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?	Not sufficient evidence to rate
Are services caring?	Good
Are services responsive?	Good
Are services well-led?	Good

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

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

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

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

Summary of findings

Letter from the Chief Inspector of Hospitals

Window to the Womb, is operated by Devon Ultrasound Limited and operates under a franchise agreement with Window to The Womb (Franchise) Limited. They provide obstetric ultrasound services for pregnant women from 16 years of age, scanning from six weeks to full term. The service is provided to self-funding women across Devon.

The service provided the single specialty core service diagnostic imaging. We inspected this service using our comprehensive inspection methodology. We carried out a short notice announced inspection on 22 May 2019.

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

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

This was our first inspection of the service since the service opened in November 2016. We rated it as **Good** overall.

We found the following areas of good practice:

- A safe service was provided. Staff had the right qualifications and skills, received and completed mandatory training, and understood how to protect people from abuse and report incidents.
- The service had a suitable environment and equipment available and infection risk was well controlled.
- Detailed records of women's care and treatment were completed, with risks assessed and clear referral pathways if a scan identified a concern or anomaly.
- An effective service was delivered based on national guidance, mental capacity and consent legislation, and improvements were made where needed.
- Staff were inducted and ensured competent in their role, to include relevant registration with the Health Care Professional Council. Staff worked well together and with other healthcare providers.
- A high level of care was provided within the service. Staff cared for women and those close to them with compassion, kindness, dignity and respect. People were truly respected and valued as individuals.
- Staff provided emotional support to women and those close to them to minimise their distress. Emotional and social needs were highly valued by staff and embedded in care and treatment.
- Staff involved women and those close to them in decisions and their care and treatment. Their individual preferences and needs were reflected in the care delivered.
- The service was responsive to the needs of women and their families, and was tailored to pregnant women. People were able to access an appointment when they needed it.
- Concerns and complaints were investigated and lessons were learned and shared with all staff.
- The service was well-led with strong local leadership, and a positive culture was promoted and present amongst staff. The service engaged with women and their families, and staff, to help plan and manage the service.
- The service systematically improved service quality and safeguarded high standards of care. There were systems to identify risks, and plan to eliminate or reduce them.

However, we found some areas which could be improved:

Summary of findings

- A limited level of health promotion was considered or shared with women using the service**.** Instead, women would receive their health promotion via the NHS maternity pathways and care.
- Some staff files did not contain two proof of identity documents, with photo and address. The registered manager was rectifying this following our inspection.

Following our inspection, we told the provider that is should make a few improvements, even though a regulation had not been breached, to help the service improve. Details are at the end of the report.

Dr Nigel Acheson

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 	This is a diagnostic imaging service run by Devon Ultrasound Limited as part of the Window to the Womb franchise. The service is based in Exeter, Devon. We rated the service as good because it was safe, caring, responsive and well-led. We do not rate effective for this type of service.

Summary of findings

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Good

Window to the Womb

Services we looked at
Diagnostic imaging;

Summary of this inspection

Background to Window To The Womb

Window to the Womb is operated by Devon Ultrasound Limited. The service opened in November 2016 and had not been inspected. It is a franchise of Window to the Womb (Franchise) limited, located in Exeter, Devon, serving those in the local community.

The service has had a registered manager in post since 8 November 2016. At the time of the inspection, a new manager had recently been appointed and was registered with the CQC in May 2019.

The service was registered to provide diagnostic and screening procedures regulated activity at the location.

Our inspection team

The team that inspected the service comprised of one CQC inspector. The inspection team was overseen by Mary Cridge, Head of Hospital Inspection for the South West.

Information about Window To The Womb

Window To The Womb is a small service, running clinics three times a week. Clinics are divided into two so earlier pregnancy scans (first scans six to 15.6 weeks) are separate to later scans (16 plus weeks).

The first scan clinic offers the following scans:

- Viability scans from six to 10+6 week gestation
- Dating scans from eight to 12+6 weeks gestation
- Reassurance scans from 12 to 15+6 weeks gestation

The Window To The Womb clinic offers the following scans:

- Wellbeing scans from 16 to 40 weeks gestation
- Wellbeing and gender scans from 16 to 22 weeks gestation
- Growth and presentation scans from 26 to 42 weeks gestation
- 4D baby scans from 24 to 34 weeks gestation

All women accessing the service self-refer to the clinic and are private (self-funding) patients.

Facilities include a scan room containing one ultrasound machine, a reception, waiting area and print room.

In total there are seven scan assistants and a clinical director (the registered manager) employed and six qualified sonographers who work for the service on zero hour contracts.

During the inspection we visited the clinic and we spoke with five staff including the clinical director, scan assistants and sonographer. We spoke with six service users. We also reviewed 20 sets of records, and relevant policies and documents.

We reviewed data submitted as part of the Provider Information Request, data covered the last 12 months which dated between 20 March 2018 and 20 March 2019.

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

Activity for 21 May 2018 to 18 May 2019:

- First scan (6-15 week gestation) performed 747 scans.
- Window to the womb (16-40 week gestation) performed 2,349 scans.
- The total weekly clinic volume equates to 61 scans per week.

Summary of this inspection

- There were 65 referrals made, which were documented and retained on file.

Track record on safety between 20 March 2018 and 20 March 2019:

- No never events.
- No clinical incidents.
- No serious injuries.
- No incidences of hospital acquired infection.
- No complaints.

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 had not previously rated safe. We rated it as **Good** because:

- **The service provided mandatory training in key skills to all staff and made sure everyone completed it.** Records confirmed all staff were up to date with their training.
- **Staff understood how to protect people from abuse and the service would refer to other agencies if required.** Staff received safeguarding training and understood what constituted a safeguarding concern and when they would refer to the local safeguarding team.
- **The service controlled infection risk well.** We observed good infection control practice being carried out by staff and found the environment to be clean and tidy.
- **The service had suitable premises and equipment and looked after them well.** The ultrasound machine was checked daily and serviced annually.
- **Staff completed and updated risk assessments for each woman and made appropriate referrals.** Women were advised to attend their NHS scans as part of their maternity pathway. There were clear referral pathways if a scan identified a concern or anomaly.
- **The service had enough staff with the right qualifications, skills, training and experience to keep people safe from avoidable harm and to provide the right care and treatment.** Rotas were completed six weeks in advance to ensure staffing met the needs of the service. The staff group discussed each clinic list, including any areas of risk.
- **Staff kept detailed records of women's care and treatment.** All records reviewed had appropriate information recorded. Referrals to other healthcare providers had clear information and detail.
- **The service had processes for reporting and managing patient safety incidents.** Although there had been no incidents, staff were clear on the processes for reporting.

Are services effective?

Not sufficient evidence to rate

We do no rate effective for this core service.

Summary of this inspection

- **The service provided care and treatment based on national guidance and evidence of its effectiveness.** Staff were aware of the guidelines and protocols they should follow, to include from the British Medical Ultrasound Society, and as low as reasonably achievable radioprotection principles.
- **Staff recorded the care and treatment provided, and where available used the findings to improve the service.** The quality of sonographer practice and outcomes were reviewed. Women were referred to other healthcare providers if necessary.
- **The service made sure staff were competent for their roles.** Staff received inductions, regular appraisals and mandatory and refresher training. Sonographers were registered with the Health Care Professional Council and were additionally signed off as competent on a regular basis.
- **Staff worked together as a team within the clinic to benefit women and their families.** During the inspection we observed the team working well together to deliver the service. They communicated clearly with each other and the women and their families.
- **The service was provided at times which were more suited to the service users.** This included lunch time, evening and weekends. Referrals would be made immediately, or as soon as other healthcare providers were open.
- **Staff understood how and when to assess whether a woman had the capacity to make decisions about their care. They understood their roles and responsibilities under the Mental Health Act 1983 and the Mental Health Act 2005.** All women accessing the service signed terms and conditions to provide their consent.

However:

- **A limited level of health promotion was considered or shared with women using the service.** Instead, women would receive their health promotion via the NHS maternity pathways and care.

Are services caring?

Good

We had not previously rated caring. We rated it as **Good** because:

- **Staff cared for women and those close to them with compassion, kindness, dignity and respect. People were truly respected and valued as individuals.** People who used

Summary of this inspection

the service were overwhelmingly positive about the care they received. There was a strong, visible person centred culture, and staff recognised and respected the totality of people's needs.

- **Staff provided emotional support to women and those close to them to minimise their distress. Emotional and social needs were highly valued by staff and embedded in care and treatment.** Staff showed empathy and a consistently high standard of care and were trained in delivering bad news. Staff told us they did not rush women and their families, and recognised sensitivity.
- **Staff involved women and those close to them in decisions and their care and treatment. Their individual preferences and needs were reflected in the care delivered.** Information was clearly communicated to women and their families, and they were open with them even when conveying difficult information.

Are services responsive?

Good

We had not previously rated responsive. We rated it as **Good** because:

- **The service was planned and provided in a way that met the needs of the women and their families who would use the service.** The service offered early pregnancy scans to enable early reassurance for women and their families,
- **The service took account of women and their families individual needs.** The service was tailored to pregnant women and care could be adapted to meet the needs of women and their families.
- **People could access the service when they needed it.** There was no waiting list and people told us they were able to get an appointment easily.
- **The service treated concerns and complaints seriously, investigating them, and learned lessons from the results, and shared these with all staff.** We saw evidence of a complaint investigated and the outcomes were shared with staff.

Are services well-led?

Good

We had not previously rated well-led. We rated it as **Good** because:

- **Managers in the service had the right skills and abilities to run a service providing high quality sustainable care.** There was strong local leadership from the clinical director and further support provided by the franchise.

Summary of this inspection

- **The service had a vision for what it wanted to achieve.** They aimed to provide the utmost care and ensure women enjoyed the experience of their private pregnancy scan.
- **A positive culture was promoted that supported and valued staff.** We observed a friendly atmosphere and all staff provided a high quality service to women.
- **The service systematically improved service quality and safeguarded high standards of care.** There were processes and systems to ensure the governance of the service, these were clear and appropriate for the size of the service. We saw evidence of staff recruited were fit and proper.
- **The service had systems to identify risks, plans to eliminate or reduce them, and cope with both the expected and unexpected.** Risk assessments were completed and there was a business continuity plan.
- **The service collected, analysed, managed and used information well to support all its activities, using secure electronic systems with security safeguards.**
- **The service engaged well with women and their families, and staff, to plan and manage appropriate services.** There was regular contact with staff. Social media was a platform used engage with people who used the service.
- **The service was committed to improving services by learning from when things went well or wrong, and promoting training and support.** Peer-led assessments were introduced and observations on sonographers to assure of competency, but also enable learning and continuous improvement.

However:

- Some staff files did not contain two proof of identity documents, with photo and address. The registered manager was rectifying this following our inspection.

Detailed findings from this inspection

Overview of ratings

Our ratings for this location are:

	Safe	Effective	Caring	Responsive	Well-led	Overall
Diagnostic imaging	Good	Not rated	Good	Good	Good	Good
Overall	Good	Not rated	Good	Good	Good	Good

Good

Diagnostic imaging

Safe	Good
Effective	Not sufficient evidence to rate
Caring	Good
Responsive	Good
Well-led	Good

Are diagnostic imaging services safe?

Good

We had not previously rated safe. We rated it as **good**.

Mandatory training

- **The service provided mandatory training in key skills to all staff and made sure everyone completed it.**
- There was a rolling programme of monthly mandatory training. Mandatory training included; induction, first scan induction, first aid, child protection/safeguarding children, adult safeguarding, mental capacity assessment, and chaperoning. Training modules also included fire safety, infection control, health & safety at work, equality and diversity and information governance.
- Records confirmed all staff were up to date with their training. A training log was held for each employee recording the date of each training completed. A training matrix clearly set out the training requirements in line with staff roles.
- Sonographers could provide evidence of their NHS training, and copies of this were maintained on their personell files. They were required to complete all training which was unique to Window To The Womb, for example induction training.
- Staff told us they had access to the training and felt the quality was appropriate to ensure they were fully trained for their role.

Safeguarding

- **Staff understood how to protect people from abuse and the service would refer to other agencies if required.**
- The clinical director was the service lead for children and adults safeguarding. They confirmed no safeguarding referrals had been necessary since the service had opened.
- All staff received safeguarding training for children and adults to a minimum level two. Safeguarding training was provided when a new member of staff was inducted, and periodically through in-house mandatory training.
- An adult safeguarding and child safeguarding policy was operated. There was a safeguarding flow chart and policy to outline the process to follow should a member of staff have concerns about a child or adult's safety and welfare. Referrals could be made to the local authority. Policies were clearly displayed within the clinic, so staff could readily access the information. A separate policy was available for female genital mutilation.
- Staff understood what constituted a safeguarding concern. Speaking with staff they fully understood the processes they would follow if they had a safeguarding concern, and to refer to the local safeguarding team. Staff also had an awareness of topics, for example female genital mutilation.

Cleanliness, infection control and hygiene

- **The service controlled infection risk well.**

Good

Diagnostic imaging

- The clinical director was the infection control lead. A safety and hygiene, and infection control policy was operated to ensure the premises was safe and clean. Staff undertook infection control training.
- An infection control risk assessment and Legionnaires' risk assessment were completed for the clinic location. We saw completed risk assessments and these were reviewed annually.
- In the scan room good infection control practice was observed in line with the provider's policy. Sonographers were observed to wash their hands between each scan and apply hand sanitiser to reduce the risk of cross contamination. The probe of the scan machine was cleaned after each use, using the correct wipes provided, in line with best practice. Paper towels were used on the couch and changed between each scan. Additionally, wipes were used to clean the couch following a transvaginal ultrasound.
- There were suitable handwashing facilities available adjacent to the scan room. All staff were observed to wash their hands as required and were bare below elbow. Hand sanitiser was also readily available. Hand hygiene audits were completed annually to review whether staff were using appropriate hand cleaning techniques. We reviewed the audit and saw evidence of further support provided to a staff member to ensure they were compliant.
- Personal protective equipment, for example gloves, was available to staff. We observed staff using their personal protective equipment when required to do so.
- The premises was kept clean to reduce the risk of infection and cleaning schedules were used. We observed the premises was very clean and tidy. Daily cleans were completed and deep cleans were completed on a six-monthly cycle. We reviewed the completion of forms for both daily and deep cleans. Recently an additional column had been included to confirm toys within the clinic had been cleaned. This had not previously been recorded although we were told was completed regularly.
- Cleaning equipment was available and those which met control of substances hazardous to health regulations were stored securely in the room adjacent to the scan room.
- There had been no incidence of healthcare acquired infection in the last 12 months.

Environment and equipment

- **The service had suitable premises and equipment and looked after them well.**
- Key items of equipment were maintained according to the suppliers recommended schedule. We observed the ultrasound machine had been checked in line with manufacturers guidance.
- Quality assurance checks were completed on the ultrasound daily. This was recorded within the morning meeting to confirm it had been done.
- There was no specific availability of bariatric equipment, although the only restriction would be the couch. This would be assessed on a case by case basis.
- Fire regulations were being followed. There were fire extinguishers available, no fire hazards and fire checks were completed regularly.
- Clinical waste was disposed of correctly. There were clinical waste bins within the scan room.
- First aid equipment was available within the clinic and observed to be well stocked with in date items. Staff were available who were first aid trained.
- Portable appliance testing had been completed on 25 May 2018 and there was a planned retest as this was due to expire.

Assessing and responding to patient risk

- **Staff completed and updated risk assessments for each woman and made appropriate referrals.**
- All scans started with a wellbeing check, this checked the baby's movement, heartbeat, position and placental position.
- Women were advised to attend their NHS scans as part of their maternity pathway and were given information about the risk of frequent scanning. Staff ensured this was clear to women and was included within the terms and conditions, which women signed.

Good

Diagnostic imaging

- There were clear referral pathways. If a scan identified an anomaly, that in the sonographer's professional opinion required medical care, the woman would be referred to their local NHS either directly or via their GP. All staff were aware of the processes to follow. The hospitals pathway folder included when; viability not confirmed/fetal demise, intrauterine fetal death and fetal anomaly. If women did not need to see another healthcare professional immediately they were fully informed of the risks and made aware of any symptoms which should require them to attend their local accident and emergency department.
- There had been 65 referrals to the NHS or GP, between 21 May 2018 and 18 May 2019. These were all documented and retained on file. We reviewed the referrals and adequate detail had been included for ongoing care to be provided by another healthcare provider. There was a clear record of any conversations held with other healthcare professionals, for example midwives.
- Staff were clear on how to respond in an emergency, this involved calling for an ambulance. As per protocol, a woman suspected of having an ectopic pregnancy would not be moved off the couch and the team would wait for the ambulance to arrive. There had been no patients transferred from the location to another healthcare provider in the last 12 months.
- Service user assessments were undertaken prior to carrying out any service on an individual. The service would not be carried out if it was believed the woman was unable to understand the service offered or the service was inappropriate for the woman.
- A full-time sonographer was available remotely to review scans if the sonographer needed a second opinion. We were told this process had been used for a second opinion and the sonographer responded in a timely manner.

Staffing

- **The service had enough staff with the right qualifications, skills, training and experience to keep people safe from avoidable harm and to provide the right care and treatment.**
- The service was fully staffed with scan assistants and there were no staffing vacancies. Eight scan assistants provided 2.75 full time equivalent, this included the clinical director. All staff were on a zero-hours contract and worked within the clinic on a rota basis.
- There were six sonographers who were on a zero-hours contract. All were registered with the society of radiographers or the healthcare professional's council. The clinic currently did not have a full-time sonographer. This put some restrictions on opening hours, however they were in the process of recruiting.
- Rotas were completed six weeks in advance, with staff providing cover for sickness or unforeseen circumstances. There was no need for bank or agency use. There was also the possibility to use staff from the Bristol clinic to meet staffing needs.
- Staff did not work alone, so there were no risks associated with lone working.
- All staff received a local induction. This included an induction specifically for first scans.
- A daily meeting was held by staff discussing all women on the list, this included any risk areas. We observed a scan assistant start work half way through the clinic, and they were fully informed of the discussion held at the start of the list.

Records

- **Staff kept detailed records of women's care and treatment.**
- All records were held securely within the clinic. Records were kept for each woman who attended for a scan, and they were also given a copy to keep. Sufficient information was obtained and recorded prior to the scan, for example pregnancy history and health, and following the scan the information about the woman and the baby.
- Women were required to bring their pregnancy notes to the clinic. However, they would still be seen if they had forgotten their notes, pending agreement by the sonographer.
- Every scan included a wellbeing check. We observed these being recorded during scans and reviewed completed proformas.

Good

Diagnostic imaging

- We reviewed 10 records for first scan, where obstetric reports were completed. We confirmed the obstetric report guidelines were followed when completing an obstetric report. The transvaginal record was always recorded as giving consent. The sonographer included their signature, name and registration.
- We reviewed 10 records for window to the womb. Fetal wellbeing reports were fully completed and all consent was signed.
- In the event an anomaly was identified, the patient was referred to their local hospital and there was a pathway to do this. In all cases the patient took a report, which was completed by the sonographer, and a referral form with clear information and details about the concerns or anomaly identified. We reviewed examples of completed referrals and all provided relevant detail.
- The completion of records was reviewed as part of the quality assurance checks.
- A smart device application, developed by the franchisor, was used to allow women to securely view their scan images and videos when no longer in the clinic.

Medicines

- The service did not store or administer any medicines.

Incidents

- **The service had processes for reporting and managing patient safety incidents.**
- There had been no incidents reported for the service in the last 12 months prior to our inspection. There were processes to record the incident within an incident book and the clinical director would be responsible for investigating and sharing learning or informing of change. Staff were clear on the incident reporting process.
- There had been no IRMER/IRR reportable incidents in the last 12 months prior to our inspection date.
- There had been no serious incidents reported in the last 12 months prior to our inspection date.
- Duty of candour is a regulatory duty that relates to openness and transparency and requires providers of health and social care services to notify patients (or other relevant persons) of certain 'notifiable safety incidents' and provider reasonable support to that person. No duty of candour notifications were required to be made in the last 12 months prior to our inspection date. Staff understood the application of the duty of candour.
- Managers were aware of the requirements for reporting incidents and submitting notifications to the Care Quality Commission. However, this had not been required in the last 12 months.

Are diagnostic imaging services effective?

Not sufficient evidence to rate

We do no rate effective for this core service.

Evidence-based care and treatment

- **The service provided care and treatment based on national guidance and evidence of its effectiveness.**
- Guidelines were followed in line with guidance for professional ultrasound practice, from the British Medical Ultrasound Society. Staff were aware of these guidelines and the protocols they followed.
- The clinic followed as low as reasonably achievable principles. This is a principle of radioprotection to ensure the radiation received by people is as low as possible. These guidelines were clearly displayed on the wall within the scan room, and within the terms and conditions which all women signed.
- Updates on national guidance and implementation was monitored by way of receiving a monthly newsletter from the franchise, bi-annual franchise meetings and communication fed from senior sonographers.
- Policies were refreshed annually to ensure they were relevant and up to date. Staff had access to policies.
- Within the franchise there was access to clinical lead sonographers and a senior midwife to support the clinic and their sonographers. They were responsible for advising the board on compliance with national

standards and ensure policies and strategy were in line with best practice and evidence-based guidance. Sonographers maintained good working relationships with these individuals.

- Peer review audit tools, which were used to assess the sonographers' practice, were evidence-based tools.
- There was an audit programme to assure the compliance of the clinic and the employees, with safety and quality of the service provided. This included an annual audit completed by the franchisor and a monthly audit completed by the clinical director.

Nutrition and hydration

- A water machine was available on the premises for women and their families to use. Refreshments were also available which could be purchased or provided to women if they felt unwell.

Pain relief

- Pain was not formerly monitored, as this was not required for the service provision. However, staff were observed ensuring women were comfortable during their scans. Staff discussed the use of cushions and adjusting the couch if a woman was experiencing back pain or discomfort.

Patient outcomes

- **Staff recorded the care and treatment the service provided, and where available used findings to improve the service.**
- The number of scans completed and the number referrals were recorded.
- A rescan guarantee was provided free of charge, if it was not possible for the outcome to be determined. For example confirmation of the gender, or detection of heart beat.
- The quality of sonographer practice and outcomes were reviewed. There was on site and remote assessments of scans completed by the franchise clinical leads, as well as peer assessments within the clinic.
- Sonographers were fully qualified in identifying an anomaly and how to conduct a referral to the NHS and there were clear pathways to do this. Scan assistants were fully trained in how to conduct referrals and how to support the sonographer in completing this.
- All referrals to the NHS were retained and the quality of these checked as part of internal audit process. However, there was no arrangement for communication from the NHS on the outcome of the referral, due to patient confidentiality and data protection regulations.
- The accuracy rate of gender confirmation scans could not be specifically monitored. However, the clinic was likely to be informed if they had gender scanned incorrectly which would be managed via the complaints process. Since the clinic opened they had been informed of one incorrect gender confirmation.

Competent staff

- **The service made sure staff were competent for their roles.**
- There was regular communication and training with staff. All staff (clinical and non-clinical) were inducted. There was scheduled mandatory training, online third-party training courses, and regular refresher training. Periodically observations on staff were carried out by senior staff.
- Annual appraisals were completed for staff, and initial three month reviews for new staff. Of the four scan assistants, who had been employed for more than 12 months, all had received an appraisal. We reviewed example appraisals, this provided an opportunity for the employee to self-appraise themselves, and be appraised with identification of additional training needs.
- Scan assistants were all trained to the specific requirements of the service, so all staff could fill each role applicable to scan assistants through the pathway.
- There were processes to confirm clinical staff were fully qualified. Sonographers were all qualified and registered with the Health and Care Professions Council or Society of Radiographers. They were signed off by a senior lead sonographer and had annual reassessments by the clinical lead. Observations on

sonographers and peer assessments were completed to further support the provision of an effective service and better level of care. Sonographers had access to educational videos on unusual anomalies which could be used for their continuing professional development.

- It was ensured sonographers were providing the best possible service by undertaking an annual competency validation. This was based on observations and feedback by another qualified individual.
- Sonographer peer assessments were completed each quarter. For each sonographer a first scan, gender and 42 week scan was reviewed, including the well-being and obstetric report. The actions required, and any follow up were recorded as necessary.
- Sonographer care and service assessments were completed to appraise the quality of customer care and service, standard of communication, and overall customer experience.

Multidisciplinary working

- **Staff worked together as a team within the clinic to benefit women and their families.**
- During the inspection we observed the team working well together to deliver the service. They communicated clearly with each other and the women and their families.
- There were clear pathways to refer women as agreed with local NHS trusts. There were difficulties identified with referring women directly to early scans for one acute hospital who did not accept private referrals, however this was mitigated by referring via the GP. This pathway was being reviewed and discussed with the franchise midwife lead, and conversations had been held with the acute hospital.
- GPs were readily accessible to refer patients to hospital. The clinic spoke of a good working relationship to meet the needs of the women.

Seven-day services

- **The service was provided at times which were more suited to the service users.**
- Typically, the clinic was open on a Thursday from lunch time through to early evening, and on Saturdays and Sundays 10am to 5pm.
- Out of hours GPs and units were not accessible. If a referral was required staff would ensure this was completed as soon as GPs or units were open, and would explain this fully to women and their families.

Health promotion

- **A limited level of health promotion was considered or shared with women using the service.**
- Health promotion was provided via the NHS maternity pathway and care.

Consent and Mental Capacity Act

- **Staff understood how and when to assess whether a woman had the capacity to make decisions about their care. They understood their roles and responsibilities under the Mental Health Act 1983 and the Mental Health Act 2005.**
- Signed terms and conditions for every service user and all service users' assessments were completed, and checked periodically as part of the audit process. Terms and conditions ensured women were informed of the risks of scans both to women and the unborn child. We reviewed completed consent forms for all women who used the service during our inspection, and confirmed these were also completed on stored records.
- Children aged between 16 and 18 years were required to attend with a parent or responsible adult over the age of 25. Children under 16 years of age were not permitted to be scanned. There was a policy for Gillick competence for information so staff were clear on consent.
- Policies and procedures were operated to ensure staff were aware of any vulnerable users or situations. Policies covered: a lone person's policy, child protection policy, adult safeguarding policy, equality policy, and mental capacity act policy. Women or staff members were not left alone in the clinic, so not to expose either to any potential risk.

Good

Diagnostic imaging

- E-learning was being developed by the franchise for mental capacity act which all staff will be required to complete. In the meantime staff had access to the policy.
- Information was provided for women in line with those published by Public Health England.

Are diagnostic imaging services caring?

Good

We had not previously rated caring. We rated caring as **good.**

Compassionate care

- **Staff cared for women and those close to them with compassion, kindness, dignity and respect. People were truly respected and valued as individuals.**
- The service was committed to delivering the highest level of care and customer service to women and their families. There was a positive atmosphere within the clinic, and everyone was passionate to meet the needs of women and their families, with great care observed.
- There was a strong, visible person-centred culture. All staff were fully aware of the importance of the service provided. Staff were recruited if they were passionate for the work, provided a caring nature and understood how important the role they played in the process of the service. Observations were conducted on staff to see they were delivering the high standard of service expected.
- Staff recognised and respected the totality of people's needs, taking people's personal, cultural, social and religious needs in to account.
- People who used the service were overwhelmingly positive about the care they received. We asked for feedback from women and their families during our inspection. Comments included:

  "Staff were brilliant and patient"

  "Staff were very helpful"

  "They were all very friendly. We are not finding out the gender and they were very supportive of this"

  "Everyone was really helpful and patient, and made me and my family feel relaxed and welcome"

  "Welcoming and friendly all the way through. Very chilled atmosphere for my two younger children too, which I was extremely happy about"
- We also reviewed the feedback the clinic had obtained from service user using feedback cards. Comments included:

  "Fantastically reassuring, all staff lovely"

  "The best scan experience we've had, staff were friendly and made for a great relaxed environment

  "Very warm and welcoming atmosphere"
- Continual positive feedback was also voluntarily left on social media or internet reviews. Comments included:

  "Absolutely amazing experience….staff are friendly and knowledgeable…such a warm, friendly atmosphere"

  "We were made to feel very welcome on arrival, the staff were all amazing"

  "Very professional in every aspect, the staff were all so friendly, kind and caring"
- Privacy and dignity was well maintained. For example, staff left the room while women prepared themselves before and after a transvaginal scan. Blankets were provided to maintain modesty. Staff were always conscious of people's privacy and dignity.
- There was sensitivity when performing ultrasounds during the first scan clinic. The sonographer started the ultrasound by only viewing on their own screen, they subtly informed the scan assistant when they were able to turn on the large television screens, so the woman and her family could also watch.
- The sonographer continued to smile throughout the scan and inform the woman and their family about the scan. The scan assistant put women and their families at ease and engaged with them throughout the process in a caring manner.
- Women could not always speak without being overheard. When in the scan room women and their families could be heard in the reception area.

However, staff spoke quietly to women and their families to limit the risk of being overheard, and there were available rooms to discuss confidential or sensitive information in private.

Emotional support

- **Staff provided emotional support to women and those close to them to minimise their distress. Emotional and social needs were highly valued by staff and embedded in care and treatment.**
- Staff showed empathy and a consistently high standard of care. As part of training all staff were trained on the emotional aspects of receiving bad news. We were told how staff were regularly thanked despite giving bad news.
- Scan assistants acted as chaperones, so women were provided with emotional support throughout their scan.
- Women were offered a card with contact details for the Miscarriage Association, so they could seek support and information.
- Speaking to women and their families who used the service they felt they were provided with emotional support.
- Staff spoke about how they did not rush women and their families and recognised sensitivity. They always put the woman and their family first. If they delivered bad news, and there were several people with the woman, they would ask them to leave while speaking to the woman and one person.
- We did not see any examples of difficult information or findings being communicated to women and their families. However, staff spoke about different ways they would communicate and the information they could provide to give additional support.
- Information leaflets were available for different outcomes of the scan, to ensure women and their families understood information and were aware of support available.
- Scan assistants and sonographers were clear on the emotional support which may be required before they saw each woman, and discussed this amongst themselves before inviting the woman in to the scan room. If women were anxious they would be put at ease. We observed this during our inspection visit.
- The daily meeting enabled the women on the list for the day to be discussed so staff were aware of any emotional support or sensitive issues. For example, if a woman had several previous miscarriages.

Understanding and involvement of patients and those close to them

- **Staff involved women and those close to them in decisions and their care and treatment. Their individual preferences and needs were reflected in the care delivered.**
- We observed information being clearly communicated to women and their families by staff on reception, scan assistants and sonographers. They were asked if they had any questions before they left the scan room.
- People told us it was ensured they understood the process and results or findings both before and after the scan. When women phoned to book scans we were told discussions were held about expectations. For example, if a woman was under seven weeks they were advised to book their appointment closer to eight weeks as there was more chance of a heartbeat being detected. This was well managed with the women.
- There were appropriate discussions about cost and available services and products.
- Women were encouraged to bring someone to the clinic with them, so they had support.
- Staff told us if they are required to make a referral for the woman they were open with them about the process and ensured they were fully informed. This was important even when conveying difficult information.

Good

Diagnostic imaging

Are diagnostic imaging services responsive?

Good

We had not previously rated responsive. We rated responsive as **good.**

Service delivery to meet the needs of local people

- **The service was planned and provided in a way that met the needs of the women and their families who would use the service.**
- There was the addition of early pregnancy scans, which had been running for 18 months at the time of our inspection. This early scan package was designed for individuals who had undergone IVF, had recurrent miscarriages or a previous ectopic pregnancy, to enable early reassurance of viable pregnancies. This was piloted at other clinics where the clinical director had visited, and a decision was made for Window To The Womb Exeter to also introduce first scans. The clinical director was able to opt in or out of different service provisions dependent on what fitted the location.
- The service had some flexibility to meet the needs of service users. Clinics were provided both week days and weekends, this included evening appointments, so the service was more accessible. There was the potential to extend hours, as required, to meet the needs of patients. With no full-time sonographer at present it was difficult to offer additional clinics. This would be reviewed when a full-time sonographer is in post, as the clinical director hoped to offer more clinics.
- The reception and print room were reorganised to enable a better flow of customers, especially when they were accompanied by family and friends. It also enabled the staff in reception to see people as they left to allow for engagement and interaction. The print room was changed so only one family at a time reviewed their photos to ensure privacy. The layout was discussed with returning customers and feedback was positive.
- There were a range of packages available to women and their families. These were displayed in the clinic, on the website and discussed in person. All packages included a well-being scan.
- Women were in safe and comfortable surroundings. The environment was appropriate. The waiting room was comfortable with enough seating, and toys available for children who accompanied their parents. Toilets were also available. The scan room was a large room which could accommodate seven family or friends to accompany the woman during her scan. Comfortable sofas were in the room and three large television screens. Relaxing music was played to provide a soothing atmosphere.
- Following the scan, the print room provided a private area to review the pictures from the ultrasound. Women and their families were able to choose images and other keep sakes. Heartbeat bears were also available to place the recording of the baby's heart beat within a cuddly bear.
- A 'bump to toddler' group had been started in May 2019. It was held in the clinic's waiting room twice a month on a Tuesday. This was because of people commenting how they don't see staff again following their scan. The 'bump to toddler' group was able to be flexible and approachable. Initial feedback from women said this was a relaxing environment.
- Leaflets were available to provide further information with regards to the services offered and about pregnancy. For example, scan packages, sickness during pregnancy and process for contacting the maternity unit.
- The service reached out to local people, for example local photography was displayed, and charity work was completed.

Meeting people's individual needs

- **The service took account of women and their families individual needs.**
- The service provided was tailored to pregnant women but considered everyone. We asked five women whether staff met their individual needs and those of their family, all five agreed this was met.

Good

Diagnostic imaging

- Clinics were split so women who were in earlier stages of pregnancy had appointments within the first scan clinic and were separate to later scans as part of the window to the womb clinic, there was a break between these two clinics. This was to ensure more sensitivity due to the fact there's a higher chance of delivering bad news to those under 16 weeks.
- Within the first scan clinic, staff worked as a team of three (two scans assistants and one sonographer). Each scan assistant took turns to accompany pregnant women through the scan process, from completing their forms, the scan itself and the after care. This provided continuity of care and allowed support to the sonographer.
- During the 16+ week scans in the window to the womb clinic staff worked as a team of four (three scan assistants and one sonographer). The scan assistants were each allocated a role which they stayed in for the duration of the clinic. One scan assistant was on reception, one within the scan room to support the sonographer and another in the print room. We were told this arrangement had proven to be the best and simplest to deliver a better level of care and customer service.
- We discussed with staff how they met the needs of different people using the service. They explained how they treated each woman and their family as individuals and adapted as required. They were sensitive to the different scenarios, for example women who were undergoing IVF, or women who may have had several miscarriages.
- One example was provided by a scan assistant where a partially deaf woman came in for a scan. The scan assistant spoke about how they ensured they communicated directly to this woman rather than to her family and made sure she understood fully and was able to write down information to make communication easier for the woman.
- Access for people who were disabled was considered. The waiting area and print room were located upstairs. Should a woman or a family member not be able to use the stairs they could wait and view their photos in the reception area. We saw this being accommodated during our inspection.
- Some families did not want to know the gender of their unborn baby. We observed staff were clear on this fact and would ensure the family were told when to close their eyes if there is a risk the gender would be visible on the screens.
- Translators were accessible where English was not a first language. Staff were aware of how to access this translation and read aloud service and explained this had been used to translate important documents.
- The length of appointments provided enough time for the women and their families to ask the sonographer and scan assistant questions. They were provided private time to review images in a separate area with a different scan assistant.

Access and flow

- **People could access the service when they needed it.**
- There was no waiting list to access the services provided. All appointments were pre-booked by the service user via an online booking system. Bookings were also taken over the phone, providing opportunity to discuss their reason for booking and choosing a service which best suits their needs. Diaries were opened months in advance to give opportunity for potential service users to book a date which best suits them. If a day was filled there was flexibility to extend hours.
- We asked five people whether they were able to get an appointment easily and at a time which suited them, everyone said yes. Comments included "simple and easy online booking" and "online tool simple to follow."
- Within the two years of the service running it was uncommon for the service to run with a delay.
- Sonographers gave results of the ultrasound to women and their families immediately after the scan. The sonographer produced a report in the time the pictures were being chosen and printed.
- During our inspection the service mostly ran to time, and women were not kept waiting too long when they arrived. One woman was unable to attend due to problems with their car, their appointment was re-arranged for later in the day.

Good

Diagnostic imaging

- Where there were difficulties with obtaining the correct information or images within the scan women were rebooked for a later date. For example, if too early to confirm a heartbeat, or if the unborn baby is in an awkward position.
- Women who did not attend their appointment were contacted after their appointment time had passed. This was done sensitively should the reason they did not attend be due to problems with their pregnancy. However, arrangements would be made to accommodate and rebook the woman.
- Cancellations of appointments by women could be done 48 hours before the appointment. Women who experienced pregnancy loss were refunded any upfront costs they had made.
- One staff member always held the phone, so the service could be contacted out of working hours.
- We were told people attending the clinic would be informed if there were any local events being held which might impact on their travel time to get to their appointment.

Learning from complaints and concerns

- **The service treated concerns and complaints seriously, investigating them, and learned lessons from the results, and shared these with all staff.**
- The clinical director oversaw and managed complaints. Complaints were usually minor and tended to come via social media. The complainants would be contacted by telephone by the clinical director who would listen to the concerns and identify any learning. Feedback was provided to the complainant and shared with staff.
- There had been one complaint received between 20 March 2018 to date of inspection on 22 May 2019. We reviewed the customer complaint log which included four complaints prior to the 20 March 2018. This included the nature of the complaint, and the action taken in response.
- We discussed the one complaint with the clinical director, this was with regards to the difficult position the baby was in which did not enable clear images and video for the customer. This was resolved by discussing the process, and a further scan was offered. It was evident in the team meeting minutes this had been fed back to staff.
- There was a Window To The Womb complaints policy, outlining the process to resolve complaints locally. This was available to service users. If complainants were not fully satisfied with the response they were directed to escalate their complaint to the franchisor, or external bodies to include the society of radiographers if the complaint is about a sonographer, or to the Care Quality Commission.
- We were told all staff working in the clinic interacted with customers, and staff were actively encouraged to ask them if they were happy with the service and identify any potential dissatisfaction while still in the clinic.
- How to complain information was documented on the back of feedback cards, and on terms and conditions which were signed by all women using the service.
- It was recognised social media was a platform regularly used for customers to raise their concerns. Social media was therefore monitored daily, so the clinical director could respond immediately.
- The service regularly received written compliments.
- Feedback cards were used for service users to tell the service about their experience. This included; ease of booking scan, initial welcome by team, care provided during scan, hygiene and comfort of the clinic, and overall experience. Feedback cards reviewed showed consistently positive results.

Are diagnostic imaging services well-led?

Good

We had not previously rated well-led. We rated well led as **good.**

Leadership

- **Managers in the service had the right skills and abilities to run a service providing high quality sustainable care.**

Good

Diagnostic imaging

- Strong local leadership was provided by the clinical director. The clinical director had recently registered with the Care Quality Commission in May 2019 as the registered manager. They were supported by a director, who was the Care Quality Commission nominated individual. Further support was provided by the franchise.
- The clinical director had not accessed specific leadership training and support, however this was available if required. They told us they received training in the role and had previous management experience and attendance on courses from other employment. They completed all shifts and roles to ensure they were able to lead by example.
- There were two appointed team supervisors who had worked within the clinic for almost two years and were fully trained in managing the clinic, the service and supporting the staff.
- Staff felt the leadership team were accessible and supported their staff.

Vision and strategy

- **The service had a vision for what it wanted to achieve.**
- They aimed to provide the utmost care and ensure women enjoyed the experience of their private pregnancy scan.
- Consideration would be given to accepting NHS workloads to lessen the burden on the NHS.
- The service was also considering other service provision, for example the 'bump to toddler' group to promote socialisation for parents.

Culture

- **A positive culture was promoted that supported and valued staff.**
- The culture within the service was extremely positive, with a friendly atmosphere, all staff spoken with loved their job and provided a high-quality service to women and their families.
- Good team work was observed, and staff were confident to raise any concerns or suggestions they may have.

Governance

- **The service systematically improved service quality and safeguarded high standards of care.**
- The clinical director was responsible for the local governance. Advice was sought from the franchisor who provided a schedule of policies to adhere too. The franchisor also kept the service up to date with current practices.
- There were processes and systems to ensure the governance of the service, these were clear and appropriate for the size of the service. This included clinic compliance and competency of sonographers. Compliance was regularly checked as part of annual and monthly audit of the clinic reviewing the quality, safety and effectiveness of the service delivered. There was evidence of action taken to respond if any improvements were needed.
- Staff meetings were held monthly, to keep staff updated. We reviewed the monthly meeting minutes to evidence this was completed, and important messages shared with staff.
- Staff were recruited through a method of selecting staff, telephone interviews, face-to-face interviews and trial shifts.
- Staff underwent appropriate checks as required by Schedule Three of the Health and Social Care Act for safe recruitment. We reviewed personnel files and saw people were recruited who were fit and proper. For sonographers the registration with the health care professional council was checked to ensure they were registered, which evidenced qualification relevant to their duties. We did identify there was not always two proof of identify documents with photo and address, some files held just a copy of the passport. Following inspection, we were informed proof of identity addresses were missing for two sonographers due to changes in address, this was being sought to be added to their files.
- All staff had a completed disclosure barring service criminal record check to ensure they were of good character.

- The group held medical malpractice insurance covering medical malpractice and sonographer vicarious liability, for private obstetric diagnostic services (ultrasound).
- All sonographers maintained their own individual professional indemnity insurance which was a requirement.

Managing risks, issues and performance

- **The service had systems to identify risks, plan to eliminate or reduce them, and cope with both the expected and unexpected.**
- The risks to the service were risk assessed using a risk assessment proforma. These risk assessments were held on file.
- Files were well organised, so information was easily accessible.
- A Window To The Womb clinic audit was completed at least every three months by a franchise representative, to review the clinic's compliance with processes and procedures. If unsatisfactory the audit would be completed within one month. We reviewed the most recent audit, completed on 13 February 2019, and identified a limited number of concerns. All concerns had relevant actions identified and had since been completed. Areas checked included; a physical clinic inspection reviewing environment, equipment and cleanliness, review of health and safety and infection control, and emergency planning arrangements. The audit also reviewed the effectiveness of the service, for example well-being reports completed accurately, review of pathways and paperwork for example when referred to NHS, and ensuring records followed obstetric report guidelines. The appropriateness of staff employed, and ongoing checks was also reviewed.
- A monthly clinic self-audit was completed covering similar areas to the annual Window To The Womb clinic compliance audit. We reviewed the March and April 2019 clinic self-audits. Relevant actions were recorded.
- Additionally, the franchisor carried out mystery calls to the clinic to evaluate the standard of staff communication and effectiveness. There was no feedback evident from this as a call had not been successfully made. We were told feedback would be received following each mystery call and additional training identified as required.
- There was a business continuity plan to ensure the service could continue to run.

Managing information

- **The service collected, analysed, managed and used information well to support all its activities, using secure electronic systems with security safeguards.**
- There was access to Window To The Womb policies and processes, covering relevant areas.
- Window To The Womb Limited was registered with the Information Commissioner's Office (ICO), in line with The Data Protection (Changes and Information) Regulations (2018). The ICO is the UK's independent authority set up to uphold information rights.
- The service was compliant with the General Data Protection Regulation (GDPR) 2018. Consent was obtained from women to store their records.
- Women using the service were provided with a statement which included terms and conditions of the service being provided to them, and the amount and method of payment fees.
- A data retention policy for Window To The Womb Limited (franchise) detailed the practice in relation to the retention of personal data and disposal of information.

Engagement

- **The service engaged well with women and their families, staff and local organisations to plan and manage appropriate services.**
- There was a Window To The Womb 'freedom to raise a concern' policy. This policy applies to employees within the organisation, to raise concerns about risk, bad practice and wrong doing. There was a Window To The Womb freedom to speak up guardian, who has been trained in receiving concerns. Staff spoken with were aware of this policy.

Good

Diagnostic imaging

- Feedback between the team was done on a daily, weekly and monthly basis. Daily meetings discussed any ongoing concerns and the diary of women due for the day. Monthly meetings were held in clinic and quarterly team training days conducted in house. There was a secure social media group and page to discuss any concerns, new developments and areas of learning to one another.
- Social media was a platform used to engage with people who use the service. It also enabled the monitoring of feedback and reviews.
- Feedback forms were available within the clinic, which clearly explained how a customer would make a complaint, should they feel it necessary. However, feedback forms did not provide open-ended questions for feedback.
- Staff felt able to share their opinions and provide feedback as required or at staff meetings.
- Following our inspection, a clinical visit of first scan by the franchise had been arranged, this was a visit from the franchise midwife lead to review and observe the first scan clinic following its first year of implementation. Discussions were also planned about future learning and challenges faced.

Learning, continuous improvement and innovation

- **The service was committed to improving services by learning from when things went well or wrong, and promoting training and support.**
- Peer-led assessments were introduced, and observations on sonographers, to assure competency but also enable learning and continuous improvement.
- Window To The Womb Exeter was keen to learn from businesses within the franchise, and made changes and improvements following feedback from other CQC inspections. They now ensured recording of practice so they could evidence compliance, and these processes had begun to embed in practice.

Outstanding practice and areas for improvement

Outstanding practice

- Women were in safe and comfortable surroundings and high standards of care was always provided to women and their families. Care was provided with compassion, kindness, dignity and respect. Each woman and their family were treated as an individual and support and care was provided to suit their needs. The service was passionate to deliver high quality care, and ensure they employed staff who demonstrated those qualities and understood the needs of the service. The quality of customer care and communication skills staff delivered was assessed on a regular basis to ensure the level of care met the standards required.
- Staff provided emotional support to women and those close to them to minimise their distress. Emotional and social needs were highly valued by staff and embedded in care and treatment. There was an awareness of the emotional needs of different women and staff were able to manage delivering difficult news in a sensitive manner. The early scan and later scan pregnancy clinics were kept separate with a natural break, so women earlier in their pregnancy who may be more anxious or more likely to be delivered upsetting news, did not share the clinic areas with women who were later in the pregnancy.

Areas for improvement

Action the provider SHOULD take to improve

- Review how the service can incorporate health promotion to be available to or shared with women using the service, in addition to what they receive as part of their NHS maternity pathway.
- Obtain two proof of identity documents with photo and address when recruiting staff. Signing and dating when copies are taken.