

Window to the Womb

Quality Report

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This report describes our judgement of the quality of care at this location. It is based on a combination of what we found when we inspected and a review of all information available to CQC including information given to us from patients, the public and other organisations

Ratings

Overall rating for this location	Outstanding	\triangle
Are services safe?	Good	
Are services effective?	Not sufficient evidence to rate	
Are services caring?	Outstanding	\Diamond
Are services responsive?	Good	
Are services well-led?	Outstanding	\Diamond

Mental Health Act responsibilities and Mental Capacity Act and Deprivation of Liberty Safeguards

We include our assessment of the provider's compliance with the Mental Capacity Act and, where relevant, Mental Health Act in our overall inspection of the service.

We do not give a rating for Mental Capacity Act or Mental Health Act, however we do use our findings to determine the overall rating for the service.

Further information about findings in relation to the Mental Capacity Act and Mental Health Act can be found later in this report.

Summary of findings

Overall summary

Window to the Womb is operated by Sussex Baby Scans Ltd. The service provides a baby scanning service which includes early pregnancy scans and gender scans. We inspected diagnostic imaging.

We inspected this service using our comprehensive inspection methodology. We carried out an announced inspection on 10 July 2019.

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.

Services we rate

We have not previously rated this service. At this inspection we rated the service as **Outstanding** overall.

- We saw extensive positive feedback from women who had used the service; including from women who had received difficult news, and those who had previously experienced pregnancy loss.
- Staff were observed treating patients with dignity, kindness, compassion, courtesy and respect before during and after their scans.

- Leaders strived to deliver and motivated staff to succeed; personal and professional staff development was positively encouraged and there was a deeply embedded system of leadership development and succession planning.
- The service had the right staff with the right qualifications to undertake a safe service for women and their families. Staff understood their responsibilities to protect patients from abuse and there were systems to ensure concerns could be
- Equipment and the environment were clean, well maintained and accessible to all. The service recently re organised the reception and "print" room to enable a better flow of customers and provide a space that could be used as a quiet room if needed.
- As part of giving consent, women had to declare that they were receiving appropriate antenatal care from an NHS provider. When booking their appointment, women were advised to bring their NHS pregnancy records with them to their appointment for reference.
- There was an effective audit programme that provided assurance about the quality and safety of the service. Clinical and local compliance audits were undertaken regularly

However, we told the service they should continue to ensure that the keep records of any referrals in patient records that they hold at the location.

Nigel Acheson

Deputy Chief Inspector of Hospitals (South-East)

Summary of findings

Our judgements about each of the main services

Summary of each main service Service Rating

Diagnostic imaging

Outstanding



Diagnostic imaging was the only activity the service provided. We rated this service as outstanding because it was safe and responsive and showed outstanding characteristics in both caring and well-led. We do not rate the key question of effective.

Summary of findings

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Outstanding



Window to the Womb

Services we looked at

Diagnostic imaging

Background to Window to the Womb

Window to the Womb is operated by Sussex Baby Scans Ltd. The service opened in 2015. It is a private service, . The service operates under a franchise agreement with Window to the Womb (Franchise) Ltd. The service is an independent healthcare provider offering antenatal ultrasound imaging and diagnostic services to

self-funding or private patients aged over 16 years of age. The hospital primarily serves the communities of West and East Sussex. It also accepts patient referrals from outside this area.

The hospital has had a registered manager in post since 2015 when the service opened. This is the services first inspection since registering with the CQC.

Our inspection team

The team that inspected the service comprised of two CQC inspectors. The inspection team was overseen by Catherine Campbell, Head of Hospital Inspection.

Information about Window to the Womb

The service is registered to provide the following regulated activity

Diagnostic Imaging

During our inspection we visited all areas at the location this included the reception area, the scanning room, and the print room of the service. We spoke to all staff members employed by the service working that day. This included the registered manager, three scan assistants, director and sonographer. We spoke with six patients and relatives during our inspection and staff also provided us with feedback from patients who had used the service. During our inspection we reviewed eight sets of records.

In the reporting period January 2019 to July 2019 there were 1679 scans undertaken at the location. Of these 461 were FirstScan for women from six weeks to 15 weeks and six days of pregnancy and, 1218 were Window to the Womb scans for women 16 weeks or more. The service ran three evenings a week and at weekends according to demand.

Four sonographers, three team leaders, seven scan assistants (three of whom are also team leaders) and the registered manager were employed at the location.

Track record on safety

- No never events, clinical incidents or serious injuries
- Four complaints

There were no special reviews or investigations of the service ongoing by the CQC at any time during the 12 months before this inspection. This was the services first inspection since registration with CQC.

The five questions we ask about services and what we found

We always ask the following five questions of services.

Are services safe?

We have not previously rated this service. At this inspection we rated it as **Good** because:

- The service provided mandatory training in key skills to all staff and made sure everyone completed it.
- 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.
- The service controlled infection risk well. Staff kept themselves, equipment and the premises clean.
- The service had suitable premises and equipment and looked after them well.
- Staff completed and updated risk assessments for each patient and removed or minimised risks.
- The service had enough staff with the right qualifications, skills, training and experience to keep people safe from avoidable harm and to provide the right care and treatment.
- There were clear processes for staff to raise concerns and report incidents. Staff understood their roles and responsibilities to raise concerns and record safety incidents. Lessons learned were shared with the whole team and the wider service.

Good



Are services effective?

We did not rate the effectiveness of this service however:

- The service provided care and treatment based on national guidance.
- Managers monitored the effectiveness of care and treatment and used the findings to improve them.
- The service made sure staff were competent for their roles.
- Staff worked together as a team to benefit patients.
- The service provided a flexible service taking into account the needs of patients.
- Staff understood the importance of obtaining informed consent, and when to assess whether a patient had the capacity to make decisions about their care.

Not sufficient evidence to rate



Are services caring?

We have not previously rated this service. At this inspection we rated it as **Outstanding** because:

Outstanding



- Feedback from several sources was consistently excellent. There was significant feedback from patients, which was overwhelmingly positive, which confirmed staff treated them well and with kindness
- Staff provided emotional support to patients to minimise their distress working in partnership with them and their families.
- Staff involved individuals and those close to them in decisions about their care and treatment.
- To help ensure good standards of communication, scan assistants periodically assessed sonographers for their quality of customer care and service, standard of communication, and overall customer experience.

Are services responsive?

We have not previously rated this service. At this inspection we rated it as **Good** because:

- The service planned and provided services in a way that met the needs of local people.
- The service took account of patient's individual needs.
- People could access the service when they needed it.
- The service treated concerns and complaints seriously, investigated them and learned lessons from the results.

Are services well-led?

We have not previously rated this service. At this inspection we rated it as **Outstanding** because:

- Leaders had the integrity, 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.
- Leaders had an inspiring shared purpose and strived to deliver and motivate staff. The registered manager promoted a positive culture and all staff reported they felt respected, supported and valued. They were focused on the needs of patients receiving
- The service collected, analysed, managed and used information well to support all its activities, using secure electronic systems with security safeguards.
- There were consistently high levels of constructive engagement with staff and people who use services. The service engaged well with patients, staff and local organisations to plan and manage appropriate services and collaborated with partner organisations effectively.

Good



Outstanding



• The service was committed to improving services by learning from when things went well or wrong.

Detailed findings from this inspection

Overview of ratings Our ratings for this location are: Well-led Safe Effective Caring Responsive Overall **Outstanding** Outstanding Outstanding **Diagnostic imaging** N/A Outstanding Outstanding Outstanding Overall



Safe	Good	
Effective		
Caring	Outstanding	\Diamond
Responsive	Good	
Well-led	Outstanding	\triangle

Are diagnostic imaging services safe? Good

We have not previously rated this service. At this inspection 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 had clear expectations of the amount and frequency of mandatory training they had to complete in the mandatory training policy. Mandatory training included health and safety, equality and diversity, information governance, fire safety, infection control, safeguarding (adults and children).
- Staff also received some mandatory training specific to the service that they provided. For example, the 'Lone Person Policy' detailed the different behaviour and actions needed when a woman arrived on her own for a scan and a fetal abnormality was discovered.
- We saw an annual programme of mandatory training which showed a different training topic for staff to undertake each month Staff reported training was effective and that they undertook each topic's training session annually.
- Staff were given reminders when training was to take place and all training recorded on their staff record.
 We reviewed seven staff records that showed training was up to date.

 All registered managers attended an external mandatory training course provided by the Health and Safety Group. This was re-attended annually to ensure they were fully up to date with current legislation and practice.

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.
- The location's director was also the safeguarding service lead and was trained to level three in line with government expectations. All other staff were level two safeguarding trained in both adult and children's safeguarding which also met national guidelines
- The safeguarding policy was clear to understand and easily accessed. Staff were clear about their responsibilities and how to follow the correct process. However, there was a useful contacts list within the policy that had not been fully completed but we saw a safeguarding flow chart where the correct contact details had been listed including the local authority adult and child protection numbers.
- Staff appeared to be knowledgeable in the areas of Child Sexual Exploitation (CSE) and Female Genital Mutilation (FGM). We reviewed the FGM policy and saw emails from staff to record that they had read and understood the policy. Staff said they felt confident to raise a concern if required.



 There were signs displayed in the reception area offering a chaperone service. Staff were all chaperone trained. Staff we spoke to were aware of their responsibilities as a chaperone.

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.
- We saw several systems to ensure the service was meeting expectations including a compliance audit undertaken on May 10, 2019 (which showed almost 100% compliance across 81 checks), hand hygiene audits and risk assessments.
- Staff completed a daily cleaning log and undertook frequent (hourly) cleanliness visibility checks of clinical areas throughout their shifts. Any concerns were documented and remedied as necessary.
- Risk assessments for infection control identified risk of cross contamination between patients and ways to reduce this risk including washing of hands and equipment between patients and the use of disposable sheaths on probes.
- Staff had access to suitable handwashing facilities and cleaning equipment was stored correctly.
- During our inspection, we saw clinical staff were bare below the elbows and adhered to the World Health Organisation's (WHO) 'Five Moments for Hand Hygiene'. A recent hand hygiene audit showed 100% compliance (April 2019).
- No incidence of a healthcare acquired infection had been reported in last 12 months.
- Staff undertook training on infection control as part of annual mandatory training to ensure standards were maintained.
- Staff followed best practice guidelines in-line with the European Society of Radiology ultrasound working group in regard to appropriate cleaning procedures for ultrasound probes. They cleaned the probe with antibacterial wipes between patients.

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 environment was appropriate for the service.
- An external organisation provided the maintenance and servicing of the equipment. We saw records of the last service occurring in March 2019.
- Staff told us that should there be a technical problem with the scanning machine there was a 24-hour telephone support service available. This would aim to resolve issues within 24 hours of reporting any technical problems.
- There was first aid kit available in the staff kitchen. An incident book was available to record any instances where someone accessing the service may require first aid. In the event of an emergency staff told us that they would call 999 for assistance. There had been no incidents where staff needed to contact emergency services since the service's registration.
- The service had a property file, which contained key documentation. We saw that there was a health and safety policy, and managerial staff at the location had undertaken a range of environmental risk assessments. Risk assessments regarding legionnaires, fire safety and infection control had been undertaken.
- There was a 'control of substances hazardous to health regulations' (COSHH) cupboard. This was locked and there was an up-to-date folder detailing the products stored.
- At inspection, we saw fire extinguishers were accessible, stored appropriately, and had all been inspected and serviced within the date shown. Fire drills were held each month.

Assessing and responding to patient risk

 Staff completed and updated risk assessments (wellbeing reports) for each patient and removed or minimised risks. Staff identified patients at risk and acted quickly when they were at risk of deterioration.



- The service was clearly marketed as an "additional baby scan service that worked in parallel with the NHS." Patients were made aware that the service did not provide any clinical diagnostics. We saw written information provided by the service strongly advised women to attend scans as part of their NHS maternity pathway and we saw staff advising patients to continue with their NHS scans.
- As part of giving consent, women had to declare that they were receiving appropriate antenatal care from an NHS provider. When booking their appointment, women were asked to bring their NHS pregnancy records with them to their appointment for reference.
- The service ensured there would be follow up if an abnormality detected. As part of consent taking processes at the service, women agreed to the service contacting NHS antenatal healthcare providers (such as GPs or NHS antenatal services) should a potential anomaly or concern be found.
- Staff offered to call NHS antenatal care providers on behalf of patients, to refer them and explain potential findings. Staff said this helped to ensure continuity of care and helped limit any distress. We saw accompanying written reports and scan images were provided to NHS antenatal healthcare providers, as appropriate.
- The service collected information before scans to identify and manage patient risk. Sonographers were required to indicate and document their work contact details and Health and Care Professions Council (HCPC) or Nursing and Midwifery Council (NMC) registration number on the referral form.
- A different pre-scan questionnaire was in use at the Firstscan service. This required women to provide GP details, and the details of their local NHS hospital. Women were also required to provide pregnancy information; for example, number of previous pregnancies, any ectopic pregnancies, and miscarriages, date of last menstrual period, and date of first positive pregnancy test.
- The service only provided ultrasound scans to women over 16 years of age. Women aged 16 or 17 years of age, were required to attend with a responsible adult (for example, someone with parental responsibility).

- Most women attended with hospital notes so their date of birth could be verified; if they arrived without notes they would be asked to prove their age if the staff were in doubt.
- Prior to the scan staff asked the patient if they had been feeling unwell or experienced any pain or bleeding. If the patient said they had experienced any symptoms then they were referred to their midwife or hospital for further investigation and the scan would not go ahead.
- There was also a log of all scans completed and the number of referrals and reasons for these referrals.
 From 1 January 2019 to the 1 July 2019 there were 33 referrals from the FirstScan clinic, 16 of these were
 Pregnancy of unknown location (PUL). Pregnancy of an unknown location is defined as the situation when the pregnancy test is positive but there are no signs of intrauterine pregnancy or an extrauterine pregnancy via transvaginal ultra-sonography. In the same time period there were four referrals from the Window to the Womb clinic.
- Guidance documents contained contact numbers for local hospital antenatal care providers. If the sonographer suspected higher-risk conditions or concerns (such as, placental abruption or an ectopic pregnancy) they were instructed to immediately dial 999 for emergency assistance.
- The service also employed two consultant advisors who were contactable for advice and for ratification of policies and documents as needed.

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.
- Four sonographers, three team leaders, seven scan assistants (three of whom were also further trained to be team leaders) and the registered manager were employed at the location. We saw evidence that they worked in shifts and there was a minimum of four staff on shift at any time, in line with the staffing policy.



- At the time of our inspection there was no plans to recruit more staff. However, there was a recruitment policy should the company, or demand for the service, grow.
- A scan assistant always accompanied the sonographer in the scan room. The reception desk was continually manned, and a second scan assistant helped with printing of photos and downloading of images, alongside signposting women if they needed further assistance with anything.

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.
- Paper copies of patient records were kept in a secure filing cabinet within the scan room. Records were kept for 30 days before being transferred to secure off site storage. Notes were clear and completed in line with the policy requirements of the provider.
- The service retained a copy of the scan report in case they needed to refer to the document in future. The service retained a digital copy of scan images for a period of 30 days, to rectify any issues following the scan.
- Pre-scan questionnaires and consent forms at the service ensured enough information was obtained from women prior to their scans; for example, in relation to number of weeks pregnant, and number of previous pregnancies. Women were also required to declare medical conditions that might affect their scan.
- It was highlighted in a recent internal audit (March 2019) that referral notes were given to women to take to the appropriate service (for example an early pregnancy unit), but the service did not retain a copy of the referral for their records. Since this matter had been raised we saw referrals formed part of the women's notes.

Medicines

 The service did not prescribe, administer, record or store medicines.

Incidents

- The service managed patient safety incidents well. Staff recognised and reported incidents and near misses. 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 reported all incidents to the registered manager or team lead. There was an incident book which all staff could access.
- The registered manager was responsible for reviewing and conducting investigations into all incidents at the location. We saw evidence this was then sent in a monthly incident report to the franchisor for review.
- We saw learning from incidents was shared with staff, at team meetings and through service circulars. For example, the provider produced a staff newsletter called 'Open Window' which outlined any learning from incidents and shared learning from complaints.
- Staff we spoke with said they would be open and honest with patients should anything go wrong and give patients suitable support. Staff could explain the process they would undertake if the needed to implement the duty of candour following an incident.
- The registered manager explained that services within the wider franchise also shared learning from incidents and events through the national network.
- In the reporting period, there were no patient deaths, never events, serious incidents at the location. In the same period, there was no duty of candour notifications.

Are diagnostic imaging services effective?

We did not rate the effectiveness of this service however:

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.



- 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). Staff were aware of how to access this information.
- The registered manager was responsible for the management of policies and procedures and their compliance
- Staff worked to "As Low as Reasonably Achievable"
 (ALARA) guidelines. As Low as Reasonably Achievable is defined as a fundamental approach to the safe use of diagnostic ultrasound using the lowest output power and the shortest scan time possible. During our inspection staff were witnessed to be working within these guidelines when undertaking an ultrasound scan.
- There was an effective audit programme that provided assurance about the quality and safety of the service. The service undertook clinical and local compliance audits regularly; for example, with respect to patient experience, cleanliness, health and safety, ultrasound scan reports, equipment, and policies and procedures. Additional assurance was provided by external audits undertaken by the franchisor.

Nutrition and hydration

- Food and drink were available in response to patients' needs.
- Due to the nature of the service food and drink were not routinely available but staff could offer patients refreshments if clinics were running late or if the need arose
- 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.

Pain relief

 Staff assessed and monitored patients regularly to see if they were in pain. Staff asked women if they were experiencing pain and apologised for the pressure of the ultrasound on the women's stomach. Staff regularly checked during the scan that the woman was comfortable.

Patient outcomes

- Staff monitored the effectiveness of care and treatment. They used the findings to make improvements and achieved good outcomes for patients
- The registered manager had overall responsibility for governance and quality monitoring. The service used key performance indicators to monitor performance, which were set by the franchisor. This enabled the service to benchmark themselves against other franchised clinics. Data was collected and reported to the franchisor every month to monitor performance. This included information about the number of ultrasound scans completed including the number of rescans and referrals made to other healthcare services.
- From1 January 2019 to 1 July 2019 the service had referred 33 women to antenatal (NHS) care providers due to the detection of potential concerns.
- Window to the Womb services at the location reported a success rate of 99.8% in correctly identifying a babies' gender.
- The service offered a rescan guarantee for when it was not possible for the sonographer to confirm the gender of the baby at the time of the appointment. If the woman received incorrect information with regards to their baby's gender, they were offered a complimentary 4D baby scan. From 1 January 2019 to1 July 2019 there were no re-scans reported.
- Any reason for a referral was recorded on the patients record form and clearly explained to the patient.
 Records of patients who had been referred were stored in a separate folder in a locked filing cabinet.
 This meant that managers could monitor the number of patients that had been referred to other services to ensure the correct process had been used.

Competent staff



- The service made sure staff were competent for their roles. Managers appraised staff's work performance and observed their practice to provide support and development.
- Staff underwent a comprehensive induction and probationary period. They were observed by the registered manager and assessed as able to work via a checklist of requirements. All new staff were given an introductory pack to include polices and scan protocols. We saw records of this in seven staff files that we reviewed on inspection.
- New sonographers worked with an experienced sonographer who assessed their skills and adherence to protocols. We were told this process lasted as long as it was needed. During these sessions, the registered manager acted as scan assistant to help assess progress and readiness to practice without supervision. The registered manager was then assigned as scan assistant for at least the first appointment reviewed their scans for the first few sessions thereafter.
- Sonographers were also assessed by either the local assessor or a clinical lead during the induction process and a quarterly quality check was carried out by the local assessor, we saw this documented in staff files.
- Staff attended quarterly training evenings to ensure they were competent, and that learning was embedded. During these sessions staff undertook quizzes to help embed their learning and understanding of key policies. These sessions were generally developed and led by the registered manager with support from others as required.
- If a sonographer needed refresher training, this was provided on a case by case basis.
- Unusual findings were also shared with the sonographer team and across the wider franchise network to aid learning and for training purposes.
- We reviewed seven staff files, all contained a curriculum vitae, records of recruitment, interview and selection processes, references from previous employment, employment contract, and Disclosure and Barring Service (DBS) checks, as required by current regulations.

- It was company policy for all sonographers to be registered with a professional regulatory body. We reviewed staff files and saw all sonographers were fully qualified and were Health and Care Professions Council (HCPC), and/or The Society of Radiographers (SOR) and the American Registry for Diagnostic Medical Sonography (ARDMS).
- Appraisals were held annually and included supervised practice and clear objectives to work towards. We saw records of these in staff files.
- Additional training was also offered towards their Continuing Professional Development (CPD). Staff could access further learning and attend training courses relevant to the service provided and their role.
- At the time of inspection staff were seen to be adhering to their scope of practice.

Multidisciplinary working

- Healthcare professionals worked together as a team to benefit patients. They supported each other to provide good care.
- Staff told us the service had good relationships with local hospitals and maternity services as well as local safeguarding specialists should they need to refer someone to them. They could contact the services by telephone and make appointments on behalf of the patients who needed them.
- During our inspection, we observed positive examples of the registered manager, director, sonographer and scan assistants working well together.

Seven-day services

Services were supplied according to patient demand.
 This meant the location was not necessarily open seven days a week. Services at the location were typically provided on Tuesday, Wednesday and Thursday evenings, and Saturday and Sunday during the day. This offered flexible service provision for women and their companions to attend around work and family commitments.

Health promotion

 The service promoted opportunities for healthy living.



• The service offered women patient information leaflets 'Information for mums to be', which detailed information about keeping healthy, foods to avoid, health promotion questions to ask their midwife for example, provision booking of flu jabs, and breastfeeding support, and information about normal baby movements after 24 weeks of pregnancy.

Consent and Mental Capacity Act

- Staff supported patients to make informed decisions about their care and treatment. They followed national guidance to gain patients' consent.
- All information about the scans were included in the service's consent forms. The consent forms set out what they would and would not do. The consent form explained what a 4D scan was, if 4D scanning is safe, that the service was not looking for abnormalities and what to expect from the scan. The consent form also asked for additional information for example, did the patient want to know the gender of their baby.
- There was a Mental Capacity Act (2005) policy for staff
 to follow, which clearly outlined the service's
 expectations and processes. Staff completed training
 in relation to consent, and the Mental Capacity Act
 (2005), as part of their induction and mandatory
 training programme. Staff told us that if they were
 unsure if a patient using the service had capacity then
 they would speak to the registered manager and the
 scan would not be carried out. Sonographers we
 spoke with could give examples of when and how they
 might assess mental capacity

Are diagnostic imaging services caring?

Outstanding



We have not previously rated this service. At this inspection we rated caring as **outstanding.**

Compassionate care

- Staff treated patients with compassion and kindness, respected their privacy and dignity, and took account of their individual needs.
- Staff were observed treating patients with dignity, kindness, compassion, courtesy and respect before

- during and after their scans. During our inspection we observed two scans, one consent and payment procedure and a discharge. Staff remained professional throughout and ensured that women understood the next steps.
- The service gave 15 to 30-minute timeslots for appointments. Staff told us this was done to ensure privacy and dignity was maintained and to allow patients more time if bad news was delivered.
- All conversations took place in a private room. If a scan
 was not successful or unable to determine the gender
 a free second scan was offered, both directors had the
 authority to do this.
- During our inspection, we spoke to three patients and their companions. All patients and companions we spoke with during our inspection described the service positively. For example, one lady reported her experience was "lovely, so nice, they talked us through everything."
- Patients and their companions were also able to leave feedback on open social media platforms, which the registered manager said were frequently monitored. We reviewed a selection of reviews (from the several hundred available) and found the service was very highly rated, and feedback was overwhelmingly positive. Recent reviews on one online review service rated the 8.8/10 from 473 reviews.
- Feedback forms were given to everyone to fill out after their scan was completed. We reviewed over 100 feedback forms from January up to July and all rated the service as five out of five.

Emotional support

- Staff provided a strong visible person-centred culture, providing emotional support to patients, families and carers to minimise their distress.
 - They understood patients' personal, cultural and religious needs.
- The service separated clinics into two categories: the Firstscan clinic, which specialised in early pregnancy scans; and the Window to the Womb clinic, which offered later pregnancy scans.
- Clinics purposely ran at different times to ensure that women who had experienced pregnancy loss or were



anxious about their pregnancy did not share the same area with women who were much later in their pregnancy. We also saw that staff removed purchasable items, such as heart beat bears, out of the waiting area before the Firstscan clinic commenced.

- There were high levels of emotional support available to women and their companions. Scan assistants acted as chaperones, to ensure women felt comfortable and received optimum emotional support.
- Staff told us they gave patients as much time as they required if they became distressed and would be supported and have time to ask questions and arrange follow up appointments with their midwife or hospital if needed. Staff told us they would ensure patients privacy was maintained by keeping them in the scan room and completing all documentation before leaving the room or moving them to the print room which could be utilised as a quiet room.
- Staff were understanding to the needs of patients and listened to any concerns that they had. These were answered appropriately, and reassurance given when needed. Patients were encouraged to contact their GP or midwife if they had any concerns and to attend their NHS scans.
- Staff had been trained on the emotional aspects of receiving bad news. We saw this documented in staff files. Patients are given information on counselling services should they need them.
- We reviewed written feedback from parents who had received difficult news and had been referred to NHS antenatal care providers.
- The service worked with a local bereavement charity to offer women a discounted scan for women falling pregnant following a previous loss. These women are also offered a free "Heart beat Bear" where the babies' heartbeat is recorded on a device which is placed inside a teddy bear for mothers to hear.
- The franchisor also offers a confidential line to staff should they wish to discuss anything that has affected them.

Understanding and involvement of patients and those close to them

- Staff supported and involved patients, families and carers to understand and make decisions about their care and treatment.
- During our inspection staff were seen interacting with patients in a respectful way and acknowledged family members when they were there. Patients and their partners or relatives were welcomed by staff and there was enough room to accommodate up to five people in the clinic.
- The service displayed their scans and packages with pricing on their website and confirmed at the time of booking. They took payment in the reception areas while patients waited for their appointment and completed their consent form. Staff then took them to the scanning room. We saw this process being carried out at the time of inspection.
- We observed that staff took time explaining procedures to women before and during ultrasound scans and left adequate time for patients and their companions to ask questions and have these satisfactorily answered.
- Patients we spoke with at inspection said that they
 had received detailed explanations of scan procedures
 and accompanying written feedback. Staff told us that
 patients were always told when they needed to seek
 further advice and support. Staff told us they always
 ensured their patient knew how to access other
 agencies for support before leaving the clinic.
- To help ensure good standards of communication, the registered manager periodically assessed sonographers for their quality of customer care and service, standard of communication, and overall customer experience. We reviewed three of these that all reported positively on the staff interaction.
- The franchisor had developed a smart device application "Bumpies" which allowed women to securely view their scan images and videos remotely. The application enabled women to share their images and video to social media sites, or other individuals, as they so wished.

Are diagnostic imaging services responsive?





We have not previously rated this service. At this inspection we rated responsive 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.
- The service offered a private scan service that complemented the NHS maternity pathway. The service offered a range of ultrasound scans for pregnant women; such as wellbeing, viability, growth, presentation, 4D and gender scans. Information about services offered at the location were accessible online.
- Clinics were separated so women who are in earlier stages of pregnancy had appointments within a FirstScan clinic (six weeks to 15 weeks and six days). The 'Window to the womb' clinic ran on separate days and offered later pregnancy scans.
- All appointments could be pre-booked by the user via an online booking system several months in advance.
 Patients could also book over the phone which enabled staff to advise on which service best suited their needs.
- There was a comfortable large seated waiting area in the main reception of the service. There was play equipment available for children including changing facilities and a television screen. Children were allowed in the scanning room but as we inspected during a Firstscan clinic there were no children present.
- There was a display of other products the service offered at an extra cost such as, gender reveal packages and heartbeat bears.
- The service had street parking around the location that was free most of the times that clinics ran.

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.

- The service offered a translation package which was accessible through an on-line system. This translated pre-completed information out loud, such as what to expect from your scan, and if issues arise, alongside free text interpretation. The system could also be used for patients who were visually impaired as it could read out loud any information the staff may need to express.
- The building and the clinic were accessible for those with a disability. The clinic was based on the ground floor. There was lots of space within the reception area and the scanning room for a wheelchair.
- The registered manager told us there was some flexibility to extend clinic hours for customers whose appointment may be time critical.
- All staff had completed training on equality and diversity and we reviewed a policy in relation to this. The service was inclusive to all pregnant women and we saw no evidence of any discrimination, including on the grounds of age, disability, pregnancy and maternity status, race, religion or belief and sexual orientation when making care and treatment decisions.

Access and flow

- People could access the service when they needed it.
- All women self-referred to the service and scans were arranged by appointment only. The service offered several different booking methods. Women could book their scan appointments in person, by phone, or through the service's website. The franchise had also developed a secure smart device application, "bumpies"; which had an appointment booking facility.
- Staff told us they left enough time in-between appointments to avoid the reception area being crowded. They allowed enough time to discuss any issues or make referrals if required. During our inspection, patients were seen on time. Staff told us if there was to be a delay staff kept the other patients informed in the waiting room and advised them of any delays and apologised.
- The service recently reorganised the reception and print room to enable a better flow of customers and a



space that could be used as a quiet room if needed. They reported this worked much better especially when large numbers of friends and family accompanied women.

- Women's details were entered on the electronic system before they entered the scan room to make their welcome smoother and more personable.
- At the time of our inspection, there was no waiting list or backlog for appointments. From January 2019 to July 2019, the later pregnancy (Window to the Womb) service performed 1218 ultrasound scans. The early pregnancy (Firstscan) service had performed 461 scans.
- Patients we spoke with at the inspection were positive about the availability of scans and said that they had received suitable appointments in a timely fashion. We also saw this reflected in written feedback we reviewed. During our inspection we observed that clinics ran on time.
- In the reporting period, no planned appointments were cancelled for a non-clinical reason; such as breakdown of equipment.

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.
- All complaints went to the registered manager, who dealt with them in line with their own complaints policy which had been reviewed in the last 12 months. Both directors of the service investigated all complaints.
- The complaints policy included details for responding to any complaint, timescales within which to respond, and any escalation process should the service user not be satisfied.
- Service users could make complaints in person, via social media and via email. Staff also asked customers post scan if they were happy with the service and aimed to identify any potential dissatisfaction whilst patients were still on site.

- The service monitored social media feedback daily.
 Women or their companions that complained through social media were contacted directly by the registered manager or team lead via telephone where possible, to listen to the concerns and identify anything the service can do to rectify these.
- Information about how to make a complaint was included on the reverse of the feedback form that all patients received. Information was also included in the terms and conditions on the reverse of the fetal wellbeing report/consent form.
- We reviewed four complaints from the previous twelve months including one received via social media. We saw examples of learning from complaints, including changes in practice and procedure resulting from a complaint. These were shared across the franchise.
- All complaints we reviewed were managed in line with the policy timescales. We saw investigations were appropriate and responses sensitive to the patient's needs.
- Patients were advised were to escalate their complaints in they were unhappy with the providers response, this was also detailed on the back of the feedback forms and patient consent forms.

Are diagnostic imaging services well-led?

Outstanding



We have not previously rated this service. At this inspection we rated well led as **outstanding.**

Leadership

- Leaders had the integrity, 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 registered manager had an in-depth understanding of the service's performance, challenges, and priorities; and insight of wider developments in diagnostic and ultrasound practice.



- Scan assistants reported to the team leader on a day-to-day basis. However, the registered manager had ultimate responsibility for oversight of all staff at the service. The sonographers reported to the registered manager for matters of administration and to the lead sonographer for clinical matters. The lead sonographer was available for advice and could review any ultrasound scans remotely.
- Managers and staff had positive relationships with each other and had good inclusive working relationships. We saw that staff respected each other's opinion and all worked together to support women throughout the scanning process.
- Staff were encouraged to progress, and three members of staff had had further training to allow them to be team leaders. This meant they could run the clinics in the absence of the registered manager.
- · We saw and heard from staff the

Vision and strategy

- The service had a vision for what it wanted to achieve and a strategy to turn it into action. The vision and strategy were focused on sustainability of services and aligned to local plans within the wider health economy. Leaders and staff understood and knew how to apply them and monitor progress.
- The service aimed to provide "high quality, efficient and compassionate to customers and their families, through the safe and efficient use of 2D/3D/4D non-diagnostic ultrasound imaging technology".
- The service had a realistic strategy which was developed by the directors and included input from the registered manager. The service aimed to set the standard for 4D baby scanning, by providing an exceptional quality service.
- Staff we spoke with could state, and understood, the service's aims and ethos of the service's vision and value. We heard from the registered manager that staff who did not meet embrace the visions and values did not pass their probationary period.

- The services values centred around seven themes:
 Focus, Dignity, Integrity, Privacy, Diversity, Safety and Staff. Staff we observed demonstrated these values and all understood the role they had in ensuring that the patients visit exceeded their expectations.
- Senior staff at the service we spoke with said that they
 had been approached by NHS commissioners, to
 provide ultrasound scanning services, which formed
 part of their strategy moving forward.

Culture

- Leaders had an inspiring shared purpose and strived to deliver and motivate staff. 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.
- We observed strong collaboration, team-working and support across all functions of the service; and a common focus on improving the quality and sustainability of care and people's experiences. For example, sonographers peer-reviewed and appraised each other's clinical practice, and scan assistants periodically reviewed the patient-centredness and quality of sonographers' communication techniques.
- Staff told us they had pride in what the company had achieved so far since their registration and enjoyed coming to work. All staff strived to give the best service possible. The service highly valued patient feedback, which could be provided through a variety of channels; and used this to improve patient experience.
- The service promoted equality and diversity which was also included in staff induction and mandatory training. Staff told us they were mindful of their service being accessible to all.
- Staff were seen to take the well-being of their colleagues in to account by offering drinks to each other. Staff said they were happy to support each other when required.
- Staff were encouraged to raise any concerns with the franchisor if they did not feel they could raise this with



clinic registered manager. This was detailed within the 'Freedom to Raise a Concern' policy. Staff told us they worked collaboratively and could raise concerns. Staff would "troubleshoot" at the time if there was a concern or uncertainty.

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.
- Governance arrangements across the franchise were proactively reviewed by franchise directors to help ensure these reflected best practice. The registered manager also reviewed all new policies and made suggestions for changes which they said were listened to and acted upon.
- There was an effective audit programme that provided assurance about the quality and safety of the service.
 eanliness, health and safety, ultrasound scan reports, equipment, and policies and procedures.
- Additional assurance was provided by external audits undertaken by the franchisor. For example, we reviewed a record keeping audit which highlighted that the referral notes were not being retained. This was immediately rectified showing the service acted promptly when concerns were identified.
- The registered manager had overall responsibility for clinical governance and quality monitoring. This included investigating incidents and responding to patient complaints. The registered manager was supported by the franchisor and attended biannual national franchise meetings, where clinic compliance, performance, audit, and best practice were discussed.
- Incident reporting and associated processes ensured the service investigated and learnt from critical incidents, both at the location and in the wider service.
- There were systems that ensured staff were, and remained, competent for their role. These included supervision of practice, appraisal and access to further training,

Managing risks, 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.
- The service had carried out numerous risk assessments. Examples of risk assessments included, spread of infection by direct contact, fire and slips and trips. We saw there were changes to practice after these risk assessments; for example, the relocation of a fire door that was not considered wide enough.
- Although the service did not have a risk register risk was discussed at monthly meetings and risk assessment undertaken or revised as needed.
- Sonographer peer review audits were undertaken in accordance with recommendations made by the British Medical Ultrasound Society, and the franchisor completed annual sonographer competency assessments.
- There were appropriate policies regarding business continuity and major incident planning, which outlined clear actions staff needed to take in the event of extended power loss, a fire emergency, severe weather, or other major incident. We saw these were audited in May 2019 compliance audit. This highlighted that there was not emergency lighting in the clinic. We saw emails with quotes for work to rectify this whist on inspection.

Managing information

- 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.
- Patients were provided with the terms and conditions of the service. These were outlined on the back of the consent form which was compulsory for all patients to sign prior to having an ultrasound scan. Patients were advised of the cost and payment was made at reception. Costs of scans were clearly outlined on the service's website. Payment methods and processes were discussed at the time of booking.



- The service held minimal data on those who used the service. However, they held most data as paper records which were kept in a locked filing cabinet inside the scan room.
- There were arrangements in place to ensure information used to monitor and manage quality and performance was accurate, valid, reliable and relevant. At the time of inspection, there had been no data security breaches since the service's registration.
- Appointments were booked using an electronic booking system. The computer used was password secured and to maintain confidentiality was positioned in the reception area in way that wasn't seen by others.
- Key performance, audit, and patient feedback data was frequently collated and reviewed to improve service delivery.
- The registered manager was the information governance lead for the service. Staff at the service had all completed information governance training.
 We saw that paper documents were securely stored in lockable filing cabinets, and computers were password protected. The service was General Data Protection Regulation (GDPR) compliant.
- 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. The franchise was also General Data Protection Regulation (GDPR) compliant.

Engagement

- Leaders and staff actively and openly engaged with patients, staff, equality groups, the public and local organisations to plan and manage services. They collaborated with partner organisations to help improve services for patients.
- Feedback from service users and partner organisations was welcomed and seen as a vital way of improving service provision and quality. The service

- actively encouraged patients to provide feedback; and patients could provide verbal feedback and leave written reviews on comment cards at the service, via email and on open social media platforms.
- The service had effective relationships with the local safeguarding team, early pregnancy units at local hospitals and midwives. All sonographers at the service also worked for local NHS trusts and nurtured good relationships with them.
- We reviewed team meeting minutes and saw that patient feedback (such as, complaints, concerns and compliments) were discussed with the team during staff meetings. Team meeting minutes were circulated by email and a paper-copy was available for staff to view at the location if they were unable to attend.
- The franchisor produced a monthly newsletter called 'Open Window'; which included new developments and important updates; such as, new clinics that had opened, changes to training delivery, and best practice developments.
- Managers constantly monitored feedback through a variety of social media platforms and email. They adapted the service where necessary. These were reviewed and discussed at monthly team meetings
- We saw evidence that staff engaged in team meetings and that when available, sonographers attended these. For staff members unable to attend, meeting minutes were available.

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.
- Innovation was celebrated. There was a clear, systematic and proactive approach to seeking out and embedding new and more sustainable models of service delivery and care. For example, the service made use of a smart device application
- Staff told us they worked together to share innovative ideas and implement changes to improve the service.
 The franchisor produced video training logs (VLOGs), these were used as additional training and continuing professional development tools for sonographers, and



scan assistants who wanted to learn more about sonography. These could also be accessed by external organisations like local NHS trusts to encourage shared learning.

- The service invested in its equipment to provide the best possible service. A new ultrasound scanning machine was purchased in the last 12 months to improve the quality of images that were produced. As a result, the service had changed gender scans from 16 weeks and 3 days to 16 weeks and 0 days. This has
- given patients the opportunity to know the gender sooner. The scanning machine had reduced the need for client to return due to image quality for example for women with high body mass index (BMI).
- The service recently reviewed and changed their scanning the protocols after receiving a complaint from a patient. Even though after investigation there had been no fault of the techniques used, the franchisor in consultation with the clinical lead took the decision to improve the protocol which was then rolled out across all franchisee locations to ensure that this did not present a risk in the future.

Outstanding practice and areas for improvement

Outstanding practice

- The service demonstrated a commitment to ensuring patients expectations were exceeded.
 Feedback from several sources was overwhelmingly positive.
- The needs of women who may be experiencing loss were considered, with clinics running at different times depending on the stage of pregnancy. A quiet room was also available, and staff were able to spend as much time with the women as needed.
- Leaders strived to deliver and motivated staff to succeed; personal and professional staff development was positively encouraged and there was a deeply embedded system of leadership development and succession planning.
- We observed strong collaboration, team-working and support across all functions of the service; and a

- common focus on improving the quality and sustainability of care and people's experiences. For example, sonographers peer-reviewed and appraised each other's clinical practice, and scan assistants periodically reviewed the patient-centredness and quality of sonographers' communication techniques.
- The service offered a translation package which was accessible through an on-line system. This translated pre-completed information out loud, such as what to expect from your scan, and if issues arise, alongside free text interpretation. The system could also be used for patients who were visually impaired as I could read out loud any information the staff may need to express.

Areas for improvement

Action the provider SHOULD take to improve

 The provider should continue to ensure that all referral records are kept with patient notes within the service location.