

# Window to the Womb Milton Keynes

## Quality Report

8 Darin Court  
Milton Keynes  
Buckinghamshire  
MK8 0AD

Tel: 01908 590015

Website: [www.miltonkeynes@windowtothewomb.co.uk](http://www.miltonkeynes@windowtothewomb.co.uk)

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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



# Summary of findings

## Letter from the Chief Inspector of Hospitals

### Overall summary

Window to the Womb is operated by Divinity MK Scans 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 living in Milton Keynes and surrounding areas, including Northampton, Oxford, Bletchley, Banbury, Kettering and Bedford.

We inspected this service using our comprehensive inspection methodology. We carried out a short notice announced inspection on 13 August 2019. We gave staff two working days' notice that we were coming to inspect, to ensure the availability of the registered manager.

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. We rated it as **Good** overall.

We found 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 and treatment.
- The service controlled infection risk well. Staff used equipment and control measures to protect patients, themselves and others from infection. They kept equipment and the premises visibly clean.
- Staff monitored the effectiveness of care and treatment and used the findings to improve them. They compared local results with those of other Window to the Womb clinics to learn from them.
- The service made sure staff were competent for their roles.
- Staff cared for women with compassion and kindness, respected their privacy and dignity, and took account of their individual needs. Feedback from women and their families confirmed staff treated them well and with kindness.
- Women could access services and appointments in a way and at a time that suited them. Technology was used innovatively to ensure women had timely access to treatment, support and care.
- The service had a clear vision and strategy for what they wanted to achieve, with quality and sustainability as the top priorities.
- The service had governance arrangements to ensure high standards of care were maintained.
- The service engaged well with women and staff to plan and manage appropriate services, and collaborated with partner organisations effectively.

We found areas of outstanding practice:

- Window to the Womb had invested in technology and equipment which it used to enhance the delivery of effective care and treatment. They had developed a mobile phone application ('app'). The app enabled women to

# Summary of findings

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. Any scan image taken during a Window to the Womb appointment was also saved on the app, which allowed women to have instant access to their scan images. Women could also book scan appointments through the app.

- Window to the Womb had developed a continued professional development platform which sonographers could access to enhance their knowledge and skills.

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

- Not all training records included details of the date and staff members name on every page
- Not all staff were fully aware of their reporting duties in relation to female genital mutilation (FGM)
- Not all staff were fully aware of the term “duty of candour” so we were unclear on how to ensure it was met
- Keys for the locked records cabinet were stored in a removable storage box

Following this inspection, that it should make some improvements, even though a regulation had not been breached, to help the service improve. Details are at the end of the report.

## **Name of signatory**

**Heidi Smoult**

Deputy Chief Inspector of Hospitals

# Summary of findings

## Our judgements about each of the main services

### Service

#### Diagnostic imaging

### Rating

Good



### Summary of each main service

The provision of ultrasound scanning services, which is classified under the diagnostic core service, was the only service provided at Window to the Womb. We rated this service as good overall because it was safe, effective, caring, responsive to people's needs and well-led.

There were processes for the escalation of unexpected findings during ultrasound scans. Feedback from women and their families was positive. Women could access services and appointments in a way and at a time that suited them. Technology was used innovatively to enhance the delivery of effective care and treatment and meet women's needs. Staff had the appropriate skills, knowledge and experience to provide safe and effective care and treatment.

# Summary of findings

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**Good** 

Divinity MK Scans Ltd.

**Services we looked at**

Diagnostic imaging

# Summary of this inspection

## Background to Window to the Womb Milton Keynes

Window to the Womb is a private diagnostic service based in Milton Keynes, Buckinghamshire. IT is operated by Divinity MK Scans Ltd. Window to the Womb (Franchise) Ltd was established in 2003 and has 38 franchised clinics across the United Kingdom. The service has not previously been inspected.

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 Milton Keynes opened in August 2017 and provides diagnostic pregnancy ultrasound services to self-funding women, from six to 40 weeks of

pregnancy. The service is available to women aged 18 years and above. However, young women from the age of 16 can also use the service if accompanied by an appropriate adult. All ultrasound scans performed at Window to the Womb are in addition to those provided through the NHS as part of a pregnancy care pathway. The service primarily serves women living in Milton Keynes and surrounding areas, including Northampton, Oxford, Bletchley, Banbury, Kettering, and Bedford. It also accepts women from outside this area.

The hospital has had a registered manager in post since registering with the CQC in August 2017.

## Our inspection team

The team that inspected the service comprised a CQC lead inspector and one other CQC inspector. The inspection team was overseen by Bernadette Hanney, Head of Hospital Inspection.

## Information about Window to the Womb Milton Keynes

The Window to the Womb clinic is located on the ground floor of a commercial building. Facilities include one scan room, play room, reception area, waiting room and staff room.

The service is registered to provide the following regulated activities:

- Diagnostic and screening procedures.

The service provides ultrasound scans to self-funding pregnant women. The Window to the Womb clinic sees between 60 and 66 women per week and offers the following pregnancy ultrasound scans:

- Early viability scans from six to 15 weeks
- Well being and gender scans from 16 to 22 weeks
- Well being scans from 16 to 40 weeks
- Well being and 4D scans from 24 to 34 weeks

- Growth and presentation scans from 26 to 40 weeks

All women accessing the service self-refer to the clinic and are all seen as private (paying) patients.

The service runs five clinics per week. Standard operational hours are 2pm and 7pm evenings and Saturday and Sunday 9.30 to 5.30 pm.

At the time of our inspection Window to the Womb employed a registered manager and nominated individual (director), who co-owned the service, four sonographers, and five scan assistants. One of the scan assistants was also the clinic manager. Three of the sonographers and the scan assistants were employed on zero hour contracts. The clinic manager and one sonographer were employed on full time contracts.

During the inspection, we visited the registered location in Milton Keynes. We spoke with five staff including a sonographer, scan assistants and the registered manager.

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We spoke with three women and three relatives. We also received 23 'tell us about your care' comment cards which patients had completed prior to our inspection. During our inspection, we observed two ultrasound scans and reviewed 14 scan reports.

There were no special reviews or investigations of the hospital ongoing by the CQC at any time during the 12 months before this inspection. We have not previously inspected this service.

## Activity (May 2018 to May 2019)

- In the reporting period, Window to the Womb performed a total of 3432 ultrasound scans. A breakdown of the type of scan is shown below:
- 990 x 6 weeks to 16 weeks well being and viability scans
- 1410 x 16 weeks to 23 weeks gender confirmation and well being scans
- 935 x 23 weeks to 34 weeks growth and presentation 4D scans
- 97 x 34 weeks to full term well being 4D baby scans

- All women were self funding
- In the reporting period one ultrasound scan was delayed or cancelled due to non clinical reasons.

## Track record on safety (May 2018 to May 2019)

- Zero Never events
- Zero clinical incidents
- Zero Ionising Radiation Medical Exposure Regulations/Ionising Radiation Regulations (IRMER/IRR) reportable incidents
- Zero serious injuries
- Zero complaints
- One urgent transfer
- The service reported zero incidences of health associated Methicillin-resistant Staphylococcus aureus (MRSA), Methicillin-sensitive staphylococcus aureus (MSSA), Clostridium difficile (c.diff), Escherichia Coli (E-Coli).

# 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?

We rated it as **Good** because:

- The service controlled infection risk well. Staff used equipment and control measures to protect patients, themselves and others from infection. They kept equipment and the premises visibly clean.
- The service assessed and managed risks to women, their babies and families.
- The service had enough staff with the right qualifications, skills, training and experience to keep patients safe from avoidable harm and to provide the right care and treatment. Managers regularly reviewed and adjusted staffing levels and skill mix.
- The service provided mandatory training in key skills to staff and made sure everyone completed it.
- Staff understood how to protect women who used the service and those who accompanied them from abuse. All staff had completed training on how to recognise and report abuse and knew how to apply it.
- The design, maintenance and use of facilities, premises and equipment kept people safe. Staff were trained to use them. Staff managed clinical waste well.
- The service assessed and managed risks to women, their babies and families.
- Staff kept detailed records of women's care and treatment. Records were clear, up-to-date and easily available to staff providing care. A copy of the scan report was given to women immediately after their scan.

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

- Not all staff were fully aware of their reporting duties for FGM
- Not all staff were fully aware of the term "duty of candour" so we were unclear on how to ensure it was met
- Keys for the locked records cabinet were stored in a removable storage box

**Good**



### Are services effective?

We do not currently rate effective, however we found:

# Summary of this inspection

- The service provided care and treatment based on national guidance and evidence-based practice. Managers checked to make sure staff followed guidance. Care and treatment provided was based on national guidance and good practice standards.
- Staff monitored the effectiveness of care and treatment and used the findings to improve them. They compared local results with those of other Window to the Womb clinics to learn from them.
- The service made sure staff were competent for their roles. Managers appraised staff's work performance and held supervision meetings with them to provide support and development.
- Staff worked together as a team to benefit women and their families. They supported each other to provide good care.
- Women were given information to help them improve their health, care and wellbeing during pregnancy.
- Staff understood how and when to assess whether a woman had the capacity to make decisions about their care. They understood the importance of gaining consent before performing any ultrasound scan.

However:

- Not all staff records contained the date and name of the staff member on each page.

## Are services caring?

### Are services caring?

Good



We rated it as **Good** because:

- Staff cared for women with compassion and kindness, respected their privacy and dignity, and took account of their individual needs. Feedback from women and their families confirmed staff treated them well and with kindness.
- Staff provided emotional support to women 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 services provided were tailored to meet the needs of the population served. The premises and facilities were innovative and met the needs of a range of women who used the service.

# Summary of this inspection

- The service took a proactive approach to understand women's individual needs and preferences. Care was delivered in a way that met those needs, was accessible and promoted equality.
- Women could access services and appointments in a way and at a time that suited them. Technology was used innovatively to ensure women had timely access to treatment, support and care.

## Are services well-led?

We rated it as **Good** because:

- The service had a clear vision and strategy for what they wanted to achieve, with quality and sustainability as the top priorities.
- The registered manager had the skills and experience needed to run a high quality sustainable service. The registered manager was visible and approachable in the service for women, their families and staff.
- Staff felt respected, supported and valued. They were focused on the needs of women using the service.
- The service had governance arrangements to ensure high standards of care were maintained.
- Effective arrangements were in place to identify, reduce and eliminate risks, and to cope with both the expected and unexpected.
- The service engaged well with women and staff to plan and manage appropriate services and collaborated with partner organisations effectively.
- Staff were committed to improving the service by learning from when things went well or wrong, continuing professional development and innovation.

**Good**







# Detailed findings from this inspection

## Overview of ratings

Our ratings for this location are:

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

# Diagnostic imaging

Safe	Good 
Effective	
Caring	Good 
Responsive	Good 
Well-led	Good 

## Are diagnostic imaging services safe?

Good 

### Mandatory training

#### The service provided mandatory training in key skills to staff and made sure most staff completed it.

- Staff completed mandatory training in accordance with the Window to the Womb franchisor rolling mandatory training programme. The programme covered key areas such as equality and diversity, health and safety, information governance, fire safety awareness, infection control and safeguarding adults and children. Training was provided through a combination of e-learning modules and face-to-face sessions.
- Staff received and kept up-to-date with their mandatory training. At the time of our inspection most staff were up to date with mandatory training. However, three of the sonographers did not have Window to the Womb Mental Capacity Act (MCA) training certificates although they had completed this during induction training and were up to date with NHS mandatory training. The registered manager also had a copy of mandatory training courses the sonographers had completed with their substantive NHS employer. Following our inspection we requested information from the service about compliance with all mandatory training. Managers told us that MCA training was included in the sonographer's induction programme and was updated six monthly. All of the sonographers had received MCA training. All staff completed online continual professional development

(CPD) including sonographers. The Window to the Womb franchisor was in the process of creating MCA CPD training certification which was to be available within a few weeks.

- The registered manager was required to attend an external mandatory training course annually. The course covered basic life support, fire safety awareness, information governance, conflict management, safeguarding adults and children, moving and handling, health and safety, control of substances hazardous to health, equality and diversity, food hygiene and lone working training. The registered manager's attendance was up to date.

### Safeguarding

#### Staff understood how to protect women who used the service and those who accompanied them from abuse. All staff had completed training on how to recognise and report abuse and knew how to apply it.

- The service had clear systems, processes and practices to safeguard children, young people and adults from avoidable harm, abuse and neglect that reflected legislation and local requirements. Safeguarding policies and pathways were in-date and were accessible to staff. They included the contact details for the local authority safeguarding teams, the police, the Care Quality Commission (CQC) and the safeguarding lead for the franchisor.
- Staff knew how to make a safeguarding referral and who to inform if they had concerns.
- Staff knew how to identify adults and children at risk of, or suffering, significant harm and worked with other agencies to protect them. A separate female genital

# Diagnostic imaging

mutilation (FGM) policy provided staff with clear guidance on how to identify and report FGM. Child sexual exploitation (CSE) and FGM was included in safeguarding training. However, not all staff were aware of their statutory duties to report female genital mutilation (FGM). All staff told us they would discuss any concerns with the registered manager. Following our inspection managers told us all staff had received FGM refresher training.

- The service was available to women aged 18 years or above. However, young women from the age of 16 could access the service if they were accompanied by an appropriate adult. Staff followed safe procedures for children visiting the service. Children also frequently attended ultrasound scan appointments with their mother. Staff told us they would not see a young person under 18 years old if they were accompanied by an appropriate adult. At the time of our inspection, 100% of staff were compliant with safeguarding adults and children level two training. Two out of four staff members were trained to level three children's safeguarding.
- This level was appropriate to their role and in line with national guidance (Intercollegiate Document, Adult Safeguarding: Roles and Competencies for Health Care Staff (August 2018); Intercollegiate Document, Safeguarding children and young people: roles and competences for health care staff (March 2014)).
- There had been no safeguarding concerns reported to the CQC in the reporting period, from May 2018 to May 2019.
- Additional safeguarding training was provided through mandatory training.
- The registered manager was the designated lead for children's and adult safeguarding. The registered manager had completed both adults and children's safeguarding training at level three. They were available during working hours to provide safeguarding advice and support for staff. Additional safeguarding advice was available from the corporate team who had level four safeguarding training and the local authority.
- Safety was promoted through recruitment procedures and employment checks. Staff had Disclosure and Barring Service (DBS) checks undertaken at the level

appropriate to their role. DBS checks help employers make safer recruitment decisions and prevent unsuitable people from working with vulnerable groups.

## Cleanliness, infection control and hygiene

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

- Staff followed infection control principles including the use of personal protective equipment (PPE).
- Reliable systems were in place to prevent and protect people from a healthcare-acquired infection. The sonographer and scan assistants were 'bare below the elbow'. This is an infection prevention and control strategy to prevent the transmission of infection from contaminated clothing and enables healthcare staff to thoroughly wash their hands and wrists. We observed staff washed their hands between each patient contact, in accordance with national guidance (National Institute for Health and Care Excellence (NICE), Infection prevention and control: QS61, quality statement 3 (April 2014)). In January and March 2019, audit results showed hand hygiene compliance was 100%. Handwashing facilities and hand sanitiser gel was available in the scanning room and toilet. Hand sanitiser gel was also available in the reception area for staff, women and visitors to use.
- Clinic staff were responsible for cleaning the premises and equipment. We observed all areas of the service were clean and tidy on the day of our inspection.
- The service had suitable furnishings which were visibly clean and well-maintained. However, some chairs in the waiting room could not be effectively cleaned as they were not wipeable.
- There were effective systems to ensure standards of hygiene and cleanliness were maintained. Cleaning records were up-to-date and demonstrated that all areas were cleaned regularly. Daily cleaning checklists were completed to ensure staff adhered to the cleaning schedule. A quarterly deep clean of the clinic was undertaken as a minimum. The last deep clean of the clinic took place in April 2019.

# Diagnostic imaging

- Compliance was monitored by the registered manager. We saw the cleaning checklists for the service were consistently completed and showed the premises and equipment were regularly cleaned. The cleanliness of the clinic, such as toilet, scanning room and reception, was also regularly monitored by staff throughout the clinic's operational hours.
- Client feedback cards scored consistently highly for cleanliness of the clinic. Women provided positive feedback about the cleanliness of the clinic. They told us that they thought the clinic was "very clean".
- The service had hygiene and infection prevention and control policies (IPC). These were up to date. They provided guidance on appropriate IPC practice such as the daily cleaning schedule, scan machine cleaning and the disposal of waste.
- The registered manager was the infection control lead.
- All staff were compliant with infection control training. The Window to the Womb franchisor required staff to undertake infection control refresher training six-monthly.
- There had been no incidents of healthcare acquired infection in the reporting period May 2018 to May 2019 (Source: Provider information request).
- Staff cleaned equipment after patient contact and labelled equipment to show when it was last cleaned.
- Cleaning equipment was available and stored securely.
- The examination couch was protected with a disposable cover which was used to cover the examination couch during scanning procedures. We observed these were changed between each appointment. If cotton towels were used these were laundered separately from other washing.
- Staff followed best practice guidance for the routine disinfection of ultrasound equipment (European Society of Radiology Ultrasound Working Group, Infection prevention and control in ultrasound – best practice recommendations from the European Society of Radiology Ultrasound Working Group (2017)). The ultrasound transducer was decontaminated with

disinfectant wipes between each woman and at the end of each day. The transducer was the only part of the ultrasound equipment that was in contact with women.

- A risk assessment for Legionella was completed in August 2018 and identified controls to minimise the risk of Legionnaires' disease. The risk of legionella was low (Source: Provider Information Request D28). Legionnaires' disease is a severe lung infection caused by legionella bacteria. People can become infected if they inhale water droplets from a contaminated water source such as air conditioning systems and water dispensers. Following our inspection managers told us that the next risk assessment was had taken place on 16 August 2019.

## Environment and equipment

**The design, maintenance and use of facilities, premises and equipment kept people safe. Staff were trained to use them. Staff managed clinical waste well.**

- Equipment was maintained according to the suppliers recommended schedule.
- Emergency equipment was not required on site due to the nature of the service. A first aid kit was available which was in-date.
- The scanning equipment used was appropriate for the ultrasound procedures provided. The manufacturer provided the maintenance and servicing of the ultrasound machine.
- The electrical equipment we inspected, which included the examination couch, air conditioning unit, scan equipment and light, had been safety tested within the last 12 months. This was in line with national guidance (Health and Safety Executive, Maintaining portable electric equipment in low-risk environments (September 2013)).
- Waste was handled and disposed of correctly. The service did not generate any clinical waste, due to the nature of the scans provided.
- Fire safety equipment was fit for purpose. The alarm system, and heat and smoke detectors were serviced annually. The fire alarm and smoke detector were

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tested monthly. Fire extinguishers were accessible, stored correctly and had been serviced within the last 12 months. Fire drills were held at monthly. Staff were able to explain the fire evacuation process.

- There was adequate storage for consumables such as ultrasound gel and baby keepsake and souvenir products, such as photo frames, soft toys and key rings.
- The kitchen and staff area contained locked cabinets for cleaning products.

## Assessing and responding to patient risk

### The service assessed and managed risks to women, their babies and families.

- Risk assessments were undertaken to address any potential risk and ensure that improvements were identified and actioned.
- There were clear processes to guide staff on what actions to take if any concerns were identified during the ultrasound scan. The service's referral pathway was followed if any concerns were detected.
- If a scan identified an anomaly that required additional medical care, the patient would be referred to the local NHS. Women were referred to the most appropriate healthcare professional, with her consent. For example, if the sonographer detected polyhydramnios (excessive amniotic fluid) they would refer the woman to her local NHS hospital's maternity day assessment or fetal medicine unit. In the event of an emergency staff would summon emergency services through a 999 call and transfer the woman to a local NHS hospital. Staff provided examples of when they had transferred women to hospital for emergency treatment.
- From May 2019 to August 2019 45 women had been referred to local NHS services.
- Risk assessments were undertaken before any scans were completed to ensure that the service was appropriate and that the service user understood the service that was offered. For example, staff told us that if a young person under 18 years old was not accompanied by an appropriate adult the scan would not be undertaken.
- The sonographers could contact the Window to the Womb lead sonographer for advice and support during their clinics. The lead sonographer was employed by the franchisor and was available to review ultrasound scans remotely when needed. Staff told us the lead sonographer responded quickly and would also visit the service on request.
- Women were advised to bring their NHS pregnancy records to their ultrasound scan appointment. This meant sonographers had access to their obstetric and medical history if needed. It also meant they had the contact details for the woman's maternity care provider if a concern was identified.
- Staff advised women about the importance of still attending their NHS pregnancy ultrasound scans and appointments. The sonographers ensured women understood that the ultrasound scans they performed were in addition to those provided as part of their NHS maternity care pathway. This information was also stated in the terms and conditions for the service, which clearly advised women to access all antenatal services made available to them by the NHS.
- Women were told when they needed to seek further advice or treatment. For example, women were advised to contact their midwife or local maternity unit if their baby's movements were reduced.
- Women were chaperoned and staff were not left alone with women. This was to ensure that neither the woman nor the member of staff were exposed to any potential risk. All staff were trained as chaperones.
- The registered manager, two scan assistants had completed first aid training. Four sonographers had completed first aid training with their substantive NHS employer. The registered manager also completed basic life support (BLS) training annually. The clinic manager who was new in post was due to undertake BLS training. BLS training provides a basic overview of how to manage a person who may have stopped breathing or had a cardiac arrest.
- Staff adhered to the 'Paused and Checked' checklist devised by the British Medical Ultrasound Society (BMUS) and Society of Radiographers. While these checks were not formally documented, we observed the sonographer completed them for each woman

# Diagnostic imaging

they saw. For example, the woman's identity and consent was confirmed and clear information and instructions were provided, including the potential limitations of the ultrasound scan.

- The service accepted women who were physically well and could transfer themselves to the couch with little support. The service did not offer emergency tests or treatment.

## Staffing

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

- The service had enough staff to keep patients safe.
- There were sufficient numbers of staff to ensure that there was flexibility within the team to ensure that services were provided as scheduled (Source: PIR V1 Final). At the time of our inspection there were no staff vacancies.
- The registered manager could adjust staffing levels daily according to the needs of patients. The registered manager told us that if a member of staff was required at late notice due to sickness, cover was available from other clinics. Scan assistants and sonographers would also cross-cover between themselves to prevent clinic cancellations, in the event of a staff member going off sick. No clinics had been cancelled as a result of staff absence. No agency or bank staff were employed by the service
- All staff we spoke with felt that staffing was managed well. The service operated with the registered manager, a minimum of two scan assistants and one qualified sonographer on duty per shift. No member of staff was required to work alone.
- Ultrasound clinics were scheduled in advance and the sonographers assigned themselves to clinics which fitted around their permanent employment positions.

- The service employed a registered manager, four registered sonographers and five scan assistants. This ensured that there were sufficient staff for all shifts and to cover annual leave and absenteeism. Staff were employed on zero hours contracts.
- A clinic manager had been appointed the month before our inspection. The manager had responsibility for the day to day running of the service.
- The registered manager monitored staff sickness rates. There had been no staff sickness absences in the three months preceding the inspection.

## Records

**Staff kept detailed records of women's care and treatment. Records were clear, up-to-date and easily available to staff providing care. A copy of the scan report was given to women immediately after their scan.**

- Women's notes were comprehensive and all staff could access them easily.
- Records were stored securely in a locked cabinet behind the reception desk. Staff did not leave the cabinet unlocked if they had to leave the area. Keys were stored separately in a locked box; however the key box was portable. This meant that it could easily be removed from the area. Following our inspection managers told us that the key box was removed and stored securely at the end of every clinic.
- Sufficient information was obtained from women prior to their scan appointment, such as the number of weeks of pregnancy and known allergies.
- The sonographer undertaking the ultrasound scan completed the paper scan report during the woman's appointment with the support of the scan assistant. This was given to the woman. A copy of the scan report was also stored at the service, in case they needed to refer to it at any time.
- Scan reports were completed immediately after the scan had taken place, which we observed during our inspection. We reviewed 14 scan reports and found staff recorded all the required information clearly and

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accurately. Scan reports included the woman's estimated due date, type of ultrasound scan performed, the findings, conclusions and recommendations.

- The sonographer would also send a copy of the scan report to the woman's GP or other relevant healthcare professional when a referral was made, if the woman gave her consent.
- The ultrasound images were saved onto a data storage device which could be purchased by the woman at the end of her appointment. Each woman was also given free access to an application (app) developed by the franchisor. The app enabled women to have instant access to their scan images via their personal computer, smart phone or tablet.
- Every scan included a well-being check. Women were provided with a report of their scan. If the woman needed to be referred to another service such as their GP, maternity unit or the local NHS hospital, a report was completed by the sonographer. The report included a referral with clear information and details of the anomaly.

## Medicines

### **The service used systems and processes to safely prescribe, administer, record and store medicines.**

- The service did not store, prescribe or administer any medicines.

## Incidents

### **The service managed patient safety incidents well. Staff recognised and reported incidents and near misses. Managers investigated incidents and shared lessons learned with the whole team and the wider service. When things went wrong, staff apologised and gave patients honest information and suitable support. Managers ensured that actions from patient safety alerts were implemented and monitored.**

- There were arrangements for the reporting, reviewing and investigating of safety incidents and events when things went wrong. The service had an up-to-date incident reporting policy which staff could refer to for guidance. The service used a paper-based reporting system, with an accident and incident log book

available for staff to access. The registered manager was responsible for investigating any incidents reported and submitted a monthly return to the franchisor.

- Staff we spoke with could describe the process for reporting incidents and provided examples of when they would do this, such as equipment breakdown or patient falls.
- From May 2018 to May 2019 the service had reported zero incidents (Source: Provider information request).
- The service had not reported any never events from May 2018 to May 2019. A never event is a serious incident that is wholly preventable as guidance, or safety recommendation providing strong systemic protective barriers, are available at a national level, and should have been implemented by all providers.
- In accordance with the Serious Incident Framework 2015, the service had not reported any serious incidents from May 2018 to May 2019. (Source: Provider information request).
- The registered manager understood the duty of candour. The registered manager could explain the process they would undertake if they needed to implement the duty of candour because of an incident, which was in line with the requirements. The service had a policy for "duty of candour". However, not all staff were fully aware of the term "duty of candour". Staff we spoke to told us they would report to the registered manager if anything went wrong. At the time of our inspection, there had not been any incidents that met the threshold for implementing the duty of candour. The duty of candour is a regulatory duty that relates to openness and transparency and requires providers of health and social care services to notify patients (or other relevant persons) of certain 'notifiable safety incidents' and provide reasonable support to that person, under Regulation 20 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014. Following our inspection managers told us that all staff had received duty of candour refresher training.
- The registered manager understood their responsibility to report any notifiable incidents to the CQC.

# Diagnostic imaging

## Are diagnostic imaging services effective?

We do not currently rate the effectiveness of diagnostics imaging services.

### Evidence-based care and treatment

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

- Staff followed up-to-date policies to plan and deliver high quality care according to best practice and national guidance. Policies and protocols were in line with current legislation and national evidence-based guidance from professional organisations, such as the National Institute for Health and Care Excellence (NICE) and the British Medical Ultrasound Society (BMUS).
- Staff demonstrated a good understanding of national legislation that affected their practice.
- The service followed the 'As Low As Reasonably Achievable' (ALARA) principles. This was in line with national guidance (Society and College of Radiographers (SCoR) and British Medical Ultrasound Society (BMUS), Guidelines for Professional Ultrasound Practice (December 2018)). Sonographers completed all ultrasound scans within 10 minutes to help reduce ultrasound patient dose, where possible.
- An audit programme provided assurance of the quality and safety of the service. Peer review audits were undertaken in accordance with recommendations made by the BMUS. Other audits, such as clinic and local compliance audits, were undertaken regularly. They monitored women's experience, cleanliness, health and safety, ultrasound scan reports, equipment, policies and procedures. We saw evidence that actions were taken to improve where indicated.
- All policies and protocols were up-to-date and reviewed in a timely manner. They included details of the author, date of publication and date for review.

- Staff knew how to access policies. They were available electronically. Paper copies were also accessible to staff.
- Technology and equipment was used to enhance the delivery of effective care and treatment. The service utilised up-to-date scanning equipment to provide high-quality ultrasound images. They also had three large wall-mounted screens situated in the scan room which enabled women and their families to view their baby more easily. Women had access to the Window to the Womb mobile phone application (app). The app enabled women to record and share images of their pregnancy 'bump' with their family and friends. They could also create a time-lapse video of their pregnancy journey. Each woman's scan images taken during a Window to the Womb appointment was also saved on the app. This meant women had instant access to their scan images.
- Women and their partners were provided with written and verbal information about where to access additional help if they required it or if they had any concerns.

### Nutrition and hydration

- Women were told they could eat and drink as normal before their scan. Women were told it was useful to drink an extra two glasses of water per day during the week running up to their appointment, and to have a snack or meal a couple of hours before their scan to help improve the quality of the ultrasound image. For women less than 20 weeks of pregnancy and for gender confirmation scans, women were also advised to come with a reasonably full bladder to help ensure the best view of their baby. This information was given to women prior to their appointment and was included in the 'frequently asked questions' on the Window to the Womb's website.
- Food and drink was not routinely provided due to the nature of the service and the limited amount of time women spent there.

### Pain relief

- Pain relief was not available because abdominal pregnancy ultrasound scans are generally pain free procedures. Staff checked that women were not in any discomfort during their scan.

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## Patient outcomes

**Staff monitored the effectiveness of care and treatment and used the findings to improve them. They compared local results with those of other Window to the Womb clinics to learn from them.**

- The service used key performance indicators (KPIs) to monitor performance. These were set by the franchisor and included the number of bookings and rescan rate. This enabled the registered manager to benchmark the clinic's performance against the other 37 franchised Window to the Womb clinics. The franchise director told us the service's performance met their expectations and the service was operating at 6% above the national average for all Window to the Womb clinics.
- The gender confirmation accuracy rate for the service was 99.9% which was in line with the brand average. Managers at the service reported three incorrect gender accuracy scans out of 2345 applicable scans.
- Women were offered a rescan within a week if the scan needed to be repeated. From 1 May 2018 to 1 May 2019 the service had performed 14 rescans. These had been due to fetal position.
- The service monitored all referrals that were made to the NHS. The quality of the referrals were monitored through the internal audit process. From May 2019 to August 2019 there had been 45 referrals to the NHS.
- The service participated in improvement initiatives to monitor the quality of ultrasound scans performed. The sonographers undertook peer review audits. This meant their ultrasound observations and report quality were reviewed by a peer. The sonographers reviewed each other's work and determined whether they agreed with their ultrasound findings and report quality. This was in line with professional guidance which recommends peer review audits are completed using the ultrasound image and written report (Society and College of Radiographers (SCoR) and British Medical Ultrasound Society (BMUS), Guidelines for Professional Ultrasound Practice (December 2018). The peer review audit assessed the sonographer's activity, technical knowledge and communication

skills, such as their scan room hygiene, accuracy of gender confirmation, knowledge of ALARA principles and their ability to answer questions and concerns. No concerns were identified.

- Managers carried out a comprehensive audit programme. This included audit from the franchisor and internal audit. Improvement was checked and monitored.
- Audit results, service activity and service user feedback were discussed at monthly team meetings.

## Competent staff

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

- Staff were experienced, qualified and had the right skills and knowledge to meet the needs of women and their families.
- All staff underwent appropriate recruitment checks prior to employment to ensure that they had the skills, competence and experience required for their roles. We reviewed six personnel records and saw that all relevant information was included such as two employment references, photographic identification, a full employment history, evidence of professional qualifications and a disclosure and barring (DBS) was included.
- All clinical staff were fully qualified and registered with the appropriate professional body. We reviewed the staff personnel records for the sonographers and scan assistants. They all contained evidence of a recruitment and selection interview, employment history, identification, disclosure and barring service (DBS) checks and one employment reference. Managers ensured that staff had a current appropriate registration with their professional body. However, dates for review of professional registration were not clearly recorded. This meant that managers could not check that staff registration was up to date without accessing the professional registers.
- The sonographers were skilled, competent and experienced to perform the pregnancy ultrasound scans provided. Of the sonographers employed, one

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was substantively employed. The other three sonographers performed obstetric ultrasound scans at local NHS hospitals where they were substantively employed.

- Sonographers had their competency assessed when they first joined the service. They were reassessed annually by the lead sonographer for the Window to the Womb franchise. The sonographers' registration, indemnity insurance and revalidation status were checked as part of these assessments. If any concerns were identified, the registered manager was expected to address them immediately and additional training or observation was provided. The staff records we reviewed confirmed that all sonographers had completed a competency assessment within the last twelve months. Additionally, clinical leads from the franchisor remotely assessed the quality of scans on a regular basis.
- Peer assessments and observation of practice by sonographers had also been introduced to further support and improve practice. The managers and scan assistants also assessed the sonographers for their quality of customer care and service, standard of communication and overall customer experience. Sonographers received verbal and written feedback and the registered manager ensured any concerns or learning points were immediately addressed. We reviewed three assessments completed in February, March and April 2019 and saw no issues were identified.
- Managers gave all new staff a full induction tailored to their role before they started work. This included staff roles and responsibilities, mandatory and role specific training. Training and education was face to face and through electronic learning. Training records confirmed staff had completed role-specific training.
- Managers supported staff to develop through yearly, constructive appraisals of their work. At the time of our inspection no members of staff were eligible for an appraisal as they had not worked for the service for more than 12 months.
- Managers ensured staff received specialist training for their role. Staff were encouraged and given opportunities to develop. For example, the Window to the Womb franchise had produced a range of training videos for sonographers covering obstetric and fetal anomalies such as ectopic pregnancy, triploid syndrome (a condition where a fetus has three copies of every chromosome instead of the normal two) and anencephaly (a condition where the brain or spinal cord of a fetus does not develop properly). The sonographers also had workbooks to complete once they had watched the videos.
- Managers identified any training needs staff had and gave them the time and opportunity to develop their skills and knowledge. Staff had the opportunity to discuss training needs with their line manager and were supported to develop their skills and knowledge.
- Clinical leaders would visit the service regularly to provide educational support for staff, they would also visit at the request of the registered manager.
- All scan assistants were trained to conduct referrals to the NHS and how to support the sonographer in completing appropriate referrals.
- The registered manager undertook regular training and participated in external mandatory training annually (Source: Provider information request D32). These included annual externally run health and safety courses. The registered manager also participated in a schedule of refresher training and additional training which included communication training.
- Managers made sure all staff attended team meetings or had access to full notes when they could not attend.

## Multidisciplinary working

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

- The service had established pathways to refer women to their GP, midwife or local NHS hospital if any concerns were detected. Staff communicated their referral by telephone and letter. The service used a printed referral template and hand wrote the woman's details and reason for referral. A copy of the scan report and images was attached.

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- The management team, sonographers and scan assistants worked together for the benefit of women and their families. We observed positive working relationships promoted a relaxed environment and helped put women and their families at ease.

## Seven-day services

- Window to the Womb was not an acute service and did not offer emergency tests or treatment. This meant services did not need to be delivered seven days a week to be effective.

## Health promotion

### Women were given information to help them improve their health, care and wellbeing during pregnancy.

- The service's website contained health and wellbeing in pregnancy advice, such as keeping healthy during pregnancy, foods to avoid, things to ask your midwife and when to seek medical advice. For example, women were advised to contact their maternity unit immediately if they thought their baby's movements had changed and/or reduced. This was in line with national recommendations (NHS England, Saving Babies' Lives: A care bundle for reducing stillbirth (February 2016)).
- The service provided clear written information that the scanning services they provided were not a substitute for the antenatal care pathway provided by the NHS.

## 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 the importance of gaining consent before performing any ultrasound scan.

- Women were supported to make informed decisions about the pregnancy ultrasound scans provided by the service. All women received written information to read and sign prior to their scan appointment. This was available in all recognised world languages. Information included the terms and conditions, such as scan limitations, consent, prices and use of data. The sonographer discussed the potential risks to the

unborn child from the additional use of ultrasound prior to commencing the scan. This enabled women to make an informed decision on whether they wished to proceed with the scan.

- Staff gained consent from women for their care and treatment in line with legislation and guidance. Staff checked that women had read, understood and signed the terms and conditions of the service before any ultrasound scan was performed. The terms and conditions included the recommendation that women access all antenatal services made available to them by the NHS.
- Staff understood their responsibilities regarding consent including Gillick competence. According to Window to the Womb's terms and conditions, women who used the service must be 18 years of age or older. However, they would see young women between the age of 16 or 17, if they were accompanied by an appropriate adult. Staff told us if they had any concerns about a young person's capacity to consent, they would not proceed with the scan. Gillick competence is concerned with determining a child or young person's capacity to consent to medical treatment without the need for parental permission. Staff provided an example of when they had refused a scan to a 16 to 18 year old because they were not accompanied by an appropriate adult.
- Staff understood the relevant consent and decision-making requirements of legislation and guidance, including the Mental Health Act, Mental Capacity Act 2005 (MCA) and the Children Acts 1989 and 2004). The service had an up to date policy for those who suffered from any condition that would be covered under the MCA. They knew how to support women who lacked the capacity to make decisions about their care. While staff had completed training in relation to the Mental Capacity Act (2005), they told us they had not seen any women who lacked capacity since the service opened in 2017.

## Are diagnostic imaging services caring?

## Compassionate care

# Diagnostic imaging

**Staff cared for women with compassion and kindness, respected their privacy and dignity, and took account of their individual needs. Feedback from women and their families confirmed staff treated them well and with kindness.**

- We saw that staff were passionate about their roles and were committed to providing women and family centred care.
- Staff were discreet and responsive when caring for women. Staff took time to interact with women and those close to them in a respectful and considerate way. We observed staff treating and assisting women and their families in a compassionate manner. We saw that staff respected women's privacy and dignity. For example, the doors to the scanning room were closed during scanning and staff knocked and waited for an answer before entering. The scan assistants and sonographer were very reassuring and interacted with the women and those close to them in a warm, friendly and respectful manner.
- Women and their families told us that staff treated them well and with kindness.
- Staff followed policy to keep patient care and treatment confidential. Women having a scan could speak to staff without being overheard.
- Staff collected feedback from women and their families. Feedback was consistently positive about the kindness and care women had received from staff. Feedback forms were available in the clinic for women and their families to make any comments about the service. Women could rate their experience from one to five stars for ease of booking their scan, initial welcome, care provided during the scan, hygiene and comfort of the clinic and overall experience. We reviewed 23 feedback forms completed between March and August 2019, all rated the service highly. Women said "fantastic experience and fantastic staff", "everyone was very friendly her today" and "lovely scan, in depth and loved the fact we get to guess the gender before being told". Women and their families could also provide feedback through a variety of social media channels.
- Managers told us that from May 2018 to May 2019 they had received "hundreds" of compliments. (Source: Provider Information Request).

## Emotional support

**Staff provided emotional support to women to minimise their distress.**

- Staff gave women and those close to them help, emotional support and advice when they needed it. Staff were aware that women attending the service often felt nervous and anxious. Staff provided additional reassurance and support to these women. Staff received mandatory training in the emotional aspects of care when women received bad news.
- Staff undertook training on breaking bad news and demonstrated empathy when having difficult conversations. Staff provided emotional support to families and were aware of the impact on families of receiving bad news.
- Bereavement support was available to women. All women were provided with contact details and signposted to the miscarriage association so they could seek support and information. If staff identified a potential concern they would communicate this sensitively and would arrange appropriate follow up care. Staff gave us examples of when they had done this. We saw positive feedback from a woman about the care that she had received when she had suffered a 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 made sure women and those close to them understood their care and treatment. Staff communicated with women and those accompanying them in a way they could understand. We saw that staff adapted the language and terminology they used when performing the scan. They took the time to explain the procedure to ensure women understood.
- Women and their partners felt they were fully involved in their care and had been given the opportunity to ask questions throughout their appointment. The women we spoke with told us, "it was good that we can be seen so quickly", staff explained things that we hadn't thought of for example pointing out vital organs on the scan".

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- Women were able to bring family members and young children to their scan appointment if they wished.
- Staff discussed the cost of pregnancy ultrasound scans with women when they booked their appointment. This information was also available on the service's website.

## Are diagnostic imaging services responsive?

Good 

### Service delivery to meet the needs of local people

**The services provided were tailored to meet the needs of the population served. The premises and facilities were innovative and met the needs of a range of women who used the service.**

- Managers planned and organised services so they met the changing needs of the local population. The service specialised in providing antenatal scans for women from 16 to 40 weeks of pregnancy. All scans started with a wellbeing check of baby's movement, heartbeat, position and placental position. Scan packages were tailored to suit each woman and their family. Gender confirmation and growth scans were also available. Women who mostly wanted a scan for souvenir purposes could view their baby in 4D as well as 2D. NHS pregnancy scans show a two-dimensional image. A 4D scan enabled women to see their baby moving as a three dimensional image. The service only provided private pregnancy ultrasound scans. They did not undertake any ultrasound imaging on behalf of the NHS or other private providers.
- The service did not have any direct links into the NHS patient record systems. In the event of any anomalies the patient was referred to their GP, the early pregnancy unit, the maternity unit or to the emergency department of the local NHS hospital.
- The service offered weekday, evening and weekend appointments. Appointments could be made at short notice, for example if a woman had a concern and wanted reassurance. Women that we spoke with told us they had been able to make an appointment the day before their scan. Staff told us that they would arrange an appointment the same day if necessary.
- Facilities and premises were appropriate for the services being delivered. The scanning room had three large wall-mounted screens which projected the scan images from the ultrasound machine. These screens enabled women and their families to view their baby scan more easily and from anywhere in the room. This was in line with recommendations (Royal College of Radiologists, Standards for the provision of an ultrasound service (December 2014)).
- The environment in which the scans were performed was spacious, homely and well arranged. There was adequate seating available for those accompanying the woman during the scan. Staff dimmed the lights when undertaking a scan to darken the room. This meant scan images could be observed more clearly.
- There was a comfortable waiting area, scan room and toilet. Baby changing facilities were available. There was a separate waiting area with a selection of toys for young children to play with.
- The service had suitable facilities to meet the needs of patients' families. There was a small play area with toys that were suitable for young children who attended the clinic with their parents. Toys were clean and in good condition.
- Staff gave women relevant information about their ultrasound scan when they booked their appointment. This included whether they needed a full bladder and when was the best gestation for their scan. This information was also included in the 'frequently asked questions' on the service's website.
- Women were provided with written information explaining the ultrasound scan prior to their appointment and were advised of who to contact if there was a concern or issue.
- The service provided women with information about pricing and scan options before their appointment. The service offered several scan packages such as wellbeing, gender confirmation, growth and presentation and 4D. This information was clearly outlined on the service's website.

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- Parking was available in the car parking area outside the clinic. The service provided information on parking and travelling to the clinic on its website.

## Meeting people's individual needs

**The service took a proactive approach to understand women's individual needs and preferences. Care was delivered in a way that met those needs, was accessible and promoted equality.**

- The service had a process for referring women to the local NHS facilities (pathways) in the event that any fetal anomaly was identified. There were clear pathways in place to make referrals to the local NHS service. All of the scan assistants within the scan room and reception were fully trained in how to conduct referrals and how to support the sonographer in completing this.
- Women received written information to read and sign prior to their scan appointment. This was available in languages other than English. The terms and conditions and other key information was also available on the service's website and could be accessed in any recognised world language. For example, the website contained information about the scan, when to call your maternity unit and advice about some pregnancy conditions such as cleft lip and anencephaly (a serious birth defect, in which a major portion of the brain, skull and scalp are absent).
- Women were given two different information leaflets. One of these provided information for women who were not experiencing any problems. The other provided information for women who were experiencing any problems, for example severe pain, reduced fetal movements or vaginal bleeding. Both leaflets provided information about the local hospital contact details.
- Managers made sure staff, patients, loved ones and carers could get help from an interpreting service. The service offered a translation and "read aloud" service for women and their families whose first language was not English. This meant that staff were assured that information was translated accurately. Printed information could be translated into any language. The "read aloud" service was also available for women and their families who were blind or partially sighted.
- Clinic appointment times were arranged so that women in the earlier stages of pregnancy had appointments within the "first scan clinic". This was because there was a greater risk of delivering bad news to women who were less than 16 weeks pregnant. This meant that appointments were tailored to the needs of women.
- The scanning couch was suitable for women weighing up to 260kg. It was electronically powered and height adjustable ensuring that it was accessible for all service users.
- The entrance and hallway was suitable for wheelchair users.
- All pregnancy ultrasound scans were undertaken in a private clinic room with lots of space for additional relatives, friends or carers to accompany the woman. Women and their partners were invited to bring up to five additional guests with them.
- All women were provided with contact details for the miscarriage association so they can seek support and information.
- The service was inclusive to all pregnant women and we saw no evidence of any discrimination, including on the grounds of age, disability, pregnancy and maternity status, race, religion or belief, and sexual orientation when making care and treatment decisions.
- The service offered women a range of baby keepsakes and souvenirs which could be purchased. These included heartbeat bears, a selection of photo frames, fridge magnets and gender reveal products. Heartbeat bears contained a recording of the unborn baby's heartbeat.

## Access and flow

**Women could access services and appointments in a way and at a time that suited them. Technology was used innovatively to ensure women had timely access to treatment, support and care.**

- Women could pre book their appointment using the online appointment system. Alternatively, they could call the clinic to make an appointment. The service had appointment availability throughout the week. All women self-referred to the clinic.

# Diagnostic imaging

- The service was flexible. At the time of our inspection the service held five clinics a week. Clinic appointments were available from 2pm to 7pm on Tuesdays, Wednesdays and Fridays and 9.30am to 5.30pm on Saturdays and Sundays.
- Managers and staff worked to make sure patients did not stay longer than they needed to. Appointment times were approximately 45 minutes. We saw that appointments ran to time. Women we spoke to and feedback we saw confirmed this.
- The service did not have a waiting list and did not take referrals from other services. All appointments were booked by women for a time that suited them.
- If patients had their appointments cancelled at the last minute, managers made sure they were rearranged as soon as possible. From May 2018 to May 2019 one planned procedure was cancelled for a non-clinical reason. The procedure was cancelled due to staff illness. (Source: Provider information request).
- During the reporting period May 2018 to May 2019, no procedures were delayed for a non-clinical reason. (Source: Provider information request)
- The service monitored rates of non-attendance. This information was submitted to the franchisor monthly. There was a low rate of non-attendance because the service required a non-refundable deposit payment on appointment booking. From May 2018 to May 2019, managers told us that 2% of women did not attend their booked appointment. Managers told us that this was due to changes in the women's circumstances, for example miscarriage. In these circumstances the women's payment was refunded.
- There was no waiting time for scan results. Women were given a written report and access to the Window to the Womb app at the end of their appointment.
- Women and their relatives knew how to complain or raise concerns.
- The service clearly displayed information about how to raise a concern in patient areas. The complaints process was available to women and their families. The policy identified the complaints process. This included details of the response to complaints, timescales for response and the escalation process should the service user remain dissatisfied. There was a specific form for service users to record a complaint. Processes were also in place for those who wished to use social media. All social media channels were monitored on a daily basis.
- The complaints policy stated all written complaints should be acknowledged within three working days and resolved within 21 days.
- Managers investigated complaints. The registered manager had overall responsibility for managing complaints. During the reporting period May 2018 to May 2019, there were zero complaints to the service. During the same period managers told us that the service had received "hundreds" of compliments. (Source: Provider information request). The last complaint was received was in March 2019. We saw that the complainant was provided with a detailed written response to their complaint including actions taken to resolve it. Face-to-face meetings were also offered where needed.
- Staff we spoke with understood the policy on complaints and knew how to handle them although there had not been any complaints to the service during the reporting period. Staff knew how to acknowledge complaints and told us women would receive feedback from managers after the investigation into their complaint.
- Managers provided feedback to staff about any complaints or feedback that were received. Minutes of meetings we saw confirmed this.
- Staff collected feedback from women and their families. Feedback forms were available in the clinic for women and their families to make any comments about the service. Women and their families could also provide feedback through a variety of social media channels.

## Learning from complaints and concerns

**It was easy for people to give feedback and raise concerns about care received. Concerns and complaints were treated seriously, investigated and measures were taken to resolve them.**

**Improvements were made from complaints received. Lessons learned from complaints were shared with all staff.**

# Diagnostic imaging

- Managers encouraged staff to ask women and their families if they were happy with the service so that any dissatisfaction could be identified and addressed whilst the woman was at the clinic.

## Are diagnostic imaging services well-led?

Good 

### Leadership

**The registered manager had the skills and experience needed to run a high quality sustainable service. The registered manager was visible and approachable in the service for women, their families and staff. They supported staff to develop their skills and take on more senior roles. They had the skills and experience needed to run a high-quality sustainable service.**

- The registered manager led the service and was also the director. The registered manager was supported by a second director and the nominated individual. The registered manager demonstrated an awareness of the service's performance, limitations and the challenges it faced. They were also aware of the actions needed to address challenges.
- Staff understood the management arrangements and told us that they felt well supported. The sonographers reported to the registered manager for matters related to the clinic and to the lead sonographer for the franchise for any clinical issues. The scan assistants reported to the registered manager. A clinic manager had recently been recruited and was responsible for the day-to-day running of the service.
- All staff that we spoke to told us that they felt supported by the registered manager. Staff told us that the registered manager was approachable and visible. Staff told us that they felt confident to raise any concerns they had with the managers.
- Leadership and management courses were available for managers and development courses were available to all members of staff. Courses included customer service skills, manager induction, behavioural styles, problem solving, performance

appraisals and development plans. The registered manager undertook regular training and had completed training in all aspects of operating the business. The registered manager had been assessed as competent by the franchisor.

- The Window to the Womb franchisor was contractually responsible for providing the registered manager with ongoing training. This was undertaken at clinic visits, training events and the biannual national franchise meetings. The registered manager told us they found these events and meetings very informative and enabled the franchisees to share their knowledge, learning and improvement ideas.

### Vision and strategy

**The service had a clear vision and strategy for what they wanted to achieve, with quality and sustainability as the top priorities.**

- The service had a vision and values which focused on the provision of safe, high quality care. The vision and values for the service were consistent with the Window to the Womb franchise. The vision was to provide, "High quality, efficient and compassionate care to our customers and their families, through the safe and efficient use of obstetric ultrasound imaging technology". The registered manager told us the vision was "always to keep improving".
- The values for Window to the Womb underpinned the vision and reflected the priorities for the service.
- The Window to the Womb's statement of purpose, which included the vision, aims and objectives and values for the service, was publicly displayed in the clinic.
- The Window to the Womb franchise had developed 12 aims and objectives to support their vision and what they wanted to achieve. Examples of these included: to meet the demand to provide pregnant ladies with a private obstetric ultrasound service in an easily accessible local environment and to provide pregnant ladies with medically relevant ultrasound findings by way of an obstetric report.
- The registered manager told us that they were hoping to develop NHS contracts in the future to undertake reassurance scans.

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- Staff were aware of the vision and values of the service. We saw staff demonstrated the vision and the values in their interactions with women and their families and the services they provided.

## Culture

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

- All staff we met were friendly, welcoming and helpful. Staff told us they enjoyed working at the clinic and providing a high standard of care to women and their families.
- We spoke with five members of staff including a sonographer and scan assistants. All staff were very positive about the service and told us they felt well supported and valued. We observed that staff were focussed on the needs of the women and their families who were using the service. We reviewed five staff feedback forms which were all mostly positive. However, a comment had been made about the notice period given about the availability of covering shifts.
- Staff were offered opportunities for career development. Staff discussed any training needs with the registered manager and were supported to develop. Staff told us they received feedback on their performance.
- We observed that staff worked collaboratively and shared responsibility in the delivery of good quality care.
- The service promoted an open and honest culture. This was supported by the franchisor's Freedom to raise a concern policy and the appointment of a 'freedom to speak up guardian'. Staff could raise any concerns they may have through a 'freedom to raise a concern' guardian should staff not want to raise a concern to clinic management. There was also a

confidential phone line for staff to contact should they wish to discuss anything that had affected them at work. Staff we spoke with were aware of this provision but none had needed to use it.

- Complaints or incidents were investigated with a "no blame" approach. The complaints policy was clearly visible in the clinic. Complaints and incidents were discussed at staff meetings and learning was shared to enable services to be improved. Staff were aware of how to raise any concerns and how to respond to women and their families if they raised any concerns.

## Governance

**The service had governance arrangements to ensure high standards of care were maintained.**

- The registered manager was responsible for the overall governance and quality monitoring of the service. This included investigating incidents and responding to complaints. The registered manager was supported by the franchisor and attended biannual national franchise meetings where matters such as clinic compliance, performance, audit and best practice were discussed.
- Staff were clear about their roles and understood what they were accountable for and to whom. Staff reported any governance matters such as complaints or incidents to the registered manager, who would in turn inform the franchisor.
- The service held monthly meetings to discuss any concerns. We reviewed a sample of meeting minutes that showed governance matters such as feedback and complaints, incidents, policies and pathways, audit results and franchisor news and updates were discussed, as well as business performance and sales matters. The meeting minutes showed staff meetings were well attended by all members of the team, including sonographers. If staff were unable to attend a meeting they had access to the minutes.
- Processes were in place to ensure that incidents and complaints were managed effectively and in a timely manner. Lessons learned and changes in practice were communicated to staff and discussed at team meetings. Staff told us about changes that had been made to practices as a result of women's feedback.

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- The service used a closed social media group to communicate any updates or new information to staff as not all staff were present at the service at the same time.
- Processes were in place to ensure that appropriate recruitment checks were made for all new staff.
- All staff underwent appropriate recruitment checks prior to employment to ensure they had the skills, competence and experience required for their roles. We reviewed six personnel records and saw that all relevant information was included such as two employment references, photographic identification, a full employment history, evidence of professional qualifications and a disclosure and barring (DBS) was included.
- The service had medical malpractice insurance. The sonographers also had their own indemnity insurance.

## Managing risks, issues and performance

### Effective arrangements were in place to identify, reduce and eliminate risks, and to cope with both the expected and unexpected.

- The registered manager had completed risk assessments for identified risks such as fire, health and safety and legionella. The risk assessments identified who or what was at risk, the hazards and their potential effects, existing control measures in place, the risk rating, whether the risk was adequately controlled and additional control measures needed. We saw most of the risks were graded low and had adequate controls in place to minimise each risk. There was also evidence that the risk assessments had been circulated to all employees and the management team. All risk assessments were reviewed annually or sooner if indicated. We saw that some risk assessments, for example the fire, health and safety, legionella and infection control risk assessments were due to be reviewed.
- Staff were aware of the main risks to the service and actions to minimise them. However, the service did not have an overall risk register but had a risk assessment folder which included risk assessments. This meant that managers may not have clear oversight of all potential risks to the service.

- There were appropriate policies and pathways in place regarding business continuity and major incident planning, which outlined clear actions staff needed to take in the event of extended power loss, a fire emergency, adverse weather, staff sickness and sonographer absence. These also contained the contact details of relevant individuals or services.
- Managers made staff aware of any new or updated policies.
- The service used feedback, complaints and audit results to help identify any necessary improvements needed and to ensure they provided a high-quality, effective service. For example, we saw improvements were made in response to complaints received.
- The registered manager compiled a monthly performance report. This was submitted to the franchisor and included the number of ultrasound scans completed, the number of rescans performed, did not attend rates, the number of referrals made to other healthcare services and complaints received. From May 2018 to May 2019, 3432 scans and 14 rescans had been undertaken. The service had referred 49 women to healthcare services from May to August 2019.
- The franchisor conducted a clinic compliance audit in February 2019. This covered all aspects of the service such as cleanliness, equipment, health and safety, infection control, emergency planning, feedback and staff. Although the clinic was compliant with the service audited there were clear action plans in place.

## Managing information

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

- Women's records and scan reports were easily accessible and were kept secure. Paper records were stored in locked filing cabinets and staff locked computer terminals when not in use. Keys were stored in a portable storage box, this meant that there was a risk that the key box could be removed.
- Electronic systems were password protected. This prevented unauthorised people from accessing women's records. Scan reports were retained for a period of 30 days in order that any issues following the

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scan could be rectified. Scan reports could be reviewed remotely by the lead sonographer to enable timely advice and interpretation of results when needed, to inform patient care.

- Staff were aware of the requirements of managing a woman's personal information in accordance with relevant legislation and regulations (General Data Protection Regulations (2016/679 EU)).
- The service had an up-to-date information governance policy which staff could refer to for guidance when needed. All staff had completed information governance training.
- The service had a data retention policy which was due for review in May 2019, this was a corporate policy. There was a privacy policy which was available on the services website and clearly detailed how information was used, collected and stored securely.
- The service had a qualified accountant who produced monthly management accounts and annual returns. These were benchmarked against other franchises.

## Engagement

**The service engaged well with women and staff to plan and manage appropriate services and collaborated with partner organisations effectively.**

- People's views and experiences were collected and acted on to improve the service. Women who used the service were encouraged to give feedback on the quality of service they received. Following feedback from women and their families managers had made changes to the service. These included introducing early pregnancy scans to reflect demand, adjusting opening times to suit demand and the introduction of a translation and "read aloud" service.
- Women and their families were asked to rate their experience from one star to five stars for ease of booking their scan, initial welcome by the team, care provided during the scan, hygiene and comfort of the clinic, and overall experience. We reviewed 23 feedback forms and found all women had rated the service as five stars.
- Social media was used to engage with the local population, promote the service and receive feedback. Staff told us that the service received a lot of feedback

was through social media channels. We saw that women's and their families feedback was discussed at team meetings and staff were encouraged to gather feedback from clients.

- Information was shared with staff in a variety of ways. This included face to face, email, the staff noticeboard, closed social media group and meetings. There was a monthly internal franchisor newsletter, "Open Window". This included updates for example, Care Quality Commission (CQC) inspections, training and policies and information about new clinics opening. Staff told us they felt well informed and were encouraged to make improvements and develop their knowledge and skills. They told us they would recommend the service to their family and friends.
- The service had introduced a closed social media group for staff to communicate updates to the whole team. This would include for example, updates on policies and requests to cover shifts. Staff also had access to a confidential telephone line if they required any emotional support.
- The service held regular team meetings. We saw this in the minutes we reviewed. Minutes of meetings were clear and included details of policies, client feedback, service updates, improvements and training. If staff were not present they were required to sign the minutes to demonstrate they had read them.
- The service engaged with local charities and organisations. The service supported local organisations including a hospice, local schools, a children's hospital and a charity providing support to women who had suffered a miscarriage. Support included providing raffle prizes and toys. Information was clearly displayed in the clinic of the support provided.
- There was transparency and openness with the franchisor about performance. The registered manager submitted performance data to the franchisor every month such as clinic activity and complaints received.

## Learning, continuous improvement and innovation

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

- Staff were committed to providing a high quality service and care to women and their families. We saw positive interactions with women and their families throughout our inspection.
- The service had introduced peer led assessments and observations of sonographers to ensure that high quality care was maintained at all contacts. This meant that sonographers were able to benchmark their own performance against colleagues and ensured consistency throughout the service.
- Window to the Womb had developed a mobile phone application ('app') to support and engage with women. The app had been designed following

feedback from women who wanted to be able to share their scan images with friends and family. The app enabled women to document and share week-by-week images of their pregnancy bump with their family and friends. They could also create a time-lapse video of their pregnancy journey. Any scan image taken during a Window to the Womb appointment was saved on the app. This enabled women instant access to their scan images. Women could also book scan appointments through the app.

- The franchise director told us that the same standards were maintained across the Window to the Womb franchise. This ensured consistency of training, staffing, governance and support from corporate clinical staff and directors. We saw that the service was supported and that learning from other franchisees was shared widely.

# Outstanding practice and areas for improvement

## Outstanding practice

- Window to the Womb had invested in technology and equipment which it used to enhance the delivery of effective care and treatment. They had developed a mobile phone application ('app'). The app 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. Any scan image taken during a Window to the Womb appointment was also saved on the app, which allowed women to have instant access to their scan images. Women could also book scan appointments through the app.
- Window to the Womb had developed a continued professional development platform which sonographers could access to enhance their knowledge and skills.

## Areas for improvement

### Action the provider **SHOULD** take to improve

- The provider should ensure that all training records include the details of the date and staff members name on every page.
- The provider should ensure that all staff are fully aware of their reporting duties in relation to female genital mutilation (FGM).
- The provider should ensure that all staff are fully aware of the term "duty of candour".
- The provider should ensure that keys for the locked record cabinet are stored securely.