would call 999.

Staff carried out daily safety checks of specialist equipment. The scan equipment was serviced annually in line with manufacturer's recommendations. The electrical equipment had been safety tested within the last 12 months. This was in line with the provider's safety policy.

Staff disposed of clinical waste safely. Staff carried out waste streaming in line with Department of Health and Social Care Health Technical Memorandum 07-01, which reflected national best practice. Staff wore correct PPE while dealing with clinical waste and followed a safe process. Clinical waste was stored in a secure, locked area in a room until collection. The service had an agreement with a professional company and clinical waste collected weekly.

Disposable equipment was labelled with dates when it was opened and disposed of when the expiry date was reached.

Fire risk assessments had been undertaken. Fire alarms were checked weekly, fire exits were kept clear. The service had two fire extinguishers which were easily accessible from reception and another two at the rear of the building.

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A screened area in the scan room was available for women who needed to undress to ensure their privacy and dignity.

Sonographers could adjust the scanning machine and chair for their comfort, as well as adjusting the scan couch. The registered manager also factored breaks into the schedule, so staff could avoid work related musculoskeletal disorders.

Assessing and responding to patient risk

Staff completed and updated risk assessments for each woman and removed or minimised risks. Staff knew what to do and acted quickly when there was an emergency.

Staff knew about and dealt with any specific risk issues. The service provided clear guidance for sonographers to follow when they identified unexpected results during a scan. This was referenced in the provider's policy, which gave clear guidance. Should any anomalies be found, staff told us they informed the woman in a caring, honest and professional manner. The woman was given a detailed medical report which clearly explained the scan findings. Staff made referrals to the woman's GP or midwife to enable access to their local Early Pregnancy Assessment Unit (EPAU).

Scan protocols stated every woman would be risk assessed. Staff asked for women's medical history and information about their health. This was recorded in their scan report.

Staff gave examples of redirecting women who were experiencing pain or bleeding to their local NHS clinical team. The registered manager explained how they tell women what they need to do, clearly document this and tell them to contact their GP, hospital, midwife or phone 111.

Staff shared key information to keep patients safe when handing over their care to others. Staff responded promptly to any immediate risks to women's health. Staff told us they would phone 999 if they suspected anything which required urgent action. This meant that staff knew what to do and acted quickly when there was an emergency. The registered manager told us they had urgently referred one woman to NHS services in the past year because of potential concerns found. The registered manager had an 'unexpected findings policy' and followed this. Staff completed a report for the woman to give to their maternity provider. These included a description of the scan findings, the reason for referral and who the receiving healthcare professional was. The registered manager had made 34 referrals for unexpected findings.

At the time of our inspection the registered manager and sonographer were peer reviewing each other's work. However, the registered manager had an informal service level agreement with a consultant in obstetrics and gynaecology to access support. In exchange for providing support, the consultant used the premises and equipment. For example, they could ask the consultant to look at scans for a second opinion. Women consented to their information being shared outside the service if necessary when they signed the consent form. The registered manager was a member of the British Medical Ultrasound Society (BMUS) and received journals and updates as well as keeping their Continuing Professional Development (CPD) up to date.

Staffing

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

The service had enough staff to keep women safe. The registered manager planned staffing levels to meet demand on the service, measured by the number of bookings made in advance. The registered manager was a sonographer and

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service employed one other sonographer and three receptionists. All members of staff were trained as chaperones. Women mostly booked their appointments online. The sonographer wrote a report and printed scan images and gave these to women in a folder. One woman who had a scan for fertility treatment had her report emailed to her, so she could forward it to her maternity provider.

All staff had to have a Disclosure and Barring Service (DBS) check before starting their employment at the location. All staff had an up-to-date DBS check. We reviewed all five personnel files and all staff had proof of identification, residence, and an up-to-date curriculum vitae on file. The service had obtained two references for staff in line with their policy. We also saw employment offer letters, evidence of induction training, qualifications, and professional memberships were kept on file.

The sonographers were registered with The Register of Clinical Technologists (RCT) which replaced the Society of Radiologists register in February and had professional indemnity insurance.

The service had no vacancies. Staff turnover and sickness rates were low and stable. The service had not used bank or agency staff.

Records

Staff kept detailed records of women's care and diagnostic procedures. Records were clear, up to date, stored securely and easily available to all staff providing care.

The service had an up-to-date information governance policy, and a data retention policy. The registered manager was the information governance lead for the service. The service was registered with the Information Commissioner's Office (ICO).

Women's notes were comprehensive, and all staff could access them easily. Women completed pre-scan forms online which were used to collect their name, address, telephone number, email address and consent.

Staff ensured women's confidential personal information (CPI) was maintained and not accessible to others.

Records were stored securely. All records were kept electronically, and computers were password protected. Printed reports were put into a folder for the woman to take so no paperwork was visible.

Incident reporting, learning and improvement

The service managed safety incidents well. Staff recognised and knew how to report incidents and near misses. Managers had protocols in place for investigating incidents and sharing lessons learned with the whole team and the wider service. When things went wrong, staff apologised and gave women honest information and suitable support. Managers ensured that actions from safety alerts were implemented and monitored.

Staff knew what incidents to report and how to report them. The service had an up-to-date incident reporting policy, which detailed all staff responsibilities to report, manage and monitor incidents. The service used a paper accident book to report incidents and an incident log was available in the clinic. The service had never had an incident. If an incident was to occur, the registered manager was responsible for conducting investigations into all incidents at the location.

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Staff understood the duty of candour. In the past year, there were no incidents requiring duty of candour notifications. The duty of candour is a regulatory duty that relates to openness and transparency and requires providers of health and social care services to notify patients (or other relevant persons) of certain 'notifiable safety incidents' and provide reasonable support to that person, under Regulation 20 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014. The registered manager could explain the process they would undertake if they needed to implement the duty of candour because of an incident, which was in line with the requirements.

Staff had opportunities to discuss feedback and look at improvements to women's care. As there were only five members of staff at the time of the inspection, information was shared daily. Staff looked at topics such as feedback, infection control, compliments, suggestions and learning during daily huddles. Staff also had access to encrypted groups where information was shared. The consultant was included in the clinical group.

Are Community health services for adults effective?

Inspected but not rated 

We do not currently rate effective.

Evidence-based care and treatment

The service provided care and procedures based on national guidance and evidence-based practice. Managers checked to make sure staff followed guidance. Staff protected the rights of women subject to the Mental Health Act 1983.

Staff followed up-to-date policies to plan and deliver high quality care according to best practice and national guidance. Staff were aware of how to access policies, which were stored electronically as well as in paper format. Local policies and protocols were in line with current legislation and national evidence-based guidance from professional organisations, such as the National Institute for Health and Care Excellence (NICE) and the British Medical Ultrasound Society (BMUS). Policies were reviewed annually, and staff were made aware of any updates. All 12 policies and protocols we looked at had a next renewal date, which ensured they were reviewed by the service in a timely manner. Staff signed a policy update sheet each year when the policies were reviewed, and they re-read them.

The service followed the 'As Low As Reasonably Achievable' (ALARA) principles. This was in line with national guidance (Society and College of Radiographers (SCoR) and British Medical Ultrasound Society (BMUS), Guidelines For Professional Ultrasound Practice (December 2018)). This meant sonographers used minimum frequency levels for a minimum amount of time to achieve the best result. Machines were pre-set to the lowest frequency and this was checked during scans.

The service had an effective audit programme that provided assurance about the quality and safety of the service. The registered manager carried out audits where they monitored women's experience, cleanliness, health and safety and ultrasound scan reports. For example, the registered manager completed monthly checks on the quality of the images and the reports written. This was to ensure any referrals had been done properly.

Sonographers audited each other's scans and scan documentation. They scored on report and image quality and checked when a referral was needed that it had been made to the appropriate people.

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The service used technology and equipment to enhance the delivery of effective care and treatment to women. The service utilised up-to-date scanning equipment to provide high-quality ultrasound images. They also had one large wall-mounted screen situated in the scan room which enabled women and their families to view their baby more easily.

The service was inclusive to all pregnant women and supported all women regardless of their age, disability, pregnancy and maternity status, race, religion or belief, and sexual orientation to make their own care and treatment decisions. The registered manager told us, “We have same sex couples using in vitro fertilisation (IVF).”

Nutrition and hydration

Staff took into account women’s individual needs where fluids were necessary for the procedure.

Due to the nature of the service, food and drink was not routinely offered to women. However, drinking water was available from a machine in reception. To improve the quality of the ultrasound image, women were asked to drink extra fluids on the lead up to their appointment. Women who were having a gender scan were encouraged to attend their appointment with a full bladder. This information was given to women when they contacted the clinic to book their appointment. It was also included in the ‘frequently asked questions’ on the service’s website. One woman left feedback on social media to say, “It’s so easy to book and their website is really clear and straightforward.”

Pain relief

Staff assessed and monitored women regularly to see if they were in pain during scans.

Pain relief was not available at the service. Staff checked women were comfortable during their scan and halted scans if women experienced any discomfort.

Patient outcomes

Staff monitored the effectiveness of care. They used the findings to make improvements and achieved good outcomes for women.

The registered manager collected data for their own use on an on-going basis. This included information about the number of ultrasound scans. This enabled the registered manager to understand what audits were needed to give valid data and identify trends and areas for improvement. Collecting such data meant the registered manager identified that early pregnancy scans were the most popular, followed by gender identification. By identifying the most popular scans, the registered manager was able to arrange appointments to ensure women had enough time allocated to ensure privacy.

In the past year, the service had made one 999 call for an urgent referral and 33 women were referred to GP’s or midwives to enable access to local Early Pregnancy Assessment Unit (EPAU) due to the detection of potential concerns.

The registered manager ensured there were clear criteria for doing scans and repeat scans. Rescans were done in the most appropriate timescales. This was to ensure women were not persuaded to have multiple scans, which would not have given them any more information than they already had.

Staff made women aware they could get non-invasive pre-natal testing blood tests through the NHS if they were high risk. Women were able to discuss their options and whether to wait for this.

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Competent staff

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

Staff were experienced, qualified and had the right skills and knowledge to meet the needs of women. Staff accessed their training online. Training records confirmed staff had completed role-specific training. Staff confirmed they had protected learning time and could identify training they would like to do.

The registered manager completed a competency assessment which included checking sonographer's registration, indemnity insurance and revalidation status when new staff were employed. The registered manager had an initial competency assessment and a buddy system in place to ensure any new sonographers employed would meet competency requirements.

The registered manager made sure staff received any specialist training for their role. For example, staff who took bloods for non-invasive pre-natal testing had done phlebotomy (blood collection) training. Phlebotomists were trained to be able to explain and discuss the benefits and limitations of non-invasive pre-natal testing with women.

The registered manager gave all new staff a full induction tailored to their role and experience before they started work. All staff underwent an induction programme which included providing information about staff roles and responsibilities, and mandatory and role-specific training. For example, staff completed health and safety and fire procedure training during induction. Staff also completed a three-month probation period.

Managers made sure staff received any specialist training for their role. Staff completed training such as specific pregnancy first aid training, chaperone training and lone working.

Managers identified any training needs their staff had and gave them the time and opportunity to develop their skills and knowledge. Staff had the opportunity to discuss training needs with the registered manager and were supported to develop their skills and knowledge. Staff told us there were opportunities to develop at the service. They told us the registered manager supported them to apply for and obtain specific qualifications.

Managers had an appraisal process in place to support staff to develop through annual constructive appraisals of their work. Staff had a review meeting after their probation then an annual review after that.

Staff were aware of incidents that occurred in other services because the registered manager received BMUS newsletters.

Multidisciplinary working

Staff worked together as a team to benefit women. They supported each other to provide good care.

The team worked well together and communicated effectively for the benefit of the women and their families. Although the registered manager had tried to develop a referral process with local maternity providers, this had not been successful.

We observed positive staff working relationships promoted a relaxed environment and helped put women and their families at ease.

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The registered manager was able to track non-invasive pre-natal testing samples from when they were received in the laboratory, when they were analysed and when the results were sent out. Women could share this information with their midwife if they chose. Staff would help women share the information if they were high risk.

Seven-day services

Early Life Ultrasound Centre was not an acute service and did not offer emergency tests or treatment, although they reminded women to call emergency services if necessary and gave women contact details of other NHS services available to them. This meant services did not need to be delivered seven days a week to be effective.

Services were supplied according to women's demand and the opening times varied each day to meet this demand. Services at the location were typically provided five days a week, including Saturdays. This offered flexible service provision for women and their companions to attend around work and family commitments. The service was open Monday and Wednesday mornings and evenings, Thursday evenings, Friday and Saturday mornings.

It was possible to book early pregnancy consultations, early pregnancy scan appointments, pelvic scan appointments and consultations with the consultant obstetrician and gynaecologist. These were available Tuesday and Friday evenings and Sundays.

Booking for appointments was available seven days a week, 24 hours a day using the provider's online booking system available to their website. Women could also contact the service via social media.

Health promotion

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

Information was available for women how to maintain good health in pregnancy. The registered manager used their social media outlets to provide guidance about healthy pregnancy, these were interactive so women could comment. For example, women were reminded to keep hydrated during the recent hot weather and given information about sun awareness for pregnant women. Women were advised to contact their maternity unit immediately if they thought their baby's movements had changed and/or reduced. This was in line with national recommendations (NHS England, Saving Babies' Lives: A care bundle for reducing stillbirth (February 2016)). Information was available in other languages.

The service provided clear information on their website that the scanning services they provided were not a substitute for the antenatal care pathway provided by the NHS.

Consent, Mental Capacity Act and Deprivation of Liberty Safeguards

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

Staff completed training in relation to consent and the Mental Capacity Act (2005), as part of their induction and mandatory training programme. There was a Mental Capacity Act (2005) policy for staff to follow, which clearly outlined

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the service's expectations and processes. Staff understood the relevant consent and decision-making requirements of legislation and guidance. The service followed the franchise policy relating to individuals who suffered from any condition covered under the mental capacity act (MCA). This detailed how staff should support women and ensure they acted in their best interests.

Staff gained consent from women for their care and treatment in line with legislation and guidance. Before their scan all women received written information to read and sign. This included information about ultrasound scanning and safety information and sharing information with other healthcare providers. There was also pre-NIPT (non-invasive pre-natal test) consent form which included terms and conditions, such as test limitations, referral consent and use of data.

Staff clearly recorded consent in women's records. Sonographers were responsible for obtaining the informed consent of women and completing ultrasound reports during the woman's appointment. A copy was provided to the woman to take away.

The phlebotomist ensured women understood the procedure for non-invasive pre-natal tests and what the results could mean before they asked for the woman's consent. Consent was obtained in line with current legislation and guidance. Where anomalies were found, the results were documented, and the phlebotomist sought the woman's consent to share the information with their maternity provider.

Staff understood the relevant consent and decision-making requirements of legislation and guidance, including the Mental Health Act, Mental Capacity Act 2005 and the Children Acts 1989 and 2004 and they knew who to contact for advice. Staff received and kept up-to-date with mandatory training on the Mental Capacity Act and Deprivation of Liberty Safeguards. Staff were aware of the providers policies for Mental Health. They understood how and when to assess whether a woman had the capacity to make decisions about their care.

Are Community health services for adults caring?

Good 

Our rating for this service stayed the same. We rated caring Good.

Compassionate care

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

Staff were discreet and responsive when caring for women. Staff took time to interact with women and those close to them in a respectful and considerate way. Staff were very passionate about their roles and were committed to providing personalised care.

Staff followed policy to keep women's care and treatment confidential. Staff ensured scans were conducted in a way that protected women's privacy and dignity. Staff kept the door to the scanning room shut during the scan to ensure women's privacy was maintained and women were covered throughout. The scan room door was lockable and was protected by a privacy screen outside, so if the door was opened it was not possible to see inside.

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Women consistently and emphatically said staff treated them well and with kindness. Staff were very warm, kind and welcoming when they interacted with women and their companions. Staff took time to interact with women and those close to them in a respectful and considerate way. For example, staff asked the woman's name upon arrival and would support them throughout their appointment. A chaperone was always present during transvaginal scans.

Feedback from women included, "Always have an amazing experience here, staff go out of their way to be kind and supportive" and, "Faultless. A fantastic service, we felt so comfortable and at ease." Comments also included, "Absolutely lovely experience!"

Women and their companions were also able to leave feedback on open social media platforms, which the registered manager frequently monitored. We reviewed a selection of reviews and found the service was very highly rated (five stars), and feedback was overwhelmingly positive. For example, responses included statements such as, "The staff were really friendly and put our minds at ease. Everything was explained really well and we left feeling very reassured."

Emotional support

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

Staff gave women and those close to them help, emotional support and advice when they needed it. The service held staggered appointment times; women booked at a time to suit them. Women completed an online booking form to provide information, so staff knew if there was a concern. Staff were mindful early scans held a higher risk of complications being identified. The sonographer gave women the option of starting the scan without the other screens in the room being turned on, especially if there was a child present. This meant if any anomalies were identified the sonographer could share the information in an informed, compassionate manner. Staff were calm and reassuring throughout the scan. The sonographer provided reassurance about the scan images and clearly explained what they observed. Women were told they could stop the scan at any time.

Staff undertook training on breaking bad news and demonstrated empathy when having difficult conversations. Staff supported women who received upsetting news. The sonographer delivered initial feedback to women and ensured they gave women more time and emotional support, for example, in the event of a scan revealing an anomaly or the lack of a heartbeat. Staff could offer women information referring them to their next medical steps, or signposted women to the miscarriage trust.

Staff understood the emotional and social impact that a woman's care, treatment or condition had on their wellbeing and on those close to them. The service's terms and conditions explained how it may be necessary to share information with healthcare providers.

Understanding and involvement of women and those close to them

Staff supported women, families and carers to understand their condition and make decisions about their care and treatment.

Staff made sure women and those close to them understood their care and procedures. Staff communicated with women and those accompanying them in a way they could understand. Staff adapted the language and terminology they used when performing the scan. They took the time to explain the procedure to ensure women understood. Family and friends were welcome in the scan room and there was one screen positioned on the wall in the scan room to ensure

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everyone could see the scan images. The registered manager told us during the COVID-19 pandemic they had restricted women to one visitor accompanying each woman, although these restrictions had been lifted and at the time of our inspection, up to six people could accompany the woman. Children were welcomed in the waiting area and the scan room.

Women and their families could give feedback on the service and their treatment and staff supported them to do this. Women and their partners felt they were fully involved in their care and had been given the opportunity to ask questions throughout their appointment. Staff took time explaining procedures to women before and during ultrasound scans and left adequate time for women and their companions to ask questions.

Staff supported patients to make informed decisions about their care. Staff made sure women were told about the different scans available and the costs associated with them. Staff reminded women they should attend their NHS appointments.

Women we spoke with were delighted with the service they received. Women told us they felt the service they received was 'excellent' and praised the staff highly. They told us staff were very friendly and kind and this made them feel very comfortable.

Are Community health services for adults responsive?

Good 

Our rating for this service stayed the same. We rated responsive as good.

Service delivery to meet the needs of local people

Women's individual needs and preferences were central to the delivery of tailored services and were delivered in a way to ensure flexibility and choice. The service also worked with others in the wider system and local organisations to plan care.

Staff planned and organised services, so they met the changing needs of people who used the service. People could access services and appointments in a way and at a time that suited them. The service had varied their opening hours depending on the appointments made and operated clinics five days a week including Saturdays. The service was flexible with the last appointment dependant on the number of bookings.

Managers planned and organised services, so they met the changing needs of the local population. At the time of our inspection, all scans were available. The service offered non-invasive pre-natal testing services and had a contract with an accredited laboratory.

Information about services offered at the location were accessible online. The service offered a range of ultrasound scans for pregnant women; such as early pregnancy or reassurance scans, endometrial lining scans for women having IVF treatment, well-being & growth scans. The service also provided gender scans, 3D or 4D scans and NIPT Harmony Testing. Staff gave women relevant information about their ultrasound scan when they booked their appointment. This included whether they needed a full bladder and when was the best gestation for their scan. Ultrasound scan prices were detailed on the service's website, and women paid a deposit for their scan when they booked their appointments and they were invoiced for the balance the day before their appointment.

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There was a proactive approach to understanding the needs and preferences of different groups of people and to delivering care in a way that meets these needs, which was accessible and promoted equality. This included people with protected characteristics under the Equality Act, and people who were in vulnerable circumstances or who have complex needs. The registered manager explained they had provided services for many same sex couples and the local area had people who spoke a variety of different languages.

Facilities and premises were appropriate for the services being delivered. The environment was appropriate for the service being delivered and was customer centred. The scan room was large with ample seating and additional standing room for several guests, and children of all ages were welcome to attend. The scanning room had one large wall-mounted screens and scan images were projected from the ultrasound machine. This enabled women and their families to view their baby scan more easily and from anywhere in the room. This was in line with recommendations (Royal College of Radiologists, Standards for the provision of an ultrasound service (December 2014)).

If a woman suffered a miscarriage before their appointment, staff would refund the deposit payment. Women were able to postpone their appointments if they phoned in advance of the appointment.

The registered manager monitored the waiting times for clinics with clinics running on time.

Meeting people's individual needs

The service was inclusive and took account of women's individual needs and preferences. Staff made reasonable adjustments to help women access services. They directed women to other services where necessary.

All staff ensured women did not stay longer than they needed to. Staff printed photos out for people to take with them.

All scans started with a wellbeing check. The sonographer always looked at the baby's movements, heartbeat, water, position, kidneys, stomach and placental position if the woman was past 20 weeks in her pregnancy.

The service specialised in providing antenatal scans for women from 6 to 40 weeks of pregnancy. Early pregnancy scans were available within the first trimester of pregnancy (7 to 12 weeks). From 16 weeks onward, well-being and growth scans were offered to monitor the growth, foetal weight and baby's position. Early gender scans were available from 15 weeks and 4 days, ranging from basic gender scan to 3D baby gender scans and gender reveal packages. Women who mostly wanted a scan for souvenir purposes had a well-being scan and could view their baby in 4D as well as 2D. NHS pregnancy scans show a two-dimensional image. A 4D scan enables women to see their baby moving as a 3D image. Appointments were available with the consultant obstetrician and gynaecologist. The service only provided private pregnancy ultrasound scans. They did not undertake any ultrasound imaging on behalf of the NHS or other private providers.

Women who wanted to find out the gender of their baby outside of their appointment, such as at a gender reveal party with their family and friends, had a range of gender reveal packages they could buy. The service offered women a range of baby keepsake and souvenir options which could be purchased. This included heartbeat bears which were offered after 16 weeks, a selection of photo frames, and gender reveal products such as scratch cards, footballs and shooting cannons. Heartbeat bears contained a recording of the unborn baby's heartbeat. Gender reveal cannons were the most popular. The sonographer could turn the screens off while looking for the baby's gender if parents didn't want to find out in the room.

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Access and flow

Women could access the service when they needed it. They received the right care and their results promptly.

All women self-referred to the service. Women could ask about scan appointments in person, by phone, by email or through the service's website and social media, but bookings were taken online. People could purchase a voucher so women could book a scan when they liked. During our inspection, clinics ran on time. Women were emailed a report if they needed to be referred to their midwife, hospital or GP. Women who did not need to be referred were given a printed copy of their report along with their scan images. Women could also purchase USB drives containing the information and images in electronic format.

The service had a foetal abnormality policy which detailed the process to follow if these were identified.

The registered manager audited response times for women having non-invasive pre-natal tests and results showed they received their results in the time frames agreed.

Learning from complaints and concerns

It was easy for women 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 women in the investigation of their complaint.

Women, relatives and carers knew how to complain or raise concerns. The service had an up-to-date complaints policy, which outlined procedures for accepting, investigating, recording and responding to local, informal, and formal complaints about the service.

The service clearly displayed information about how to raise a concern in patient areas. Staff understood the policy on complaints and knew how to handle them. Women could make complaints through the service's website or social media, as well as in person, by phone or email. The registered manager said they would attempt to deal with concerns at the time to resolve women's concerns. Staff asked women if they were happy with the service they received at the end of their appointments, this helped identify any potential dissatisfaction whilst the woman was still on-site. Staff asked women to provide feedback after their appointments to monitor customer's satisfaction.

The registered manager had a policy in place for investigating complaints and identifying themes. In the past year, there had been no complaints. The complaints policy stated how all complaints would be investigated and closed in a timely manner in line with the policy.

Staff could give examples of how they used patient feedback to improve daily practice. The service actively encouraged feedback, both in person, via email and open platform social media sites. The service had acted on feedback. For example, the registered manager had increased the range of souvenirs and keepsakes following a request for more items.

Early Life Ultrasound Centre's induction programme included a course on customer care and dealing with complaints which all staff had completed. All staff knew who to contact if they received a complaint.

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Are Community health services for adults well-led?

Good 

Our rating for this service improved. We rated well-led 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 women and staff. They supported staff to develop their skills and take on more senior roles.

The registered manager led the service and was also a director of the business. The registered manager was aware of the service's performance, limitations and the challenges it faced.

Staff informed us that the registered manager was very friendly, approachable, and effective in their roles. Staff felt confident to discuss any concerns they had with them; and were able to approach the registered manager directly, should the need arise.

Vision and Strategy

The service had a vision for what it wanted to achieve and a strategy to turn it into action, developed with all relevant stakeholders. The vision and strategy were focused on sustainability of services. Leaders and staff understood and knew how to apply them and monitor progress.

The registered manager had a plan to grow the business and a strategy how to achieve this. This included having the service identified on a well-known mapping service and updating the website. The registered manager had achieved an increase in the number of scans booked as a result. The registered manager had identified the next steps to take to grow the business; this included moving premises to a larger building, and this was planned in the near future.

The service had a clear vision and values which were focused on providing a first-rate service consistent with the provider's vision and values. The registered manager told us the key qualities for the service was that staff always showed empathy, kindness and compassion. Staff underwent extra counselling training on top of their existing medical ultrasound qualifications to achieve this. Staff were passionate about treating women with empathy and understanding and this led staff to make everyone's experience the best it could be. Feedback from women overwhelmingly praised staff for the friendly and supportive environment that surrounded them. Everyone we spoke with confirmed this and said they would highly recommend the service.

Culture

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

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Staff we met were friendly, welcoming and confident. Staff told us they felt supported, respected, and valued by their manager. They enjoyed coming to work and were proud to work for the service. We observed staff working well as a team. Staff were aware of the whistleblowing policy and could raise any concerns.

Staff completed equality and diversity training. Staff were encouraged to raise concerns openly and without fear of recrimination.

Governance

Leaders operated effective governance processes, throughout the service and with partner organisations. 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.

At our previous inspection in January 2020, we found two breaches of regulations because there was no programme of audit to identify how the service was performing and to identify areas for improvement and the service was not compliant with Schedule three of the Health and Social Care Act. At this inspection, we found the service had improved. The registered manager had a range of audits in place which ensured standards were monitored and staff files had all the required information.

We found a clear line of governance to communicate information throughout the service, and to also escalate and cascade information up and down lines of management and staff. Staff were clear about their roles and understood what they were accountable for and to whom. Staff could describe the governance processes for incidents and complaints and how they were investigated.

Staff were able to access the provider's policies both electronically and in paper format. The service had a system to ensure the paper versions were the most up to date.

The registered manager had an information governance policy, which staff were aware of. The registered manager provided feedback to staff through appraisals, daily staff huddles and electronically. Staff also benefitted from one-to-one meetings with the registered manager.

The registered manager provided feedback to staff about women's feedback, performance, compliance with policies and procedures, any clinic issues, audit results, staffing and rotas.

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. They had plans to cope with unexpected events. Staff contributed to decision-making to help avoid financial pressures compromising the quality of care.

The service had an online risk register and staff were aware of the risks. The registered manager told us the top concern had been around increased risks of infection during COVID-19 and had taken action to mitigate the risks. Other risks had been around equipment failure and business continuity. The service had a business contingency plan with identified actions to be taken in the event of an incident that would impact the service. For example, extended power loss, short notice staff sickness and equipment failure. The contingency plan included contact details of relevant individuals or services for staff to contact.

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The registered manager had an effective audit programme to provide assurance of the quality and safety of the service. Local audits, such as clinical and compliance audits were undertaken regularly; data was collected by the registered manager to monitor performance.

The registered manager had completed risk assessments for identified risks such as COVID-19, fire, health and safety and Legionella. Legionella is a bacterium that causes illnesses such as Legionnaires' disease or a fly-like illness. A standard template was used to ensure consistent information was captured. The risk assessments identified who or what was at risk, the hazards and their potential effects, existing control measures in place, the risk rating, whether the risk was adequately controlled, and additional control measures needed. Most of the risks were graded low and had adequate controls in place to minimise each risk. Staff were aware of the risk assessments because they had been circulated. All risk assessments were reviewed annually or sooner if indicated.

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.

The service was up-to-date with information governance and had data retention policies. These stipulated the requirements for managing patients' personal information in line with current data protection laws. The service was registered with the Information Commissioner's Office (ICO), which is in line with 'The Data Protection (Charges and Information) Regulations' (2018). The ICO is the UK's independent authority set up to uphold information rights.

Scan reports and images were backed up and retained for a period of 25 years, so that any issues following the scan could be identified and rectified. This information was clearly detailed in the terms and conditions of the service.

We saw that appropriate and accurate information was effectively processed, challenged and acted upon. Key performance, audit, and patient feedback data was frequently collated and reviewed to improve service delivery.

Engagement

Leaders and staff actively and openly engaged with women, staff and local organisations to plan and manage services. They collaborated with partner organisations to help improve services for women.

The registered manager engaged with women, families and staff and used the feedback to develop and improve the service they provided. Women and families were able to scan a barcode as they left the scan room to leave feedback. Sixteen responses had been left using this method, these all rated the service excellent. Questions included if the service had met their needs, how responsive they found the service, if women's privacy and dignity had been respected, the cleanliness of the service and if they would recommend the service. People were also able to leave feedback through well-known web-based applications, the service had strong five-star ratings across all media.

The staff survey from January to December 2021 showed staff strongly agreed they were satisfied with opportunities for professional growth, were happy with their training and development and were confident in the leadership. Staff said there was open and honest communication in the service, and they felt motivated.

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The registered manager had engaged with local businesses to share leaflets, such as baby massage, baby photographer and a baker for gender reveal cakes. The service also engaged with local shopkeepers and local antenatal classes.

Women and their families were asked to provide feedback when they visited. The service also used social media and internet reviews to obtain feedback from women and their families. Feedback included, “Cannot recommend Early Life enough! The lady explained everything in full detail. Was made to feel very welcome from the second we walked through the door. Lovely clean place. Very professional staff” and, “Absolutely amazing experience would definitely recommend.”

The registered manager had tried to develop close working relationships with local NHS hospitals.

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.

The service demonstrated a strong commitment to professional development. This included on-line and site based continuous professional development training for personal and professional growth. Staff attended baby life-line courses and British Medical Ultrasound Society (BMUS) lectures, as well as online conferences. One member of staff said, “We’re always studying. We enjoy what we do.”

The registered manager had acquired new premises and was in the process of fitting them out, with a view to moving premises in the coming months. This would not only provide bigger premises but would mean the registered manager could manage the layout to expand the services offered.

The service won the Private Healthcare Awards Most Trusted Ultrasound Practice South West England in 2021 and 2022.