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	Good
Are services safe?	Good
Are services effective?	
Are services caring?	Good
Are services responsive?	Good
Are services well-led?	Good

Overall summary

Window to the Womb is operated by DJC Studios Ltd. The service operates under a franchise agreement with Window to the Womb. The service is provided through a ground floor clinic with direct access from the high street. Facilities include one scan room, a reception and waiting area, and toilet. The scan room contains an ultrasound machine, medical couch, sofa, computer on wheels, sink and projector.

Window to the Womb offer a wide variety of gender scans, 3D and 4D ultrasound scans. They provide diagnostic obstetric ultrasound services for pregnant women (aged 16-65) from six weeks to full term. We had not previously inspected this location. This was the 25th clinic inspection for the franchise nationally.

We inspected this service using our comprehensive inspection methodology. We carried out the short notice announced part of our inspection on 3 March 2020.

Summary of findings

To get to the heart of women's 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 service understood and complied with the Mental Capacity Act 2005.

Services we rate

We had not previously rated the service. We rated it as **Good** overall.

- Leaders operated effective governance processes, throughout the service and with partner organisations. We reviewed 25 policies which were up to date and within review date. Franchise policies were adapted to provide effective guidelines for each clinic location.
- Leaders and staff actively and openly engaged with women, staff, the public and local organisations to plan and manage services. The service used feedback cards to obtain feedback from women and their families. We checked 116 feedback cards. The service had made changes as a result of women's feedback.
- All staff we spoke with told us they felt supported, respected, and valued. They were focused on the needs of women receiving care. Staff enjoyed coming to work and were proud to work for the service.
- 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. All staff received a comprehensive induction. Scanning assistants completed a training and induction programme including chaperone training. Sonographers received a full induction which included working alongside a currently employed sonographer.
- 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.
- The service provided mandatory training in key skills to all staff and made sure everyone completed it. Staff were up to date with their mandatory training. At the time of our inspection, 100% of staff had completed their mandatory training.
- Staff understood how to protect women from abuse and the service worked well with other agencies to do so. The clinic had clear safeguarding processes and procedures in place. All clinic staff were trained to at least safeguarding level two for both vulnerable adults and children.
- 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.
- The service treated concerns and complaints seriously. If a complaint was received the registered manager would complete a comprehensive investigation and share lessons learnt with all staff.
- Staff treated women with compassion and kindness, respected their privacy and dignity, and took account of their individual needs. Staff were caring, compassionate, kind and engaged well with women and their families.
- Women could access services and appointments in a way and a time that suited them. The service used technology innovatively to ensure women had timely access to ultrasound scans.

We found the following areas of outstanding practice;

- Staff provided emotional support to women, families and carers to minimise their distress. The service had organised separate clinic lists to ensure women who may have had an early miscarriage were not sat waiting with heavily pregnant women. Separating the clinics meant if a woman received bad news, they did not have to share a waiting area with women who were further along in their pregnancy.
- All staff were committed to continually learning and improving services. The franchisor produced in house training videos used for further training and development. The service could access a

Summary of findings

smartphone application called 'Bumpies.' This allowed women to document and share images of their pregnancy. Women could share scan images with friends and family if they wished.

- Clinic staff could escalate any concerns to a franchise freedom to speak up guardian (FTSUG). Staff we asked knew who the FTSUG was.

Heidi Smoult

Deputy Chief Inspector of Hospitals

Summary of findings

Our judgements about each of the main services

Service	Rating	Summary of each main service
Diagnostic imaging	Good 	Diagnostics was the only activity the service provided. We rated this service as good because it was safe, caring, responsive and well-led. We do not rate the key question of effective for this type of service.

Summary of findings

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Summary of this inspection

Background to Window to the Womb

Window to the Womb is operated by DJC Studios Ltd. The service opened in May 2014. It is a private ultrasound clinic in Norwich, Norfolk that provides diagnostic pregnancy ultrasound services to self-funding women, who are more than six weeks pregnant. All ultrasound scans performed at Window to the Womb are in addition to those provided through the NHS. The service primarily serves the communities of Norfolk. It also accepts women from outside this area.

The service has had a registered manager in post since 2014.

The service was registered with the CQC to undertake the regulated activity of diagnostic and screening procedures. We have not previously inspected this service.

Our inspection team

The team that inspected the service comprised of a CQC lead inspector and one other CQC inspector. The inspection team was overseen by Mark Heath, interim head of hospital inspection.

Information about Window to the Womb

The service provides diagnostic imaging service (ultrasound scans) to self-funding pregnant women aged 16 and above across Norfolk and the East of England. The service is a single ground floor clinic with direct access from the street. The clinic is located near the city centre and the building is part of a shopping and car park premises.

Window to the Womb has separated their services into two clinics: the 'first scan' clinic, which specialises in early pregnancy scans for between 6-16 weeks, and 'Window to the Womb' clinic which offers later pregnancy and wellbeing scans (Window scans) from 16 weeks to full term. The service runs three clinics per week. The clinics are separated either by day or half day.

Standard operational hours are Tuesday (for early scans only; 6 weeks to 15 weeks +6 days), Wednesday evening, Thursday evening and all-day Saturday and Sunday.

During our inspection, we visited the reception and waiting area, the scanning room with a storage room and a toilet. We spoke with five members of staff including the registered clinic manager/franchisor and director, franchisor, a sonographer and two scan assistants. We spoke with four women and their relatives. During our inspection, we reviewed ten sets of women's records and 31 scan reports.

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 service's first inspection since registration with the CQC in May 2014.

The service employed three part time sonographers and six scan assistants.

Track record on safety (from November 2018 to November 2019):

- Zero never events
- Zero clinical incidents
- Zero serious incidents
- 15 complaints (two of which were upheld)
- 116 compliments

Summary of this inspection

The five questions we ask about services and what we found

We always ask the following five questions of services.

Are services safe?

Good

We rated safe 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 women from abuse and the service worked well with other agencies to do so.
- The service controlled infection risk well infection. They kept equipment and the premises visibly clean.
- The design, maintenance and use of facilities, premises and equipment kept people safe. Staff were trained to use them.
- Staff completed and updated risk assessments for each woman.
- The service had enough staff with the right qualifications, skills, training and experience.
- The service managed women's safety incidents well. Managers investigated incidents and shared lessons learned.

Are services effective?

We do not rate effective, however:

- Staff monitored the effectiveness of care and treatment. They used the findings to make improvements and achieved good outcomes for women.
- The service made sure staff were competent for their roles.
- Staff worked together as a team to benefit women.
- Staff supported women to make informed decisions about their care and treatment.

Are services caring?

Good

We rated it as **Good** because:

- Staff treated women with compassion and kindness, respected their privacy and dignity.
- Staff provided emotional support to women, families and carers to minimise their distress.
- Staff supported and involved women, families and carers to understand their condition and make decisions about their care and treatment.

Are services responsive?

Good

We rated it as **Good** because:

Summary of this inspection

- The service planned and provided care in a way that met the needs of local people and the communities served.
- The service was inclusive and took account of women's' individual needs and preferences.
- People could access the service when they needed it.
- 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.

Are services well-led?

Good

We rated well-led as **Good** because:

- 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.
- The service had a vision for what it wanted to achieve.
- Staff felt respected, supported and valued. They were focused on the needs of women receiving care.
- Leaders operated effective governance processes. 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.
- 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 collected reliable data and analysed it. The information systems were integrated and secure. Data or notifications were submitted to external organisations as required.
- Leaders and staff actively and openly engaged with women and staff. They collaborated with partner organisations to help improve services for women.
- The service was committed to learning and improving services.

Detailed findings from this inspection

Overview of ratings

Our ratings for this location are:

	Safe	Effective	Caring	Responsive	Well-led	Overall
Diagnostic imaging	Good	N/A	Good	Good	Good	Good
Overall	Good	N/A	Good	Good	Good	Good

Good

Diagnostic imaging

Safe	Good
Effective	
Caring	Good
Responsive	Good
Well-led	Good

Are diagnostic imaging services safe?

Good

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. Topics included fire safety, infection control, health and safety, equality and diversity and mental capacity. At the time of our inspection, 100% of staff had completed their mandatory training.

The mandatory training was comprehensive and met the needs of women and staff. Mandatory training (MT) was delivered by a combination of on-line training and face to face training. Face to face training was delivered during the monthly staff meeting focusing on a different module. For example, the staff focused on fire safety in January, infection control in February and so on. MT compliance was monitored by the clinic manager. Managers monitored mandatory training and alerted staff when they needed to update their training. Staff confirmed they were given time to do training.

The clinic manager also attended annual updates for MT. At these meetings they were updated as to any changes in MT and provided with resources to deliver training to staff in the clinic as required. We checked the clinic's MT policy which was in date.

The clinic manager and senior scan assistant completed a more in-depth yearly MT course than the other staff. We saw the course summaries at the front of their MT folder. Fire evacuation was part of manual revalidation which was revisited twice a year. The clinic manger told us whenever the team overcame a challenge, learning was shared. They teamed up on the mini first aid course for infants and gave staff with family commitments a free place on a two-hour evening training course. The service followed the franchise's in-date first aid policy which outlined staff requirements. Six team members had completed the first aid and mini first aid course for infants.

The clinic sonographers had a clinical lead team with a group of clinicians employed by senior management. Sonographers could log-in remotely and complete on-job assessments. All staff's MT was refreshed yearly. The two national franchisors travelled the country conducting spot-check audits. The franchisor told us they would rather have excessive training compliance than not enough. Training compliance oversight included an e-learning induction, first aid, child protection, adult safeguarding, mental capacity act (MCA) e-learning, chaperone e-learning (for scan assistants). This was all covered in one MT course. We saw training certificates completed for all staff in March 2020.

All staff training was completed in-house. Scan assistants told us they completed their annual MT as a full day course including basic life support (BLS), first aid and 'mini first aid' for infants.

Staff's infection prevention control (IPC) training was ongoing as part of their annual MT refresher.

Safeguarding

Good

Diagnostic imaging

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.

The service followed the franchise's in-date adults safeguarding policy accessible to all staff. This was next due for review in September 2020 and reflected legislation and local requirements in place. The policy detailed the responsibilities of all management and employees, clarifying safeguarding was everybody's business. It explained the definition of a vulnerable person, abuse and how staff might notice it. Staff we spoke with were aware of the policy and knew how to access it.

The clinic had clear safeguarding processes and procedures in place. All clinic staff were trained to at least safeguarding level two for both vulnerable adults and children. This was in line with the expectation of training for this staff group in this setting, as referred to in the safeguarding children and young people: roles and competencies for healthcare staff fourth edition: January 2019 intercollegiate document.

Staff knew how to identify adults and children at risk of, or suffering, significant harm and worked with other agencies to protect them. The clinic had links with local safeguarding specialists and professionals. The franchisor told us the clinic always followed the franchise level process when referring cases. The clinic was linked with their local authority's multi-agency safeguarding hub (MASH). The clinic manager told us MASH were good with advice. Clinic staff also had a safeguarding flowchart they could follow if unsure. We saw this flowchart which gave key contact details of relevant authorities, including the children's advice and duty service (CADS).

Staff received training specific for their role on how to recognise and report abuse. The clinic manager and senior scan assistant were both trained to level three safeguarding for both vulnerable adults and children. Scan assistants (SAs) completed their safeguarding training including children as part of an annual full day course MT refresher. The clinic also had a child protection policy which covered the same level of detail and key contacts as their adult safeguarding policy.

Staff knew how to make a safeguarding referral and who to inform if they had concerns. SAs told us they had never had to raise a safeguarding referral. However, they could give examples of when they felt it may be necessary to raise and escalate a concern appropriately. For example, if the woman's partner was doing all the talking and seemed overly protective. If SAs found a women's abdomen was bruised, they asked if they were injecting for in vitro fertilisation (IVF) or anti-coagulants to help prevent the formation of blood clots. If women were not injecting SAs would document and raise a SG referral.

Staff could give examples of how to protect women from harassment and discrimination, including those with protected characteristics under the Equality Act. SAs ensured women who used the service were safe from harm. Before their scan, women were given information on their wellbeing and safety as well as the terms and conditions. Staff made clear to women when booking their appointments, the scan's primary objective was the safety, health and wellbeing of mother and baby. Staff explained this purpose again when women arrived for their scan, especially if they were unsure women fully understood the service offered, or worried the scan was inappropriate for them. Women less than six weeks pregnant were not scanned and referred to other services. The service never tried to assess the gender of a women's foetus before 16 weeks. SAs honoured the wishes of women with separated partners. For example, they would change appointments at their request so partners would not attend the scan.

SAs understood their responsibilities around female genital mutilation (FGM) but had never seen a case at the clinic. The service followed the franchise FGM policy. The sonographer we asked was aware of their responsibilities. SAs told us if the woman was under 18 years of age, staff would report this to police.

Safeguarding scenarios were discussed during team meetings to ensure staff were aware of what to do if they had safeguarding concerns. The service did not perform ultrasound scans on women under the age of 16 years. If women were 16 to 18-years-old, they needed an adult to accompany them. The clinic's electronic system flagged the date of birth of any women under 18 and staff requested to see identification to cross-check this.

Cleanliness, infection control and hygiene

Good

Diagnostic imaging

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 clean and had suitable furnishings which were clean and well-maintained. All areas we visited were visible clean and tidy.

The service followed the franchise infection control policy that was within review date and accessible to staff. This detailed how staff minimised the risk of infection in the clinic. The clinic manager was the service's infection control and prevention (IPC) lead.

The service followed the franchise scan room safety and hygiene policy. This detailed how staff ensured the scan room was safe, clean and hygienic. The policy confirmed cleaning schedules should be displayed in the clinic and we saw this was the case. The service also followed the franchise in-date clinic cleaning and laundry policy next due for review in September 2020. Staff adhered to this policy. For example, they used a new paper roll, a clean towel to ensure dignity, antibacterial hand gel and clean gloves for each customer.

Staff followed infection control principles including the use of personal protective equipment (PPE). The clinic could access enough personal protective equipment (PPE) to meet their needs. For example, gloves were available for staff to use.

We observed staff washing their hands before and after each scan. We saw they cleaned equipment after use. For example, the couch was wiped clean after every scan using appropriate cleaning wipes. Sonographers wore gloves when carrying out scans in line with infection protection and control compliance.

Staff cleaned equipment after any contact with women. Sonographers used single use probe covers when undertaking trans-vaginal scans. During the early stages of a pregnancy, it is sometimes necessary to conduct an internal scan in order to observe the foetus. Probe covers were disposed of in the clinical waste bin after use. The probes were then cleaned with the recommended disinfectant. All staff were trained in cleaning ultrasound probes and had certificates in a competency folder to evidence their successful completion of the training. Staff decontaminated transvaginal (TV) probes and would follow protocol after a Medicines and Healthcare products Regulatory Agency (MHRA) safety alert.

Cleaning records were up-to-date and demonstrated that all areas were cleaned regularly. The clinic was cleaned daily, and we reviewed daily cleaning check sheets. We were assured all areas had been cleaned as required. All staff were responsible for cleaning. We saw cleaning and 'fire up' checklists kept in the scanning room as part of the clinic's quality assurance folder. A fire up checklist is a list of everything staff needed to prepare at the start of each clinic before scanning women.

Staff completed a deep clean every month, although the policy only stated quarterly. Staff members were allocated each month. The deep clean utilised antibacterial cleaning products and followed the clinic cleaning and laundry policy checklist. The senior scan assistant ensured the clinic's deep clean rota was signed off every shift. This meant the clinic was always visibly clean for the start of their next shift. Scan assistants were responsible for cleaning and wiping beds, as well as emptying the yellow bins of clinical waste. The deep clean included removing all the waiting area seat covers and washing them at 60 degrees as per the clinic cleaning and laundry policy. Staff also washed linen and uniforms at this temperature in non-biological washing detergent separate from the other washing. We checked the deep cleaning records and saw deep cleans were completed with all areas signed, dated and checked in the three months from September to November 2019. Staff added notes where needed. For example, the toilet's inside cupboard door was checked and replaced as it was splitting, and a new bin was needed.

The clinic audited their cleaning rigorously. The clinic manager was responsible for conducting audits on all their cleaning paperwork. This included a weekly cleaning check audit to ensure the clinic was clean. We saw a log showing this was completed every week for the previous two months prior to our inspection.

Staff used different coloured mops for different areas as per the Health and Safety Executive's (HSE) colour coded cleaning guidelines.

Environment and equipment

Good

Diagnostic imaging

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 design of the environment followed national guidance. The clinic's environment was fit for the purpose of service provided. The environment was a single ground floor clinic with direct access from the street. This comprised of a scan room, reception area and toilet which was roughly 600 square feet. The clinic's scan room contained their ultrasound scanning (US) machine. This had been upgraded to reflect increased demand for image quality. The scan room also contained a medical couch, a computer on wheels, monitor screens and a locked room for documentation and cleaning materials. The clinic's reception area contained a desk, seating area and computer equipment.

The clinic was uncluttered, and equipment was stored appropriately. Staff carried out daily safety checks of specialist equipment. Staff completed daily in-house checks which included the scan room, toilet, reception area and the store room. The service had adequate space to store extra equipment and souvenirs.

The scanning equipment displayed a thermal index and a mechanical index which allowed the sonographer to monitor levels throughout the scan.

The clinic's equipment was serviced annually by a private contractor. All the clinic's electric equipment was also portable appliance tested (PAT) annually by the same contractor. We saw the latest electrical safety test log where all equipment was tested and compliant in February 2020. We also saw the clinic's air conditioning (AC) annual service report from Spring 2019. The clinic's air conditioning system was serviced annually. At the time of our inspection this was due in March 2020.

The service had enough suitable equipment to help them to safely care for women. The clinic's US machine and model had an inspection conducted in October 2019 and scored 100%. The clinic manager told us they were always present when the engineer carried out maintenance or repairs. At the time of our inspection the machine was four years old so this was due for renewal in 2021. We saw the machine certificates were signed and in date. On the week of our inspection 76 scans had been completed. However, a consistent average was approximately 70 scans per week.

The clinic had processes for the servicing and maintenance of equipment, including fire safety and first aid equipment. We saw the clinic's certificate on inspection for firefighting equipment dated September 2019. The service had five extinguishers; three aqueous firefighting foam (AFFF) extinguishers and two carbon dioxide ones.

The sonographer escalated concerns if there was a problem with image quality. Staff told us the service contract provider was responsive if there was an equipment fault. In the event of a mechanical failure the company providing the ultrasound scanning machines and equipment had standby replacements the service could use and receive within 24 hours of reporting.

The clinic had completed an emergency action plan in September 2019 with evacuation routes, a map and assembly point. For example, contingencies were sonographer or staff sickness/absence at late notice, weather conditions or studio electrical failure, water supply disruption and failure of key equipment.

The service stored cleaning materials in a locked store cupboard in line with the Control Of Substances Hazardous to Health regulations 2002 (COSHH). COSHH is the legislation which requires employers to control substances which are hazardous to health. We saw the next COSHH review date was due in February 2021.

Staff disposed of clinical waste safely. Waste was separated and disposed of appropriately. Clinical waste was collected by an external provider who provided clinical waste bins.

Assessing and responding to patient risk

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

Staff completed risk assessments for each woman on arrival, using a standardised tool. The first part of every scan was the wellbeing check. This meant the woman and their baby's safety was always the priority. When the

sonographer was not on site, the senior scan assistant acted as deputy. They acted as the first port of call if women had any concerns and helped with policies and procedures.

Women were asked to bring along their NHS maternity medical record when they came to the clinic. This was to help assure the service that the woman was on an NHS maternity pathway. We saw staff advising women to continue with their NHS scans as part of the maternity pathway.

The sonographer made all the necessary observations during scans. For example, they checked for the amniotic fluid, skull and brain, lungs and heart position, abdominal contents and limbs. They would tick any which were observed or if their view was restricted. Restrictions could be due to the foetal or placenta position, habitus or other.

Staff knew about and dealt with any specific risk issues. The clinic had a clear pathway in place that staff could follow in the event of anomalies seen by the sonographer on the ultrasound scan. The sonographer informed the women if they saw something on their scan which needed to be checked at the hospital for a full clinical diagnosis. Staff told us they would immediately contact 999 for urgent hospital treatment if an ectopic pregnancy was detected during a scan. They would keep the woman in the scanning room on the medical couch until emergency support arrived. The service had no urgent transfers to another healthcare provider from November 2018 to November 2019.

The service provided women with a leaflet about when they should contact their maternity unit. This included swelling of hands face or feet, vaginal bleeding, reduction in foetal movement, persistent headache and a high temperature. Local hospital contact details were given to women in an information pack.

Staff shared key information to keep women safe when handing over their care to others. Staff made referrals to the woman's place of choice where they were undergoing NHS care. Staff told us they contacted the NHS service directly and ensured women had an appointment at the relevant NHS clinic. The clinic manager told us if staff were unable to secure an appointment before the woman left the clinic, they would contact them later to confirm an appointment time.

The service had access to a sonographer clinical lead who was sometimes available to review scans remotely whilst the woman was still at the clinic. Failing this, the clinical lead would review scans within one to two hours. This service was used if the sonographer required a second opinion of the scan. Referrals were made on dedicated referral sheets. Referrals made were documented, stored securely and monitored by the clinic manager as to how many had been made each month. We reviewed ten referrals and saw they contained the woman's details and the reason for the referral.

Staff were aware of the service's main risks. For example, scan assistants knew not using the ultrasound scanning machine any more than necessary would keep women's exposure to ultrasound waves as low as reasonably possible. We saw pause and check lists were clearly visible on the scan room wall. Pause and check posters act as a ready reminder of the checks ultrasound sonographers need to make when any examination is undertaken.

The service did not require a resuscitation trolley. There was a first aid box which was sealed and 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. For example, if a woman or visitor collapsed in the clinic.

Staffing

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

The service had enough nursing and support staff to keep women safe. There were ten members of the team which included, three part-time qualified, health and care professions council (HCPC) registered sonographers, a clinic manager and five scan assistants and one senior assistant. The registered manager ensured contingency was built into the team. For example, there were enough staff members to cover the clinic sessions, sickness and holidays so absenteeism could be adequately covered. This meant the service never needed to use agency staff.

Good

Diagnostic imaging

The number of staff matched the planned numbers. The service operated with a qualified sonographer, clinic manager and a minimum of two scan assistants on duty for each shift. The service always had a minimum of three staff members on duty for the early pregnancy scan clinics; two scan assistants and one qualified sonographer. This was to ensure enough staff were onsite should an anomaly be found on the scan and additional staff were required to support the woman and those accompanying her for the scan. The service had a minimum of three scan assistants and a qualified sonographer on duty per shift for the 16 weeks plus wellbeing clinics. The sonographer was supported by a scanning assistant as chaperone for every scan.

Scan assistants (SAs) scribed wellbeing reports for the further along in pregnancy women's 'Window' scans on behalf of the sonographer. SAs would talk with women to reassure them throughout their visit. SAs were aware of the continuity of care from the woman's paperwork to accompanying them in the scanning room.

All staff received a full induction, which included completion of mandatory training and being aware of policies and procedures. There were different inductions for staff depending on their job role.

We checked staff records. These included a contract of employment, photographic identification, references, their CV and an in-date disclosure and barring service (DBS) certificate. We also reviewed induction checklists. These included a company introduction, terms and conditions, DBS, training, policies and procedures, health and safety, their job role and accountabilities.

The clinic had staff recruitment processes that resulted in good retention, as shown by their long-standing team. The clinic manager considered contingency planning and recognising staff's skillset. The senior scan assistant told us they were used to meeting compliance and customer service standards as they had a retail background. At the time of our inspection, the service had no vacancies.

The clinic manager could accommodate flexible working hours for staff. Scan assistant staff were on flexible contracts with guaranteed minimum hours which they felt the clinic manager managed well. As working mothers, they told the clinic manager their preferred hours in advance on a staff rota.

Records

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

Women's notes were comprehensive and all staff could access them easily. Staff maintained records by paper and electronic means. Records were stored securely. They stored paper records in a locked filing cupboard in the reception area. Electronic records such as Ultrasound images stored on the scanner were password protected. The service had a central storage point off site where records were stored securely.

We reviewed 10 sets of records including onward referral forms and all were complete. The clinic had a referrals log with the dates and reasons for the referral were recorded with the sonographer's initials. Staff accurately recorded all women's necessary information. Information included the woman's estimated due date, observations of the scan, conclusions and gender (if requested). The hospital pregnancy was registered with the woman's signature and date which women signed to confirm they understood the terms and conditions. The scan assistant recorded the chaperone's initials, sonographer name, registration number and signature and any extra relevant notes.

We reviewed 31 scan reports which were all complete, signed and dated. Reports were always legible, so information shared with other healthcare providers was easy to interpret.

Staff ensured women's confidential personal information (CPI) was maintained and not accessible to others. For example, women's registration forms were kept at reception in a covered clip board prior to the woman being called in to the scanning room.

Medicines

The service did not use any medicines.

Incidents

The service managed 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 women honest information and suitable support.

Good

Diagnostic imaging

Staff knew what incidents to report and how to report them. Staff reported incidents and appropriate action was taken. Staff raised concerns and reported incidents and near misses in line with franchise policy. The service used a paper-based reporting system and had an accident and incident book available in the clinic. Staff told us they felt confident reporting incidents or concerns. Staff received feedback from investigation of incidents. We reviewed an incident in the clinic's incident log from October 2019. A gentleman had entered the clinic complaining of chest pain. Staff sat him down and a call was made to security as they appeared inebriated and suffering from mental health issues. Security arrived with medical help. Paramedics were then called to assist and took the man to hospital. Staff discussed this incident to identify any learning.

At the start of each clinic, the team had a "fire up" meeting before the first woman arrived. This ensured staff discussed the day's diary of women and any issues or concerns. Staff we asked felt they could raise or discuss any queries during these or debriefs afterwards. We reviewed team meeting minutes from November 2019 and saw feedback from incidents and complaints was discussed at each team meeting. Meeting minutes were fed back to the staff unable to attend the meeting. The franchisor offered both the sonographers and scan assistants extra training and advice from any incidents. Clinic staff could also access a corporate sonographer available for advice.

Managers investigated incidents thoroughly. The clinic manager was responsible for conducting investigations into all incidents supported by the franchisor, national head office and other directors in more serious incidents.

We saw the clinic's incident policy and what was defined as an incident. This could be a break-in or theft from the clinic, a major accident or an assault on a staff member. The incident policy was signed and dated February 2020. We reviewed this policy and found any identified areas of learning or improvement from incidents were implemented with immediate effect.

The service reported no serious incidents (SIs) or never events (NEs) from November 2018 to November 2019. NEs are entirely preventable SIs as guidance or safety recommendations provide strong systemic protective barriers available at national level.

The service had a duty of candour policy which detailed how staff should behave when needed. Staff understood the duty of candour. They were open and transparent, and gave women and families a full explanation if and when things went wrong. Staff were aware of the term duty of candour. They understood the principle behind the regulation and the need to be open and honest with women and apologise if incidents occurred. The duty of candour is a statutory (legal) duty to be open and honest with women (or 'service users'), or their families, when something goes wrong that appears to have caused or could lead to significant harm in the future.

Are diagnostic imaging services effective?

We currently do not rate effective.

Evidence-based care and treatment

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

Staff followed up-to-date, evidence-based local policies to plan and deliver high quality care according to best practice and national guidance. We reviewed 25 policies which were up to date and within review date. The policies were written centrally by the franchise. However, policies were adapted to provide effective guidelines for each clinic location. Staff were made aware of updates to policies at monthly team meetings and signed to confirm they had been notified of any updates.

Staff worked to as low as reasonably achievable (ALARA) guidelines. ALARA is defined as a fundamental approach to the safe use of diagnostic ultrasound using the lowest output power and the shortest scan time possible. We saw staff working within these guidelines when undertaking an ultrasound scan.

Regular audits and clinical reviews were completed. Audits were carried out internally and there was an annual clinic audit conducted by the franchisor. This included a review of risk assessments, policies and staff

training. The franchisor also completed annual sonographer competency assessments. We reviewed records and saw these had been completed annually as per the guidance.

The service had an audit programme in place to provide assurance of quality and safety within the service. For example, we saw a clinic compliance audit conducted by the franchisor from January 2020. This audited the physical clinic inspection, health and safety, infection control, emergency planning, both types of clinics, policies and procedures, quality assurance, customer feedback, actions, summary and a mandatory training schedule. Actions were agreed and progress was reviewed at the next visit. Any actions agreed relating to process/regulation were acted upon immediately. For example, the clinic had actioned more local audits to be completed since the end of February 2019. The audit outcomes graded overall clinic compliance as outstanding. For comparison, the franchisor had graded the 2019 audit to a very good standard with minor administration action needed. The written summary stated the clinic team clearly took ownership of their compliance and responsibilities extremely seriously. This meant women's care was at the forefront of their approach to delivering excellence.

The service's three sonographers audited each other's notes, records and image quality. The senior scan assistant audited sonographers governance every two months and wrote up notes on their findings. Audit results were shared with all staff members.

Nutrition and hydration

Women did not spend an extended amount of time at the clinic. Water was available and there were outlets to buy food and drink nearby.

Pain relief

Staff did not formally monitor pain levels. However, we saw staff checked women were comfortable during their scan.

Patient outcomes

Senior managers monitored the effectiveness of care and treatment. The clinic used the findings to make improvements and achieved good outcomes for women.

Due to the type of service offered, there were limited ways the clinic could measure women's outcomes. However, the franchisor and senior management peer reviewed the clinic's outcomes against other provider locations to monitor their progress.

Managers and staff carried out a comprehensive programme of repeated audits to check improvement over time. The service used key performance indicators (KPIs) to monitor performance. For example, the clinic monitored first scans and the average value spend on scan package price. The clinic's rescan rate was 3.5% but their expectation rate was 5%. For comparison a new clinic's rescan rate averages 10%.

The service had a display in the waiting area of "not perfect" scan images called the 'VIP baby board'. This was part of their programme to manage women's expectations regarding image quality when carrying out a baby scan.

Staff referred women to NHS services if their scan showed an anomaly or any follow up care and treatment was needed. All referrals to the NHS were documented on the woman's form and clearly explained to them. Records of women who had been referred were retained and stored securely by the service. Although referral monitoring was part of the service's monthly audits the service was not informed of the outcome of the referral due to women's confidentiality.

Improvement was checked and monitored. Window to the womb reported a 99.9% accuracy rate for their gender confirmation scan. They could prove this by providing back up monitoring.

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. Managers gave all new staff a full induction tailored to their role

before they started work. All staff received a comprehensive induction. Scanning assistants completed a training and induction programme including chaperone training. They also completed abdominal aortic aneurysm (AAA) scanning only following appropriate training.

Sonographers received a full induction which included working alongside a currently employed sonographer. Scanning competencies were signed off by the clinical lead sonographer. The clinical lead sonographer was also available to offer clinical advice when needed. We saw new staff members were supported with a relevant buddy to better understand their role and patient flow.

The clinic had a peer review process in place. We saw monthly peer assessments for all three sonographers. Sonographer scans and reports were reviewed by a sonographer colleague to ensure their competencies were up to date. The sonographer told us peer review provided an opportunity to stay up to date and share learning from other sonographers' experiences. Sonographers within the service were registered with the Health and Care Professions Council (HCPC) and registrations were up to date.

Managers supported staff to develop through yearly, constructive appraisals of their work. The sonographer had an annual competency assessment provided by the clinical lead sonographer employed by the Window to the Womb franchise. We saw evidence the sonographer had received annual reviews by this lead sonographer.

Managers made sure staff attended team meetings or had access to full notes when they could not attend. The service provided ongoing training for staff and managers, delivered during team meetings. For example, the clinic manager told us they discussed safeguarding scenarios in the meeting to ensure staff were up to date with actions they would take if they had a safeguarding concern. These were shared with all staff after meetings had been completed.

Staff received an annual appraisal. Information provided by the service showed that 100% of staff had received their annual appraisal. The clinic's appraisals incorporated the service's values. This ensured staff were compatible and they continued to attract the right staff.

The franchisor told us from day one they planned to set high standards of service delivery. This meant the service's induction process has always been very thorough.

Part time staff had one to ones with the clinic manager and minutes were recorded.

The clinic manager clarified there were three parts to the induction training. The clinic maintained two front of house staff for every one staff in the scan room. This meant staff must be front of house trained first, before they assist the early scans which were more problematic. Staff's appraisal performance areas were all scored between A to C, A being exemplary and C average. Training needs were identified by staff or the clinic manager. Staff completed online courses and had access to modules on their smartphones through a training app.

Sonographers were trained and certified for the use of a leading product cleaning. This meant they were qualified to use specialist instruments for the high-level disinfection of endocavity ultrasound probes in line with best practice. We saw the latest clinic compliance audit from January 2020 stated this was the correct in-date purple product due for renewal in May 2021.

Managers identified poor staff performance promptly and supported staff to improve. The service managed poor staff performance or attitude within the team. This was done by setting and managing expectations and communicating them clearly, so staff understood. The clinic manager told us there were no problems with staff performance.

The service had their own in-house platform for online continuous professional development (CPD) and learning. All the clinic's three sonographers worked two to four days a week. CPD was built into their training yearly. The clinic team were directed to the director level at the franchise's national office in Holmfirth.

We saw evidence of sonographer's continuous professional development (CPD). The franchisor told us the clinic kept expanding and improving upon CPD which was unique. One sonographer shared their CPD work with the local acute trust as the franchise was happy to share learning. Sonographers took many scans at each appointment and talked through the videos' images with women. Clinic staff could undertake franchise clinical

development training videos as evidence of their CPD. Examples included the identification of anencephaly, ectopic pregnancy, spinal bifida, foetal omphalocele and triploidy.

Multidisciplinary working

All those responsible for delivering care worked together as a team to benefit women. They supported each other to provide good care and communicated effectively with other agencies.

During our inspection we saw the team worked well together and communicated well with each other. This included the franchisor, registered clinic manager, sonographer and scan assistants.

Staff held regular and effective multidisciplinary meetings to discuss women and improve their care. Registered managers in the franchise attended monthly meetings where training was delivered and learning shared. The clinic manager reported the registered managers in the group worked well together and supported each other.

Staff worked across health care disciplines and with other agencies when required to care for women. The service had links with the local NHS trusts to ensure they had effective referral pathways for women when needed. Staff told us they had established good working relationships with local trusts and were able to telephone the service to secure an appointment for the woman before she left the clinic. The service had established pathways in place to refer women to their GP or local NHS trust if any abnormalities or concerns were identified. However, the clinic manager told us some local hospitals did not accept direct referrals.

Seven-day services

The service was not available seven days a week. However, the service had organised clinic lists to enable women's access.

The service was not open seven days. However, evening and weekend clinic appointments were available to allow women access to the service outside of working hours. Booking for appointments was available seven days a week, 24 hours a day using the franchise online booking system available to their website. The demand for scan appointments was constant and year around. We heard Christmas day was the only time women could not book appointments on their online system.

The clinic was open five days a week. All days had been tried and tested to give people maximum flexibility. For example, the clinic tried to book in women for 4D scans in the early evening as in their experience images were clearer and easier at this time of day.

Scan assistants (SAs) could contact women through social media and then call back securely to book in their appointments. SAs told us they had a couple of walk-in bookings per week, especially for early scans. If SAs spotted any errors with online bookings, they called the women back.

Health promotion

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

The service had relevant information promoting healthy lifestyles. The service provided leaflets that contained information for "mums to be". This included eating well, smoking and alcohol cessation, and foods to avoid. Smoking cessation posters were displayed in the clinic advising women of the harm smoking can do to their unborn baby.

Leaflets also recommended what information was best for women to ask their midwife about. This included discussing birth plans and what breastfeeding services were available.

We saw a community board featuring the 'spinning tots class', yoga, swimming and other healthy activities available to pregnant women.

Consent and Mental Capacity Act

Staff supported women to make informed decisions about their care and treatment. They knew how to support women who lacked capacity to make their own decisions or were experiencing mental ill health. Staff also supported women to deal with bad news and make decisions around their planned baby's health issues.

Staff understood the relevant consent and decision-making requirements of legislation and

guidance. Before their scan all women received written information to read and sign. This included information about ultrasound scanning and safety information, a pre-scan questionnaire and declaration form which included the franchise terms and conditions. This was a self-declaration stating the woman were receiving or intended to receive maternity care through the NHS and consented to their information being shared.

For early pregnancy scans, women were given extra information telling them more about the scan. This included information should the sonographer need to perform a trans vaginal scan due to the early stage of the pregnancy.

Staff gained consent from women for their care and treatment in line with legislation and guidance. Staff gained consent before scanning women. The clinic gained all women's consent in writing, as staff asked women to sign a consent form which detailed the scan, any risks and outcomes. We observed the sonographer explaining the scan to women and their families and obtained verbal consent before commencing scanning.

Staff told us if they felt a woman lacked the capacity to consent, they would not scan them. The clinic staff ensured women made informed decisions before having their scans. They did this by asking women to complete a foetal wellbeing report. The clinic manager made clear to the women they were not the sonographer.

Staff received and kept up to date with training in Mental Capacity Act (MCA) and Deprivation of Liberty Safeguards. Staff covered both these in their e-learning during induction and annual mandatory refresher training.

Staff we asked were aware of the Mental Capacity Act (MCA) and how and when this applied. However, they could not recall a time they had a concern about a woman's capacity to consent to a scan. The service followed the franchise policy relating to individuals who suffered from any condition covered under MCA. This detailed how staff should support women and ensure they acted in their best interests.

Are diagnostic imaging services caring?

Good

We rated caring as **good.**

Compassionate care

Staff treated women with compassion and kindness, respected their privacy and dignity, and took account of their individual needs. We observed staff treating women and their family and friends with kindness and courtesy.

Women said staff treated them well and with kindness. Women screened were treated with dignity and respect. Staff followed policy to keep women's care and treatment confidential. The door to the scanning room was always kept shut during the scan to ensure women's privacy was maintained. Door were locked during intimate examinations. Women who required a trans-vaginal scan were provided with a screen to get changed behind and a basket to keep their clothing in. They were provided with a towel to cover themselves during the scan.

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. Personalised care was delivered as the team prepared for women. For example, staff asked the woman's name upon arrival and would support them appropriately from then on. The sonographer checked the woman was comfortable, especially for abdominal scans as images could be obscured. Sonographers addressed any concerns the women raised throughout the scan. A scan assistant stayed in the scanning room with the sonographer for all scans. The scan assistant acted as a chaperone and offered support to the women and their families.

Staff understood and respected the personal, cultural, social and religious needs of women and how they may relate to care needs. The waiting area had a privacy screen for parents to choose their preferred photo images without feeling rushed and overlooked by other women or families.

We reviewed feedback cards from women who had used the service. Customers from August 2019 had commented

the staff were "amazing, very friendly and helpful". A customer from December 2019 remarked "all the staff were welcoming, professional and friendly". Another the same month remarked "the sonographer was so reassuring and made the experience wonderful". Women and their families said that they would recommend the service to other people.

We heard women were given plenty of information about their scan beforehand. Staff explained the process over the phone and sent booking confirmations by email and text message with all relevant details. Women told us they knew what to expect before arrival. Costs were clearly explained to women.

Women were advised of the potential risks associated with ultrasound scans. One high alert woman who had eight previous scans due to medical problems said she felt reassured by staff after her wellbeing check at 16 weeks. They had a complex medical history and were at high risk of foetal anomaly. The woman felt staff were very reassuring given their background and ensured their concerns were resolved before their children came into the scan room.

We saw and heard all staff introduced themselves to the women. Women told us reception staff were very good with their children. Women found staff very polite and friendly, the service clean and told us they saw staff cleaning their hands and using gloves. Women felt staff treated them with kindness and compassion. They felt their privacy and dignity was respected and maintained. Women told us staff explained their scan results to them in a way they could understand, explaining clearly throughout. Women also told us they were given the opportunity to ask questions which staff answered.

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 separate clinics for early scans and 16+ week scans. Staff were mindful early scans held a higher risk of complications being identified.

The sonographer initially started scans without the other screens in the room being turned on. This meant if any anomalies were identified the sonographer could make their diagnosis and share the information in an informed, compassionate manner. We observed staff were calm and reassuring throughout the scan. The sonographer provided reassurance about what was being imaged and displayed on the screen and shared what they observed.

Staff supported women who became distressed in an open environment and helped them maintain their privacy and dignity. Staff informed us in the event of finding abnormal results, women and their partners would remain in the scanning room whilst a referral was made to an NHS provider. The clinic staff explained the psychological benefits of bonding with the baby once women's wellbeing checks were done. All clinic staff were trained on the emotional aspects of supporting women receiving bad news and could demonstrate examples of when to apply this. For example, we heard about a 'windows' pre-20-week scan which showed spinal bifida a few months before our inspection. Staff spotted this anomaly early and managed the woman's expectations. This meant they had more time and choice to decide what they wanted to happen next.

Staff undertook training on breaking bad news and demonstrated empathy when having difficult conversations. The clinic staff supported women who received upsetting news. The sonographer delivered initial feedback to women. They were then given aftercare and offered a drink. They could offer an early scan leaflet with information referring to their next medical steps or signpost women to the miscarriage trust. The service could signpost women to bereavement counsellors if needed. Scan assistants told us about a 'green towel' code they had with sonographers. If staff asked for this, it meant they needed to give women more time and emotional support. For example, in the event of a scan revealing an anomaly or the lack of a heartbeat.

Staff understood the emotional and social impact that a person's care, treatment or condition had on their wellbeing and on those close to them. The clinic staff recognised the emotional impact their service could have on women. If women were concerned about their online

booking experience, the clinic had someone contactable between 9am and 7pm seven days a week. Three staff rotated to check social media responsibilities daily who were supported by the national head office.

Staff were invested in ensuring the experience of having a scan was special for the women and their families and appeared to share in the excitement of the experience.

Understanding and involvement of women and those close to them

Staff supported and involved 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 treatment. Family and friends were welcome in the scan room and there were three screens positioned in the room to ensure everyone could see the scan images. Scan room visitors were limited to two per woman for the early scans as the outcome may be bad news.

The clinic offered women apps available on smartphones and tablets through 4G available locally. The clinic manager felt this represented the clinic's caring aspect and gave reassurance to women. Women were given a unique code to the 'Bumpies' mobile phone application which gave them access to their scan images and videos. Women could choose when to share these with their wider families, friends and support network if they wished to.

Staff talked with women, families and carers in a way they could understand, using communication aids where necessary. We saw staff speaking to family members, involving them with the scan and checking they were ok. We observed a scan taking place where a sibling was present, and the sonographer and scan assistant ensured they were included.

The regional manager told us they encouraged a "non-judgemental" approach and their priority was to ensure everyone had a unique and special experience. This was confirmed by all the staff we spoke to. Women and their partners gave positive feedback about the service.

Are diagnostic imaging services responsive?

Good

We rated responsive **good.**

Service delivery to meet the needs of women.

The service planned and provided care in a way that met the needs of local people and the communities served. It also worked with others in the wider system and local organisations to plan care.

Managers planned and organised services so they met the changing needs of the local population. The service operated extra opening hours to enable women to access the service in the evening and at weekends.

The clinic was located in a busy retail area. It was easy to find and clearly signed outside. Nearby parking was available in a shopping centre.

Facilities and premises were appropriate for the services being delivered. The scanning room was spacious and contained a US machine, couch, and seating area for family and friends. There were two monitors and a large screen positioned so that the woman and their family could see the scan clearly. 'Slave' monitors were used for foetal scanning as recommended to allow parents to see images without the sonographer tilting their screen. The scan room's monitors were only switched on when the sonographer shared good news with women and their families. This avoided unnecessary distress.

There was a large waiting area with sofas and chairs for the women and their families to sit whilst they waited. Children's toys were available in a play box. Women or their family members could also buy heartbeat bears. Heartbeat bears recorded the baby's heartbeat and replayed this for women or families to hold and offer comfort. There was a variety of different scan packages for the women to choose from. Details of these were available at the clinic and on the services website. A wellbeing scan was included as part of all the packages.

All scans started with a wellbeing check. The service's sonographers looked at the baby's movements, heartbeat, position, and placental position. Early scans

included the wellbeing check, but also included presentation of the baby, head and abdominal circumference measurements, femur length measurements and estimated foetal weight.

Staff would tick boxes from a checklist, so they knew what was important to women and their family on the day. For example, their wellbeing as well as the baby, the gender or pictures of the scan. The form clearly indicated if the women did not want to know their babies gender.

The service had systems to help care for women in need of additional support or specialist intervention. The service had established good working relationships with local trusts and there were established NHS referral pathways.

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.

The service held separate clinics for early pregnancy scans (6-15+6 weeks) and window scans (16 + weeks). Window scans was the term the service used for later pregnancy and wellbeing scans. Staff told us there was a higher likelihood of abnormalities being detected in early stages of pregnancy. The service followed the franchise foetal abnormality policy which detailed their policy and process if these were identified. Holding separate clinics meant if a woman was given bad news, had experienced pregnancy loss or were anxious about their pregnancy they did not have to share the same area with women who were much later in their pregnancy. Staff told us souvenirs were only displayed at the well-being scan clinics.

Scan assistant duties could be tailored to meet people's individual needs. For example, they could record the images in film format and convert them onto their app to show women's families.

The clinic was accessible for people with reduced mobility. The service was in a ground floor building so the reception, toilet and scan room were all wheelchair accessible. The scan room bed was adjustable and could withstand weights of up to 600 pounds or 48 stone.

Staff gave us examples of adjustments they had made to help women with learning disabilities access the service. For example, they ensured any woman with a known learning disability were accompanied by a relative and carer and were given additional time for the scan.

Managers made sure staff, women, their loved ones and carers could get help from interpreters or signers when needed. Staff had access to a translation service for women who did not speak English. At the time of our inspection the clinic was about to subscribe to a newer language line system. The service had information leaflets available in languages spoken by women and the local community. The clinic manager told us nearly all their women whose first language was not English were Polish or Eastern European and spoke good English. The service provided information leaflets for women using the service. The clinic had their own in-house system to translate a word document into any language if needed.

Staff understood and applied the policy on meeting the information and communication needs of women with a disability or sensory loss. The service provided a 'read aloud' system which made it more accessible to women who were visually impaired, had hearing loss or could not read. The service followed the franchise provision of key information policy. This gave staff guidance on how to provide key information to women with sight or hearing impairments. They gave the example of a blind couple who booked in for a 4D scan and gave positive feedback. The mum was very partially sighted, so staff talked through each part of the scan and spent extra time choosing images with them. They had also gladly complied with a deaf families request for a heartbeat bear for their child.

Following their scan images were uploaded to an app. Women were given a unique access code to their scan images. They were then able to share this image with friends and family of their choosing.

Access and flow

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

Bookings could be made online through the service website or by telephone. The franchise's national booking system offered appointments according to where women needed them. The clinic's appointment slots were 30 minutes, but staff could extend these. Women could also

be given two booking slots back to back if staff expected their scans to take longer or they needed extra support. The senior scan assistant told us they would sometimes come into the clinic on weekends to check referrals were sorted and contacted as soon as possible.

We heard women were seen promptly for their scans and hardly ever had to wait. One woman was seen a few minutes earlier than her appointment time. Scan assistant staff told us about the booking process. Women booked most of their own appointments, but staff could book these over the phone according to urgency. For 'windows' scans the woman chose a slot from the full calendar's availability. We heard the example of staff prioritising a woman who was six weeks pregnant. They needed an urgent scan as their partner was working offshore.

The franchisor told us the franchise was launching brand new website a week after our inspection. This had a new booking system which was designed to be easier to use. All company data storage would be cloud-based which included 21 years of past wellbeing checks.

We heard women's feedback about the clinic's current booking system was extremely positive. We spoke to women who used the clinic. They said it was very easy to make an appointment and they did not have to wait long. One woman who couldn't get through by phone left a voicemail and staff rang her back within minutes to book. Women had a good choice of available appointments and could get the suitable times they wanted. For example, one mother told us she was given her choice of appointment six days after booking. The online booking system was flexible.

How far in advance the service could book in women was led by shifts with local hospitals. The clinic manager told us women generally booked three to four months in advance. However, some women would book as far as nine weeks ahead. Between 28-30 weeks was the best time for 4D scans.

If clinics were running late then staff told us they would keep those waiting in the waiting room updated. At the time of our inspection, we saw all appointments were running on time. From November 2018 to November 2019 the service had not had to cancel any appointments. The service followed the franchise cancellation policy in place, giving staff instructions on dealing with cancelled appointments.

The service clearly displayed scanning packages that were available and costings for each package both in the clinic and on their website. We saw a clear pricing guide displayed in the reception area. Women paid a deposit through a secure payment system (SPS) which the franchisor explained gave them extra reassurance their appointment guaranteed.

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 women in the investigation of their complaint.

The service followed the Window to the Womb franchise complaint handling policy. The policy detailed staff's responsibility and the complaints process. A copy of the policy was sent with an acknowledgement letter to any women who complained in writing within three days. The registered clinic manager then sent complainants their findings within 21 days of the acknowledgement letter. The policy also had an escalation process where the complainant could contact the franchise co-founder and director if their complaint had not been resolved satisfactorily. This policy was reviewed yearly and was next due in September 2020. We saw the policy displayed on a board within the clinic. The complaints policy, procedure and information about how to make a complaint was included on the back of the services feedback forms given to women following their scan.

Staff understood the policy on complaints and knew how to handle them. The registered manager investigated any complaint received through the comment's cards, website or social media. The registered manager told us that they attempted to deal with concerns at the time to resolve women's concerns. They told us about examples where women who had previously made a complaint came back to the service for a scan for subsequent pregnancies as they felt their concerns had been addressed satisfactorily and professionally.

Good

Diagnostic imaging

Women we asked knew how to complain or raise concerns about the service if they had any concerns or issues. From November 2018 to November 2019 the service received 15 complaints. Two of these were upheld and went through the formal complaints procedure. The clinic manager contacted the complainants and resolved the issue within the policy's given timeframes. The main themes were image quality.

We saw complaints were followed up and actions taken to address concerns in a timely manner. For example, the clinic manager told us in response to complaints about image quality, staff had put actions in place to manage women's expectations. The senior scan assistant reviewed the clinic's social media account pages daily and responded to any negative feedback promptly. Complaints were also shared with staff at the pre-shift meeting and during the monthly team meetings. Clinic staff discussed any new or ongoing complaints at every staff meeting. The clinic manager gave us an example of a complaint where they used the audit trail as a training aid with the team.

The service clearly displayed information about how to raise a concern in the waiting area. The clinic manager actively encouraged staff to ask women if they were happy with the service and identify any potential dissatisfaction whilst still onsite. This helped minimise the number of complaints they received. Complaints were usually minor and received by social media or email. The clinic manager monitored feedback through a variety of social media platforms. Women were given a feedback form following their scan and were encouraged to give feedback. Feedback, compliments and complaints were shared at team meetings and any learning discussed.

Between January 2019 and February 2020, the service received 116 compliments through feedback cards which did not include those on social media. All except one of these cards rated the service five stars. Card feedback given included ease of booking the scan, initial welcome by the clinic team, care provide during the scan, hygiene and comfort of the clinic and overall experience.

Are diagnostic imaging services well-led?

Good

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.

We saw the corporate structure for the clinic. Leadership was provided by the owner, director and registered clinic manager who were supported by the senior scan assistant and accountants. Sonographers and scan assistants reported to the clinic manager.

Staff told us the clinic manager was approachable and they were happy to go to them with any concerns or queries. Staff told us they were supported by the manager and given time to recover when off sick.

The clinic manager was also the registered manager, director and owner of the clinic. They were supported by the franchisor who had responsibility for all the clinics operated by the franchise. The clinic manager was available by telephone when they were not on site. They told us their franchisor and other directors were very supportive, and they could contact them any time for help and advice.

The franchise was committed to supporting clinic staff to develop. For example, the clinic manager had been supported by the franchisee to train and develop to take on the role. At the time of our inspection, the manager told us they were offering development opportunities to current scan assistants.

There were twice-yearly national franchise meetings for the franchisees which registered managers were encouraged to attend. The franchisor provided leadership and support and all the staff we spoke with told us they were approachable and responsive when they contacted them. The franchisor delivered ongoing training to registered managers. This included clinic visits and training events.

Staff could access clinical leadership from clinical leads employed by the franchisor. The clinical leads assessed all new sonographers and were available to offer clinical advice when needed, they also offered supervision training which was done annually.

The franchisor attended the clinic on the day of our inspection to clarify or refine any policies and procedures, share good practice and take our feedback onboard. They explained this helped ensure the clinic was in keeping up with rest of their franchise network.

Vision and strategy

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

The company had a vision which was reflected in the local service.

The service had identified values, which underpinned their vision. The service values included, dignity, integrity, privacy and safety. During our inspection we saw staff worked in line with these values. All staff we spoke to knew and understood the values. Staff told us they were committed to providing a high-quality service to all women who used it. The service's vision was 'outstanding caring'. Being a small clinic, the service did not have a strategy.

The franchisor felt 50% of the clinic's reputation for quality service was word of mouth. They felt their performance was reflected in the fact many mothers keep coming back to have their third or fourth baby scanned.

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[SP1][SP2]**. The service had an open culture where staff encouraged feedback from women and their relatives and were responsive to any concerns raised.**

All staff we spoke with told us they felt supported, respected, and valued. They enjoyed coming to work and were proud to work for the service. Both scan assistants we spoke to had worked at the clinic since March 2017.

During our inspection we observed good team working between all members of staff including, the managers, the sonographer and scanning assistants. They supported each other and treated each other with mutual respect. Staff we asked felt the safety and wellbeing of staff was promoted.

Clinic staff's continuous professional development (CPD) involved a fully signed off and accredited management development programme. This meant the clinic manager could develop staff accordingly from the front door as assistants right up to senior management level.

The service promoted an open and honest culture. The service followed the franchise freedom to raise a concern policy and had access to a 'freedom to speak up guardian'. Scan assistants we asked were aware of the freedom to raise a concern policy. They told us they could go straight to the clinic manager with any concerns. Staff were trained on the freedom to speak out policy. Staff knew who the freedom to speak up guardian (FTSUG) for the franchise was. Staff also knew the confidential phoneline to call if they had any concerns.

We saw staff were passionate in what they did and were highly invested in the service they delivered. We observed a very caring culture where staff demonstrated a caring approach to service users and each other. Two staff members told us they loved coming to work and felt privileged to share in a special time for women and their families.

The culture was inclusive, and staff treated all women equally. The service followed the franchise's in-date equality policy which included sexual orientation, disability, age, race and religion. A member of staff told us they were non-judgmental and treated everyone the same to ensure women and their partners, friends and families had a unique and special experience.

Governance

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

The clinic manager was responsible for local governance as the sole director, registered manager and franchisee.

Good

Diagnostic imaging

The company DJC Studios Ltd traded as Window to the Womb. The clinic manager sought advice from the franchisor that provided their team with a schedule of policies they must adhere to. The franchisor kept staff up to date with current practices. The clinic also had full vicarious liability insurance. This meant they needed to follow the national model to maintain this cover.

The service had a clear governance policy and procedures in place. This outlined the responsibility of board members, the relationship between the franchisor and registered clinic manager and the requirement for regular audits.

Staff could describe the governance processes for incidents and complaints and how they were investigated. The service's policy folders were extensive as staff constantly adapted clinical as well as operational governance.

Scan assistants reviewed sonographers to assess their quality of customer care and service, communication standards and the overall customer experience. These reviews included the scan room set up such as equipment and hygiene, initial welcome and introductions by building rapport and positive body language, initial explanations of the whole scan process to put the customer at ease, a clear explanation of the wellbeing process and if an anomaly was identified.

The clinic manager had overall responsibility for clinical governance and quality monitoring and reported this to the franchisor. This included investigating incidents and responding to women's complaints. The manager was supported by the franchisor. They attended biannual national franchise meetings, where clinic compliance, performance, audit and best practice were discussed. The national franchise meetings were two days of intensive strategy and sharing of best practice. The franchisor felt this led to tighter relationships amongst senior staff.

The manager also attended monthly senior staff meetings with peers across the franchise. We reviewed meeting minutes and saw items discussed included performance, complaints, compliments, training and compliance with policies and procedures. We saw an action plan for issues discussed and a completion date.

Staff had feedback from clinical governance and national franchise meetings. Monthly local team meetings were held at the clinic. Team meetings also covered any complaints, incidents, women's feedback, performance, compliance with policies and procedures, both types of clinic issues, audit results, staffing and rotas. Meetings began with a recap of the previous month's agenda items to ensure all staff were aware of the actions and completed them. For example, staff at November 2019's meeting were reminded to double check paperwork before handing it to women, as sometimes the printer printed the previous woman's wellbeing report.

The clinic had an audit programme in place which included monthly local audits, annual audits and peer review audits. Internal audits were completed at clinic level. For example, we saw the latest 2019 audits for deep cleaning and hand washing. These were stored in a quality assurance folder as well as by head office. This folder also contained local and franchise audits, service and care assessments, peer reviews undertaken at least quarterly, other sonographer reviews of scan reports and images. Scan reviews covered ultrasound observations, the effective use of equipment and report quality.

Annual compliance audits included premises checks, health and safety, emergency planning, accuracy and completion of scan reports, completion of pre-scan questionnaires, professional registration and staff records. We saw clear actions were identified and agreed with clinics.

Managing risks, issues and performance

Leaders and teams used systems to manage performance effectively. They identified relevant risks and issues to the service and reduced their impact. They had plans to cope with unexpected events.

The clinic had good processes for identifying and assessing risk. We saw up to date risk assessments for fire, legionnaires' disease, infection control, health and safety and the Control Of Substances Hazardous to Health (COSHH), housekeeping, mechanical, electrical, chemicals and agents, violence and aggression, lifting, working alone/lone working and fixed wire test.

The registered clinic manager recorded risk assessments on a form which identified the risk and control measures. Risk assessments were easily accessible to all staff. The

manager told us the legionnaire's risk assessment was generic across most clinics so they checked this by exception. They got the senior scan assistant to peer review all assessments for extra assurance.

The service did not have a risk register in place. However, the franchisor and clinic manager reviewed all risk assessments and documented any changes or identified new risks. They assured us all location and/or franchise level risks were replicated in their policies. The service had vicarious employee and public liability insurance which covered all sonographer activity. The service had never had a claim made against them since registering in 2014. The service followed the franchise medical malpractice policy that covered all clinics.

The service had a clinic contingency plan in place to identify actions to be taken in the event of an incident that would impact the service. For example, extended power loss, severe weather events, short notice staff sickness and equipment failure. The contingency plan included contact details of relevant individuals or services for staff to contact.

Managing information

The service collected reliable data and information systems were secure.

The clinic had a data retention policy. We saw this was in date and next due for review in May 2020. This ensured any confidential personal information (CPI) documents were protected and maintained, then disposed of securely when no longer required. The policy considered the legislation and general data protection regulations (GDPR). The policy also outlined guidelines by record category, record security, record review and disposal methods.

We saw paper and electronic records as well as scan reports were stored securely. Paper records were in a locked filing cabinet in the reception area. These were removed monthly by the clinic manager and stored centrally. The service retained records in line with GDPR. The clinic was registered with the information commissioner's office (ICO).

The service followed the franchise clinic security policy. This gave staff guidance on security issues their clinic could face. Systems where electronic records were stored were secure and password protected. For example, the bookings system password was changed if a member of staff left the service. However, the Ultrasound machine could not be password protected due to the machine type. A staff member was always in the scan room when it was unlocked with the machine so there was no risk.

The service followed the franchise's in-date information governance (IG) policy. This policy covered data retention and (internal) privacy policies. We reviewed this and found all staff had completed IG training as part of their mandatory training.

Engagement

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

The service used feedback cards to obtain feedback from women and their families. We checked 116 feedback cards. The service had made changes as a result of women's feedback. For example, they had added a dignity curtain in the scan room and replaced furniture in the reception and waiting area. Staff told us they also supplied a courtesy bag of goodies to all early scan women. Women were also able to leave reviews on the services website and through social media sites.

The service had established good links with local NHS trusts. Staff told us they liaised with NHS trusts when women needed a referral following an anomaly found on a scan. They contacted staff at the trust directly and ensured that the woman had an appointment to see the trust's relevant team. Referrals were securely emailed through to the appropriate hospital with the woman and referrer's details, what was seen during the scan. Staff then followed up these details with a telephone call to check the referral was received. At the time of our inspection, the clinic was talking to local acute trusts who told them their 12-week scans had massive implications on their ability to provide follow up care and support.

Staff told us they felt supported to make suggestions and contribute at monthly team meetings onsite. For example, they gave input about how to reveal the gender to women and their families as many women asked

about this. Staff worked closely as a team and ensured all feedback between the team was done daily, weekly and monthly. The franchisor was also present at least every other month to take onboard any staff feedback.

The franchise engaged well with staff. This was done through regular meetings with all partners taken to a hotel for a two-day development conference. This was inclusive and focused on the next steps for their strategy. The franchise had a very specific corporate strategy around growth, and they had met every business plan objective for the last five years.

Staff could access a confidential phoneline to discuss anything that affected them.

Staff told us they were kept well informed and felt involved in the business. Information was shared with staff face-to-face informally, daily and via monthly team meetings. Information was also shared with the team via email. The service received the franchise's monthly 'open window' newsletter sent out to all clinics. This was shared with the team and kept in a folder upstairs.

We heard the clinic staff enjoyed their working environment which was happy and inclusive so there were never staff shortages. The small group of ten staff enjoyed occasional week nights out when they could find childcare. One of the clinic's scan assistants ran a 'spinning tots' business in the photo studio above the clinic every Monday. They were fully qualified to lead this interaction class with babies from three months to three years old.

The clinic manager told us that they had a good relationship with other Window to the Womb clinic managers and the regional manager and franchisee. They told us they could go to them for advice and support when required. The clinic had established a working relationship with the miscarriage association. There were cards staff could pass on to women with information about how they could access support.

The clinic manager planned to mentor and support a local children's charity. At the time of our inspection this website was being built. The clinic did lots of family events and all the team were forward thinking.

Learning, continuous improvement and innovation

Staff were committed to improving the service by learning from when things went well or wrong, continuing professional development and innovation.

All staff were committed to continually learning and improving services. The franchisor produced in house training videos used for further training and development (T&D). These were mainly aimed at sonographers but could be accessed by scan assistants who wanted to learn more. The T&D folder contained a monthly checklist, training record cards, induction checklist, firstscan induction record, appraisal (if needed), evidence of first aid, level two safeguarding and child protection training.

The clinic manager spent time with the senior scan assistant and their new starter to mentor their learning and development. The service had links to other clinics in Liverpool and the Midlands but only for front of house staff.

Window to the womb had developed a smartphone application called 'Bumpies'. This allowed women to document and share images of their pregnancy. Women could share scan images with friends and family if they wished. It was optional for women to use.

The clinic manager told us theirs was the only clinic that offered women extra gifts. For example, they had lanyards for big brother, and could give women the Bumpies code on printed card with a baby image on the back to takeaway. The service gave each expectant parent an extra photo shoot for the price of their scan.

Outstanding practice and areas for improvement

Outstanding practice

- The service provided separate clinics for early pregnancy scans and well-being scans. The displays in the clinic were altered as to what was most appropriate for each clinic. Staff were mindful there was a higher risk of complications being detected during early pregnancy scans. Separating the clinics meant if a woman received bad news, they did not have to share a waiting area with women who were further along in their pregnancy.
- All staff were committed to continually learning and improving services. The franchisor produced in house training videos used for further training and development. The service could access a smartphone application called 'Bumpies.' This allowed women to document and share images of their pregnancy. Women could share scan images with friends and family if they wished.
- Clinic staff could escalate any concerns to a franchise freedom to speak up guardian (FTSUG). Staff we asked knew who the FTSUG was.