Window to the Womb Reading

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

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.

Summary of findings

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 Reading is operated by Divinity Ltd and operates under a franchise agreement with Window to The Womb (Franchise) Ltd. The service provides diagnostic pregnancy ultrasound services to self-funding women across Berkshire.

The service provides diagnostic imaging for children aged 16 years to 18 years and adults over the age of 18 years. It is registered to provide the regulated activity of diagnostic and screening procedures.

We inspected this service using our comprehensive inspection methodology. We carried out a short notice announced inspection on 5th March 2019. We gave staff two working days' notice that we were coming to inspect to ensure the availability of the registered manager and clinics.

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

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

Services we rate

We have not previously inspected this service. At this inspection we rated it as **Good** overall

We found the following areas of good practice:

- 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. Managers appraised staff's work performance annually and checked to make sure staff had the right qualifications and professional registration for their roles.
- Staff understood how to protect patients from abuse and the service worked well with other agencies to do so.
- The environment was appropriate and met the needs of the range of people who accessed the service including toys for children to play with whilst waiting for parents' appointments. The service controlled infection risks effectively.
- 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.
- The service provided care and treatment based on national guidance and could evidence its effectiveness. Managers monitored the effectiveness of care and treatment and used the findings to improve them. The service evaluated images to ensure they were of good quality.
- The service treated concerns and complaints seriously. The registered manager completed comprehensive investigations and shared lessons learnt with all staff.
- The service improved service quality and safeguarded high standards of care by creating an environment for good clinical care.
- Staff were caring, compassionate, kind and engaged well with women and their families.
- The service took account of patient's individual needs for example if an early scan showed a miscarriage the women could exit the clinic via another exit rather than passing other waiting pregnant women.

Summary of findings

- Managers promoted a positive culture that supported and valued staff. Staff reported their team worked well together and staff trusted and respected each other.
- The service collected, analysed, managed and used information to support all its activities, using secure electronic systems with security safeguards.
- The service effectively managed risks and could cope with both the expected and the unexpected.

However, we also found the following issues that the service provider needs to improve:

- The service's policy folder detailed an out of date children and adults safeguarding policy from another organisation
- The service's children's safeguarding policy did not reference child sexual exploitation and the staff had not received any training. This was against best practice.
- The service offered to look after children during scans without completing risk assessments.

Following this inspection, we told the provider that it should make 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
Chief Inspector of Hospitals (London and South)

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 Divinity Ltd as part of the Window to the Womb franchise. The service is based in Reading, Berkshire. We rated this 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

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Services we looked at
Diagnostic imaging

Summary of this inspection

Background to Window to the Womb Reading

Window to the Womb Reading is operated by Divinity Ltd

As part of the agreement, the franchisor Window to the Womb Ltd provides the service with regular on-site support, access to their guidelines and policies, training. And the use of their business model and brand.

Window to the Womb Reading opened in 2017 and provides diagnostic pregnancy ultrasound services to self-funding women, who are more than six weeks pregnant and aged 16 years and above. All ultrasound scans performed at Window to the Womb are in addition to those provided through the NHS.

The service is registered with the CQC to undertake the regulated activity of diagnostic and screening procedures. The service has had a registered manager in post since 2017.

We have not previously inspected this service.

The service did not use or store any medications.

Our inspection team

The inspection team comprised of one CQC inspector. The inspection team was overseen by Amanda Williams, Head of Hospital Inspection for South London and South Central regions.

Information about Window to the Womb Reading

The service provides diagnostic imaging service (ultrasound scans) to self-funding pregnant women across Berkshire. The service is run in a unit within a row of shops all on the same level.

Window to the Womb has separated their services in to two clinics: the 'Firstscan' clinic, which specialises in early pregnancy scans, and 'Window to the Womb' clinic which offers later pregnancy and wellbeing scans.

The First scan clinic offers the following scans:

- Viability scans from six to 10+6 weeks 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 all seen as private (self-funding) patients.

The service runs four clinics a week. Tuesday afternoons, Thursday evenings and all-day Saturday and Sundays.

At the time of our inspection, Window to the Womb Reading employed four scan assistants two of which were on a 16-hour contract and two on zero hours contracts. There were three part time sonographers who were on zero hours contracts. They had one vacancy for a full-time sonographer.

During the inspection, we visited the registered location in Reading. We spoke with six staff including the

Summary of this inspection

registered manager, franchise director, scan assistants and a sonographer. We spoke with five women and their partners and observed four ultrasound scans. During our inspection, we reviewed 14 sets of patient records.

There were no special reviews or investigations of the service ongoing by the CQC at any time during the 12 months before this inspection. This was the services first inspection since registration with CQC in 2017.

Activity

- First scan (6- 15-week gestation) performed 1,189 scans from December 2017 to November 2018.
- Window to the Womb (16 -40 weeks gestation) performed a total of 2,566 ultrasound scans from December 2017 to November 2018.

Track record on safety for the period December 2017 to November 2018:

- No Never events
- Clinical incidents none.
- No serious injuries
- No incidences of hospital acquired Methicillin-resistant Staphylococcus aureus (MRSA),
- No incidences of hospital acquired Methicillin-sensitive staphylococcus aureus (MSSA)
- No incidences of hospital acquired Clostridium difficile (c. diff)
- No incidences of hospital acquired E-Coli
- The service received six complaints

Services provided under service level agreement:

- Clinical and or non-clinical waste removal
- Interpreting services
- Maintenance of medical equipment
- Maintenance of fire extinguishers and smoke alarms.

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

Are services safe?

We rated it as **Good** because:

- The service provided mandatory training in key skills to all staff and made sure everyone completed it.
- Staff understood how to protect people from abuse and the service worked well with other agencies to do so. Staff had training on how to recognise and report abuse and they knew how to apply it.
- The service controlled infection risk effectively. We observed well-presented staff who kept the equipment and premises clean. They used control measures to prevent the spread of infection.
- Staff completed and updated risk assessments for each woman through individual referral forms. They kept clear records and asked for support when necessary from the franchise directors.
- 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.
- Staff kept detailed records of women's appointments and referrals to NHS services and completed scan consent documents. Records were clear and up to date.
- The service had appropriate processes for staff to raise concerns and report incidents. Staff understood their roles and responsibilities to raise concerns and record safety incidents. Managers investigated incidents and shared lessons learned with the whole team and the wider service. When things went wrong, staff apologised and gave patients honest information and suitable support.

However:

- We noted the children's safeguarding policy did not reference child sexual exploitation (CSE) and staff had not received training in CSE.

Are services effective?

We do not rate effective for this type of service:

- The service provided care and treatment based on national guidance and there was evidence of its effectiveness. Managers checked to make sure staff followed guidance.

Summary of this inspection

- Staff ensured women were comfortable, relaxed and reassured during ultrasound scans.
- Staff monitored the effectiveness of care and treatment and used the findings to improve them.
- The service made sure staff were competent for their roles. Managers appraised staff's work performance and there were processes in place to assess sonographer competencies and suitability for their role.
- Staff of different kinds worked together as a team to benefit women and their families.
- Staff provided women with information regarding the scan findings and health promotion information regarding their pregnancies.
- Staff understood how and when to assess whether a woman had the capacity to make decisions about their care.

However,

- We noted the service kept a hard copy of another organisations safeguarding policy which was out of date.

Are services caring?

Good

Are services caring?

We rated it as **Good** because:

- Staff cared for women and their families with compassion. Feedback from women and their partners confirmed that staff treated them well and with kindness
- Staff provided emotional support to patients to minimise their distress.
- Staff involved women and those close to them in decisions about their care and treatment.

Are services responsive?

Good

We rated it as **Good** because:

- The service planned and provided services in a way that met the range of needs of people accessing the clinic.
- The service took account of patients' individual needs, it had a proactive approach to understanding individual needs, was accessible and promoted equality.
- Women could access the service and appointments in a way and at a time that suited them. There were no waiting times for appointments and women could self-refer to the service.
- The service was currently available four days of the week, open all day Saturday and Sunday and could accommodate same day appointment requests.

Summary of this inspection

The service had a complaints policy and treated concerns and complaints seriously. The registered manager investigated complaints and shared outcomes with all staff.

Are services well-led?

Good

We rated it as **Good** because:

- Managers at all levels in the service had the right skills and abilities to run a service providing high-quality sustainable care.
- The service had a vision for what it wanted to achieve and workable plans to turn it into action.
- Managers across the service promoted a positive culture that supported and valued staff, creating a sense of common purpose based on shared values.
- The service systematically improved service quality and safeguarded high standards of care by creating an environment for good clinical care to flourish.
- The service had good systems to identify risks, plan to eliminate or reduce them, and cope with both the expected and unexpected.
- 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, their partners and local organisations to plan and manage appropriate services.
- The service was committed to improving services by learning from when things went well or wrong and promoting training.

However:

- Staff told us they would offer to look after children during scans, however the service had not performed a risk assessment around the safety of this practice.

Detailed findings from this inspection

Mental Capacity Act and Deprivation of Liberty Safeguards

Start here...

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 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.

- Mandatory training subjects included: infection prevention and control, fire safety, information governance, safeguarding adults and children, chaperoning, and more recently the mental capacity act. This ensured all staff had information to care for people with a diverse range of needs.
- All staff we spoke with had completed mandatory training. Staff we spoke with said their mandatory training was easily accessible. The registered manager oversaw mandatory training requirements and allocated time for staff to complete this, the registered manager paid staff overtime if required to complete it.
- The service provided mandatory training on a rolling programme basis and accessed via e-learning modules or face to face sessions during their team meetings.
- At the time of inspection all four scan assistants were 100% compliant with their required training modules.
- Sonographers who worked for Window to the Womb on a zero-hour contract completed their mandatory training at their substantive NHS employment as well as completing mandatory training provided by the service. We saw evidence of training completed by the sonographers.
- The registered manager attended an external mandatory training course each year. The course covered important topics such as: safeguarding adults and children training, basic life support, fire safety, information governance, complaints handling, conflict resolution, and moving and handling training.

Safeguarding

Staff understood how to protect people 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.
- There were clear safeguarding processes and procedures in place for safeguarding adults and children. All policies were available to staff in a paper format.
- At the time of our inspection, 100% of the scan assistants were compliant with safeguarding training. All staff we spoke with had received training in levels two or three for children's safeguarding as appropriate. The registered manager was trained to level three and could access advice from the local council safeguarding teams if required. This met the intercollegiate guidance 'Safeguarding children and young people: roles and competences for health care staff' (January 2019).

- However, we noted that the children's safeguarding policy did not cover child sexual exploitation (CSE) and staff had not received training on CSE. As the service completed ultrasound scans on children aged 16 years, staff should have an awareness of CSE.
- Staff were aware of their responsibilities if they identified a woman who had undergone female genital mutilation(FGM). Staff could describe the escalation process if they were to have safeguarding concerns and were aware of the policies and where to find them. The service had a separate FGM policy.
- Although staff reported they had not had any safeguarding concerns to raise they were aware of the correct pathways to follow to raise their concerns.
- To safeguard people against experiencing incorrect ultrasound scans staff asked patients to confirm their identify and date of birth. This evidenced staff followed best practice and used the British medical ultrasound society's (BMUS) 'paused and checked' checklist which the service displayed in the scanning room.

Cleanliness, infection control and hygiene

The service controlled infection risk well.

- We observed well-presented staff who kept the equipment and premises visibly clean. They used control measures to prevent the spread of infection.
- The registered manager completed daily checks to ensure staff had updated cleaning checklists throughout the service. We reviewed the January 2019 checklists and found they were complete.
- During inspection we saw staff to be compliant with uniform policies, which included all staff involved in clinical work to be bare below the elbows and long hair tied up, which followed good infection control practice. The service had an infection prevention and control policy which provided staff with guidance on such things as cleaning and waste control.
- Personal protective equipment such as gloves were available to staff. We saw appropriate use of gloves when staff cleaned couches and equipment after patient use. We observed the sonographer wear gloves whilst scanning women.
- Staff cleaned and stored equipment such as probes used for intimate ultrasound investigations (for example, trans vaginal investigations). Staff covered the probes during investigations and cleaned them with the recommended wipes post ultrasound scan. This eliminated the risk of cross infection between patients.
- We saw hand sanitiser dispensers placed in prominent positions throughout the service to encourage use by both staff and patients. We observed staff use the hand sanitiser appropriately.
- We observed staff to wash their hands in between scan appointments and staff completed hand hygiene audits monthly. For February 2019 the service had 100% compliance with hand hygiene. This followed the World Health Organisation's (WHO) 'Five Moments for Hand Hygiene'. These guidelines are for all staff working in healthcare environments and define the key moments when staff should be performing hand hygiene to reduce risk of cross contamination between women.
- Staff handled waste and disposed of it in a way that kept people safe. Staff followed correct procedures to handle and sort different types of waste. The service had an agreement with a clinical waste removal company to remove clinical waste.
- There had been no incidences of healthcare acquired infections at the service in the last 12 months.

Environment and equipment

The service had suitable premises and equipment and looked after them well.

- Women and their partners and families arrived in the reception area. This was an open area which included the printing station where women and their partners could choose photographs. The waiting area had two large sofas' and many example scan pictures at different stages of pregnancy on the walls.
- The service was on the ground floor with access to a single toilet which was not suitable for the disabled. This was detailed on their website. Outside the toilet there were baby changing facilities.
- The scan room could comfortably accommodate up to six people including the mother with room for the

sonographer and the scan assistant. It included a scan couch, some chairs and a sofa and a privacy screen. There were three large screens around the room so all in the room could see the images.

- The couch in the scan room could accommodate women with a weight of up to 260 kg. This meant they were suitable for bariatric women.
- Sonographers who were not familiar with the ultrasound scanner received training from the franchises lead sonographer. This ensured all sonographers using the equipment were familiar with how it worked. The registered manager also received training in the use of the ultrasound machine.
- The ultrasound machine's manufacturer regularly maintained and serviced it. We reviewed service records for the equipment, which detailed the maintenance history and service due dates. The service had systems in place to ensure machines or equipment were repaired in a timely manner, when required. This ensured women would not experience prolonged delays to their care and treatment due to broken and out of use equipment.
- Staff completed daily quality assurance checks for the ultrasound machine to ensure the equipment was safe to operate.
- Due to the nature of the service they did not require a resuscitation trolley, however they did have a sealed and in date first aid box and there was always someone on duty who had adult and children first aid qualifications. In the case of an emergency the service would call 999.
- Fire extinguishers were accessible, stored appropriately, and were all up to date with their services. The service held regular fire drills and documented each one.
- The service stored cleaning materials locked in cupboards within the staff kitchen 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.

Assessing and responding to patient risk

Staff completed and updated risk assessments for each woman through individual referral forms.

- Staff told us what action they would take if a patient became unwell or distressed while waiting for, or during, an ultrasound scan. The action taken depended on the specific situation and staff provided examples which showed they would take appropriate action.
- There were clear processes and pathways in place to guide staff on what actions to take if the sonographer found unusual findings on the ultrasound scan. When asked, staff were clear on what these actions were and we observed staff refer two women to the early pregnancy unit at their local NHS trusts as per the pathways.
- Staff documented referrals on dedicated referral forms which the registered manager reviewed for completeness.
- The sonographer described a recent scan where a molar pregnancy (an abnormal form of pregnancy in which a non-viable fertilized egg implants in the uterus and will fail to come to term.) The sonographer followed policy by referring the woman to the local early pregnancy unit, and at the same time letting the local NHS trust know of their arrival. They produced the report immediately and gave it to the woman to share with the NHS trust whilst keeping the woman calm and reassured. We were told in the event of an ectopic pregnancy an ambulance would be called.
- The Window to the Womb Ltd franchise employed a full-time sonographer who was available to review real time scans if the sonographers needed a second opinion. Response times varied from 10-15 minutes to half an hour.
- Upon booking their appointment, the service asked women to bring their NHS pregnancy records with them. This meant the sonographers had access to the woman's obstetric and medical history. It also meant if there were any concerns staff could contact the women's relevant medical provider and GP.
- For women aged 16 years the service would not perform the scan without their pregnancy records and the service requested a parent or responsible adult over the age of 25 years accompanied the young

women. If there were any concerns regarding the legitimacy of the responsible adult, the service requested identification documents. We observed a young woman arrive without their pregnancy notes and the service advised they could not scan her without them.

- Staff advised women about the importance of still attending their NHS scans and appointments. The sonographers made sure women understood the ultrasound scans they performed were in addition to the routine care they received as part of their NHS maternity pathway.
- The registered manager reported they had not had a woman who requested frequent scans but they did advise women who wanted longer appointments that their scanning time was restricted to 10 minutes as per the British medical ultrasound societies (BMUS) and followed the as low as reasonably achievable (ALARA) principles, outlined in the 'guidelines for professional ultrasound practice 2017' by the Society and College of Radiographers (SCOR) and BMUS.

Sonographer and scan assistant 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 employed four scan assistants, two were on part time permanent contracts and two were on zero hours contracts. There were three, part time sonographers who were all employed on zero hours contracts and held substantive posts in NHS trusts.
- The service was currently recruiting for a full-time sonographer, this work was being covered by the service using sonographers from other franchises and they had not had to cancel any appointments because of the vacancy.
- Scan assistants were responsible for manning the reception desk, managing enquiries, appointment bookings, supporting the sonographers during the ultrasound scans, and helping the families print their scan images.
- The service did not have a clinic manager and the registered manager, or the nominated individual took on the role as part of their day to day role which was effective for the everyday running of the clinic.
- All staff we spoke with felt staffing levels were adequate. At all times there were at least three staff in the clinic, this included two scan assistants and a sonographer. No staff members worked as a 'lone worker'.
- In the event of a staff member going off sick the service did not use bank or agency staff instead, the scan assistants and sonographers would cross-cover between themselves to help prevent clinic cancellations. In circumstances where this was not possible, the registered manager covered the scan assistant role. This helped to prevent clinic cancellations.
- The service's sickness rate for the period December 2017 to November 2018 was 2.6%.
- All staff including sonographers employed by Window to the Womb undergo a local induction over a three-day period which covers all aspects of the service.

Records

Staff kept detailed records of women's appointments, referrals to the NHS services and completed scan consent documents.

- Records were clear, up to date and easily available to all staff providing care.
- Women having a Firstscan would receive a report written by the sonographer at the time of the scan to add to their notes.For the later Window to the Womb scans women received a pre-printed foetal wellbeing report which detailed the baby's position, gender (if requested), foetal anomaly sweep, a check of the brain amniotic fluid, lungs and heart, abdomen and limbs, growth and placental position. The service stored a copy of the information in case they needed to refer to the document in future.
- Where appropriate, and with consent, the sonographer would also send a paper copy of the scan report to the woman's GP or another relevant healthcare professionals when making a referral.

Good

Diagnostic imaging

- Staff saved the ultrasound images onto a memory stick, which they uploaded to Window to The Womb's 'mobile phone application ('app'), which was a free application for the women. The app enabled women to have instant access to their scan images and any video recordings made. Once staff uploaded the images they deleted the images from the memory stick.
- We reviewed 14 records including referral forms from the Firstscan and Window to The Womb clinics. Staff recorded information in a clear and accurate way. This included the woman's estimated due date, the type of ultrasound scan performed, the findings, conclusions, and recommendations as well as the women's consent to the scan.
- The registered manager audited correct completion of patient records every month. We reviewed the audit for December 2018 and saw no issues identified.
- Upon request of the women and her partner the scan assistants recorded the unborn baby's heartbeat on a small electronic device during the scan. If women chose not to purchase the recording it was deleted after 24-hours.
- The service had an up-to-date information governance policy in place for staff to refer to. The policy detailed staff responsibilities, documentation standards, and the retention of records.
- The service kept completed service user records securely in locked drawers within the premises. Any electronic records or systems were password protected and access to the ultrasound machine was password protected and restricted to the sonographer and registered manager.

Medicines

The service did not store or administer any medicines.

Incidents

The service had appropriate processes for staff to raise concerns and report incidents. Staff understood their roles and responsibilities to raise concerns and record safety incidents.

- The service used a paper-based reporting system and had an accident and incident book available in the clinic for staff to access. The registered manager was responsible for conducting investigations into all incidents. The registered manager used the incidents paper log to identify any themes and learning, and shared with staff at their team meetings.
- Staff we spoke with knew how to report incidents and could give examples of when they would do this. Managers investigated incidents and shared lessons learned with the whole team and the wider service. When things went wrong, staff apologised and gave patients honest information and suitable support.
- From January 2018 to December 2018 there were seven incidents documented which included flooding and toilets blocking.
- Never events are serious patient safety incidents which should not happen if healthcare providers follow national guidance on how to prevent them. Each never event type has the potential to cause serious patient harm or death but neither need have happened for an incident to be a never event. From December 2017 to November 2018, the service did not report any incidents classified as a never event taking place in their diagnostics services.
- The service did not report any serious incidents from December 2017 to November 2018.
- Duty of candour is a regulatory duty that relates to openness and transparency and requires providers of health and social care services to notify patients (or other relevant persons) of certain 'notifiable safety incidents' and provide reasonable support to that person. The service had not needed to do this but staff we spoke with were aware of the term and the principle behind the regulation and the need to be open and honest with women where incidents occurred.
- Managers were aware of the requirements for reporting incidents and submitting notification to the CQC. However, at the time of inspection the registered manager had not been required to submit any notifications.

Good

Diagnostic imaging

Are diagnostic imaging services effective?

We do not 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.

- The registered manager checked to make sure staff followed guidance. Staff had to sign and date a checklist to confirm they had read policies as part of their induction and when the service updated policies. We saw evidence of these completed checklists.
- We reviewed five local policies which were up-to-date. The clinical lead, a diagnostic sonographer and clinical nurse specialist from the franchise wrote the policies, and the lead sonographer and a consultant in obstetrics and gynaecology reviewed them. They followed national guidance from the Royal College and Society of Radiographers, the foetal abnormality screening programme (FASP) standards and British Medical Ultrasound Society (BMUS). For example, the service did not offer transvaginal scans to women over 10 weeks gestation in line with BMUS guidance.
- All policies and protocols contained a next renewal date, which ensured the service reviewed them in a timely manner. However, the safeguarding folder contained a out of date policy that had been provided by an outside organisation.
- Staff demonstrated a good understanding of national legislation that affected their practice. For example, sonographers followed the 'Ectopic pregnancy and miscarriage: diagnosis and initial management' guidance (NICE, 2012) when they identified a foetus did not have a visible heartbeat and measured less than 7.0 mm.
- The service followed ALARA (as low as reasonably achievable) principles outlined by the Society and College of Radiographers. Sonographers did not scan for longer than 10 minutes and would not repeat scans within seven days of the previous scan.
- The service had an audit programme to assure itself of the quality and safety of the clinic. The franchisor completed annual sonographer competency assessments and an annual clinic audit. The registered manager completed monthly clinic audits. Included in this audit were the signed terms and conditions to ensure staff had requested all women to read and sign the conditions.
- The registered manager also sent a random selection of videos to the franchisor's lead sonographer to review on an ad hoc basis. This assured the service the scans were of a good standard.
- The franchisor (Window to the Womb Ltd) employed a consultant radiographer to advise the board on compliance with national standards and ensure policies and strategy was in line with best evidence-based practice.

Nutrition and hydration

The service did not offer food and drink to women.

- Staff gave women appropriate information on drinking water before a scan to ensure they attended with a full bladder which enabled the sonographer to gain a better view of the unborn baby.

Pain relief

- Staff did not formally monitor pain levels as the procedure was pain free. However, we saw staff asked women if they were comfortable during their scan.

Patient outcomes

Staff monitored the effectiveness of care and treatment and used the findings to improve them.

- The service monitored patient outcomes and experience through their monthly clinic audits and patient satisfaction feedback cards.
- The franchisor (Window to the Womb Ltd) carried out an annual compliance audit and we saw the service was compliant with all aspects of the audit. The audit showed a sonographer was due their annual review.
- The service used key performance indicators to monitor performance, which the franchisor set. The service benchmarked themselves against the other clinics in the group for number of reviews received, number of rescans and number of completed scans. We reviewed performance against the indicators for

the past year. The franchisor set a target for the number of rescans to be 10% or less of the total scans. We saw for the past year Divinity Ltd achieved a rescan rate of 1% with a total of 41 rescans.

- We saw that compliance with audits was a standing agenda item and discussed at monthly team meetings. Staff discussed feedback from women and local performance during team meetings.
- From December 2018 to January 2019 the service had referred 16 women to a local NHS trust due to the detection of potential concerns and 103 for the year from December 2017 to November 2018.
- Window to the Womb Ltd reported a 99.9% accuracy rate for their gender confirmation scans. This figure was based on over 20,000 gender scans completed at the 36 franchised clinics across the UK. There was a rescan guarantee in place for when it was not possible for the sonographer to confirm the gender of the baby. If the woman received incorrect information with regards to their baby's gender, the service offered a complimentary 4D baby scan. To date the service reported they had never got the gender wrong.

Competent staff

The service made sure staff were competent for their roles. Managers appraised staff's work performance and there were processes in place to assess sonographer competencies and suitability for their role.

- The registered manager appraised staff's work performance and had introduced individual supervision meetings to provide additional support and monitor the effectiveness of the service.
- The registered manager appraised all scan assistants and we saw 100% of eligible staff had received an appraisal.
- The sonographers had an annual competency assessment from the lead sonographer for Window to the Womb Ltd. As part of the assessment the lead sonographer checked the sonographers' registration, indemnity insurance and revalidation status. We saw confirmation of the sonographers' registration with the Health and Care Professions Council (HCPC) kept in the staff folder. We saw evidence the franchisor's sonographer completed annual reviews of sonographers within Window to the Womb.
- Sonographer to sonographer peer reviews took place in line with The British Medical Ultrasound Society (BMUS) recommendations, we reviewed a sample of the peer review audits and found the sonographers had raised no concerns with each other's reporting.
- We saw evidence of all sonographers working for the service having correct and up to date HCPC registrations.

Multidisciplinary working

Staff of different kinds worked together as a team to benefit women and their families.

- During the inspection we saw the team worked well together and observed positive communication between the scan assistant and sonographer.
- The service had liaised with local NHS trusts to ensure their referral pathways were effective and appropriate.
- The service ensured where the woman had consented for their information to be shared, GP's received a copy of the ultrasound report by post or electronically.

Seven-day services

- The service ran four clinics a week. Tuesday afternoons, Thursday evenings and all-day Saturday and Sundays. Clinic sessions were designed to accommodate the needs of women and their families, for example evening and weekend appointments enabled working mothers and siblings to attend.
- Women and their partners could book appointments online or by telephone at a time to suit them.
- The service was hoping once the sonographer vacancy was filled they could offer more appointment availability.

Health promotion

- The service provided families with a wide range of information leaflets about pregnancy specific issues or concerns, for example morning sickness, complications in pregnancy and information for mums to be.

Good

Diagnostic imaging

Consent and Mental Capacity Act

Staff understood how and when to assess whether a woman had the capacity to make decisions about their care.

- Staff followed the service policy and procedures when a patient could not give consent. However, staff reported they had not scanned a woman who could not give consent but were able to describe the process.
- All women received written information to read and sign before their scan. This included a technology and safety briefing, terms and conditions, information on scan limitations, a crib sheet on what was and was not included in the scan package, information on medical records, consent and use of data. The pre-scan questionnaire and declaration form included a self-declaration stating the woman was receiving appropriate pregnancy care and consent to share information with the NHS. We saw clear signed consent in 14 pre-scan questionnaires and foetal wellbeing reports we reviewed.
- All staff were aware of the importance of gaining consent from women before conducting an ultrasound scan. The sonographer confirmed names and spellings and dates of birth prior to the scan and obtained verbal consent to begin.
- Window to the Womb Ltd had a position statement on the Mental Capacity Act (2005) for staff to follow. This outlined the requirements for staff and the process to follow, all staff had signed to say they had read this statement. Managers told us the service was designing a bespoke Mental Capacity Act online training course and it would start at the end of June 2019.

Are diagnostic imaging services caring?

Good

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

Compassionate care

Staff cared for women and their families with compassion.

- Feedback from women and their partners confirmed staff treated them well and with kindness.
- We observed staff did not rush women through their scans, checked they were comfortable throughout and spent time explaining their findings from the ultrasound scans.
- Staff demonstrated a kind and caring attitude to women and their partners. This was evident from the interactions we witnessed on inspection and the feedback provided by the women and their partners.
- Staff introduced themselves and explained their role and went on to fully describe what would happen during the procedure. Staff wore name badges which were visible and clear.
- Staff ensured they maintained the women's privacy and dignity during ultrasounds by using a privacy screen and towel during transvaginal scans**.**
- Scan assistants chaperoned all women undergoing an ultrasound scan. All staff had undergone formal chaperone training.
- All women and their partners we spoke with said they would recommend the service to friends or family.
- We reviewed many feedback forms which all gave the service a five-star rating. Women and their partners reported:

"It was an excellent experience and we are really happy with the service"

"Had the best experience today every member of staff has been so helpful and lovely. 100% would recommend"

"All the staff are so welcoming and friendly, would not go anywhere else for a private scan"

"Fantastic family experience, friendly and welcoming team thank you"

- We observed a scan assistant talking to a family about what their package included and helping them to choose images. They were warm and friendly and clearly explained how the woman could use and access the mobile phone application.

Emotional support

Staff provided emotional support to patients to minimise their distress.

Good

Diagnostic imaging

- Staff supported women and their partners through their ultrasound, ensuring they were well informed and knew what to expect.
- Staff provided reassurance and support for anxious women during their Firstscan appointment. Staff demonstrated a calming and reassuring demeanour so as not to increase anxiety for women and their partners.
- Women and their partners remained in the scanning room if the scan showed abnormal results whilst the scan assistant made the referral to an NHS provider. The woman and their partner could remain in the room for as long as they required and were able to exit the clinic via an alternative exit to prevent them having to pass waiting pregnant women.
- We observed the sonographer providing reassurance throughout an ultrasound scan because the woman was anxious regarding the gender of their baby. Both the scan assistant and the sonographer offered kind words of reassurance to both the woman and her partner.
- The service provided training to staff on supporting women who had received bad news and the emotional impact of this.
- The service provided information on bereavement support services and charities which supported woman following miscarriage.

Understanding and involvement of patients and those close to them

Staff involved women and those close to them in decisions about their care and treatment.

- Staff said they took the time wherever possible to interact with women and their partners. We observed staff taking time to speak with women in a respectful, friendly and considerate way.
- Staff took time to explain the procedure before and during the scan. We saw the sonographer fully explain what was going to happen throughout the scan. They used appropriate language to explain the position of the unborn baby, the images on the monitors and asked women if they had any questions throughout and at the end of the scan.
- Women and particularly their partners we spoke with told us they were involved with decisions about the outcomes of their ultrasound scans and were aware of what the next steps in their pregnancy journey were.
- The staff assured women and their partners that the service stored their scan in a confidential way. They gave women a unique access code to the mobile phone application, so the women could choose who to share the images with.
- The service collected feedback from internet sites and we saw wholly positive feedback. The service scored 4.9 out of 5 for the services on an internet rating site and 5 out of 5 rating of 391 people on a website.

Are diagnostic imaging services responsive?

Good

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

Service delivery to meet the needs of local people

The service planned and provided services in a way that met the range of needs of people accessing the clinic.

- The facilities and premises met the needs of women and families, including children, that accompanied women to their scan. The large waiting area had children's toys, seating and books.
- The clinic was located close to public transport links and provided free parking. The service provided information on travelling to the clinic on their website.
- The service had developed an innovative mobile phone application. The application enabled women to document and share week-by-week images of their pregnancy 'bump' with their family and friends and create a time-lapse video of their pregnancy journey. Scan assistants saved any scan image taken during a Window to the Womb appointment onto the application. This enabled women to have instant access to their scan images.

- The service had a range of packages with different price options which the service clearly displayed in the clinic.
- Staff discussed the packages with the women and their partners upon entering the clinic, and the service displayed clearly each package on the website. All packages included a wellbeing scan.

Meeting people's individual needs

The service took account of patients' individual needs, it had a proactive approach to understanding individual needs, was accessible and promoted equality.

- The service could accommodate women in wheelchairs for an ultrasound appointment as staff could control the examination couches electronically. However, the service's toilet was not accessible for wheelchair users and this was detailed on the services' website.
- Women received written information to read and sign prior to their scan appointment. The franchise had recently introduced a new online translation service where written information could be translated into many different languages for the Window to the Womb scans. The service was currently developing the Firstscan documents for translation.
- The ultrasound scan room provided a calm and relaxing atmosphere with relaxing music playing in the background and dimmed lighting.
- The service has separated the Firstscan early pregnancy scans from the Window to the Womb sessions. Staff removed all soft toys and keepsakes for the Firstscan sessions to be sensitive to the needs of women and families who may have required reassurance or had complications with their pregnancy. This also ensured women who may have miscarried were not sharing the same area with women who were at a later stage in their pregnancies.
- Staff gave information leaflets to women when they had a pregnancy of an unknown location, for example, an ectopic pregnancy, a second scan that confirmed a complete miscarriage or an inconclusive scan. The leaflets contained a description of what the sonographer had found, advice, and the next steps they should take.
- Women could buy a range of baby keepsakes and souvenirs after their scan.
- Scan assistants could look after children that accompanied women to the scan in the waiting area if it were the mother's choice or there was a risk the mother had miscarried. However, the service had not completed risk assessments and we were not assured of the safety of this practice.

Access and flow

Women could access the service and appointments in a way and at a time that suited them.

- The service did not have a waiting list for ultrasound appointments. Women could self-refer to the service on the same day particularly for Firstscan appointments. Two women we spoke with had booked their early scan the same day. Women could book their scans through the website, telephone or email.
- The sonographer gave the results of the ultrasound scans to the woman and their partner immediately after the scan. The sonographer produced a report whilst the women and their partner were choosing the pictures they would like to keep.
- We observed women and their families arrive in the reception area and wait no longer than five minutes for their scan. However, the service did not audit the patient waiting times for staff to call them through. This would help identify any areas for service improvement.
- If a woman did not attend for her appointment the service would not follow up due to the risk the woman may have miscarried.
- The registered manager explained the booking system was flexible and allowed change to packages to meet women's choices. Women paid a small deposit and were given written information on what was and not covered in their scan package. Women could change the package when they attended for their scan appointment if they wished.
- From January to December 2018 the service cancelled eight ultrasound scans due to a flood incident. Staff rebooked four scans and four scans deposits refunded.

Good

Diagnostic imaging

Learning from complaints and concerns

The service had a complaints policy and treated concerns and complaints seriously. Complaints were investigated and lessons learned from the results, and shared with all staff.

- The service received six complaints in the period between November 2017 – December 2018 which the service did not uphold. (The service was not to be at fault).
- Window to the Womb had a policy for managing complaints, which included timescales for acknowledging a complaint (three days) and responding within 21 days. We reviewed three complaint responses and found the registered manager had responded to these complaints within the three and 21 working day rule. All three women received a written response to their complaint which offered an apology.
- We noted the complaints recording sheet did not have a date resolved section. The franchise director reported they had amended the complaints sheet and new recording sheets were under development to add in the resolved date to ensure a recording that the service responded to complaints in a timely manner and against policy.
- There was information for patients within the reception areas, leaflets and website on how to make a complaint.
- All five women and their partners we spoke with during the inspection saw no reasons to make a complaint and could not suggest any improvements the service could make.
- We saw evidence and staff we spoke with told us during team meetings, complaints and compliments were discussed to continually improve their service.

Are diagnostic imaging services well-led?

Good

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

Leadership

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

- The registered manager oversaw the sonographers and scan assistants and was responsible for the everyday running of the clinic. The registered manager shared business information with the directors of the franchise Window to the Womb Ltd. We observed clear management and reporting arrangements in place.
- The registered manager owned Divinity Ltd with other family members and owned the Window to the Womb Reading franchise.
- The registered manager attended six monthly national franchise meetings organised by Window to the Womb Ltd. During these formal meetings there was an opportunity to network and share best practice ideas as well as receive ongoing training as well as discussions around clinic compliance, performance, audit, and best practice. We observed positive working relationships between the registered manager and the Window to the Womb Ltd franchise director.
- Staff told us the registered manager was accessible and approachable if they wanted advice or to make suggestions. The registered manager kept staff informed of any developments for the service.
- Staff told us the registered manager had the skills and experience to appreciate the roles they completed and offered valuable support.
- Staff could access clinical leadership from three clinical leads employed by Window to the Womb Ltd. This included a consultant radiographer and specialist nurse in early pregnancy. The clinical lead for Window to the Womb Ltd assessed all new sonographers and had over 35 years NHS sonography experience. The specialist nurse in early pregnancy provided clinical leadership regarding Firstscan early pregnancy scans and completed an annual check of the clinic.

Vision and strategy

The service had a vision for what it wanted to achieve and workable plans to turn it into action.

Good

Diagnostic imaging

- Divinity Ltd was committed to providing high quality, efficient and compassionate care to their customers and their families, through the safe and efficient use of obstetric ultrasound imaging technology.
- There were also aims, which identified what the service needed to do to achieve their vision. Examples included: "to provide pregnant ladies with medically relevant ultrasound findings by way of an obstetric report", and "to report any suspected abnormalities identified using the pathways we have established with our local NHS hospitals".
- Divinity Ltd vision was to increase the scanning appointments to meet demand.
- The service had also identified values, which underpinned their vision. Their values included: Focus, dignity, integrity, privacy, diversity, safety and staff.
- Window to the Womb Ltd had clear values of honesty, value and loyalty which underpinned the vision and which Window to the Womb Reading shared. Staff worked within these values and told us they tried to provide a positive customer experience

Culture

Managers across the service promoted a positive culture that supported and valued staff, creating a sense of common purpose based on shared values.

- The service had a freedom to speak up guardian and a freedom to speak out policy and a whistleblowing policy which staff were aware of. Staff told us they could make comments and suggestions, could talk freely and felt supported to drive improvements by the registered manager.
- Staff told us they worked together well as a team and there was an open and honest culture. We saw a 'no blame' approach to the investigation of complaints and the registered manager addressed performance issues through open and honest one to one feedback with staff.
- All staff spoke proudly about their roles within the service and staff felt supported in their work. Staff told us they felt valued and supported by colleagues and the registered manager.
- There was a strong emphasis on the care of the women and their families. Staff promoted openness and honesty and understood how to apply the duty of candour. All staff were aware of what the term duty of candour meant.
- Throughout our inspection, the registered manager responded positively to feedback. They told us of improvements they had introduced immediately following feedback from inspections at other Window to the Womb locations. This demonstrated a culture of openness and willingness to learn and improve.

Governance

The service systematically improved service quality and safeguarded high standards of care by creating an environment for good clinical care to flourish.

- The service had a clear governance process to continually improve the quality of service provided to women and their families. Staff understood their roles and responsibilities in relation to governance.
- The service improved service quality through regular audits and clinical reviews by lead clinicians employed by Window to the Womb (Franchise) Ltd. Governance arrangements were clear and appropriate to the size of the service.
- Window to the Womb Ltd had indemnity and medical liability insurance which covered all staff working within the service for the case of a legal claim and was in date until October 2019.
- Window to the Womb Ltd had a clear governance policy which outlined the responsibility of board members, the relationship between franchisor and franchisee and the requirement for regular audits. Information was shared between their board and the board of Divinity Ltd including business accounts to ensure oversight of both boards across the service.
- Divinity Ltd followed a robust recruitment process for all staff, which included references and Disclosure and Barring Service checks. Window to the Womb Ltd conducted due diligence checks on all franchisees in line with its fit and proper persons policy.

- There were policies and procedures in place for the operation of the service and these were available to staff in a folder in the clinic. All policies were up-to-date and reviewed annually by Window to the Womb Ltd.
- Staff told us they had monthly team meetings where clinical staff would attend. Full team meetings required all members of staff to participate. We saw all scan assistants attended these but not all sonographers due to external working circumstances. The minutes were available to all staff on line and printed out. If staff could not attend a meeting the registered manager asked them to sign a printed version of the minutes to confirm they had read them.
- While the service did not hold formal governance meetings, items discussed at team meetings included risks, complaints and incidents as well as mandatory training update sessions and general updates regarding the business's overall performance.The registered manager asked staff to complete a questionnaire before and after the meeting to seek their opinions regarding if the information was relevant and useful to everyone.

Managing risks, issues and performance

The service had good systems to identify risks, plan to eliminate or reduce them, and cope with both the expected and unexpected.

- The registered manager had an awareness of the service's performance and challenges. They could describe actions to address these challenges. For example, the service was short of a sonographer and the registered manager had completed a risk assessment that they reviewed monthly regarding the impact there may be on the service
- The service did not have a risk register however, we saw evidence the registered manager reviewed all risk assessments monthly to ensure they documented any changes or identified new risks. However, the risk of children being cared for by scan assistants whilst their mother was in the scan room had not been risk assessed and was not detailed in the monthly risk assessments.
- We saw up-to-date and complete risk assessments for fire, health and safety, legionnaires' disease and the Control of Substances Hazardous to Health (COSHH). The registered manager recorded risk assessments on a form which identified the risk and control measures and the member of staff responsible for monitoring and managing the risk. We saw risk assessments were easily accessible to all staff and all staff had seen them.
- To mitigate the risks of lone working, there were always at least three staff on site when the service was open.
- The service used key performance indicators (KPIs) to monitor performance, which the franchisor set. This enabled the service to benchmark themselves against the 35 other franchised clinics. At the time of our inspection, the registered manager reported they were in the top 10 performing clinics for both their later and early pregnancy services.
- The ultrasound machine had a backup battery pack for use in circumstances where there may be a loss of power to the building. This ensured the sonographers could finish and report on scans.
- The service had a documented business continuity plan and undertook monthly fire alarm drills to ensure staff were aware of the process to take in the event of an emergency.

Managing information

The service collected, analysed, managed and used information well to support all its activities, using secure electronic systems with security safeguards.

- Window to the Womb Ltd was registered with the Information Commissioner's Office (ICO), in line with The Data Protection (Charges and Information) Regulations (2018). The ICO is the UK's independent authority set up to uphold information rights.
- Women consented for the service to store their records. This was part of their signed agreement within the form detailing the ultrasound process. This demonstrated the service's compliance with the General data protection regulation (GDPR) 2018.
- There was sufficient information technology equipment for staff to work with across the service.

- The ultrasound machine was password protected and the sonographers and registered manager were the only authorised staff to access it. This ensured there was no unauthorised access.
- Staff could access reported ultrasound scans easily. The registered manager stored the reports in a locked filing cupboard in the reception area. The registered manager held the key.
- Videos of the ultrasound scans were kept for one month and then deleted off the system as per Window to the Womb Ltd.'s record keeping policy.

Engagement

The service engaged well with women, their partners and local organisations to plan and manage appropriate services, and collaborated with partner organisations effectively.

- The service asked women and their partners to fill in a comment card whilst they were waiting for their photographs. There were also opportunities for women and their partners to leave comments on social media pages and online review sites.
- The registered manager shared customer feedback at the monthly team meeting and the team agreed any actions for improvement.
- The management team supported staff to give feedback and they were listened to. For example, a sonographer suggested a privacy screen for women requiring transvaginal scans to undress behind and the registered manager provided a screen the following week.
- We observed effective management engagement with staff. All staff we spoke with told us the management was supportive accessible and visible.
- Window to the Womb Ltd produced a six-weekly newsletter called 'open window'. Open Window contained information on what was happening across the franchise and updates on e-learning and policies. We saw all staff signed to say they had read the newsletter and the service kept copies in a communication folder.

Learning, continuous improvement and innovation

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

- The registered manager took immediate actions to address some of the concerns raised during previous inspections.
- The service had developed the 'Instant Midwife' service to respond to questions and concerns women frequently raised. This was a social media based messaging service which answered the most common questions asked by women during pregnancy. The service advertised the apps on leaflets given to women.

Outstanding practice and areas for improvement

Areas for improvement

Action the provider SHOULD take to improve

- The service should ensure that child sexual exploitation is referenced in their children's safeguarding policy and staff undergo training in child sexual exploitation.
- The service should ensure risk assessments are completed for scan assistants caring for children outside of the scanning room.
- The service should ensure any external policies are current, up to date and relevant.