Baby Bonding Limited Window to the Womb Southampton

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

Summary of findings

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

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

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

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

Overall summary

Window to the Womb Southampton is operated by Baby Bonding Limited.

The service provides diagnostic imaging for women aged 16 and above. 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 12 August 2019. We gave staff one working days' notice that we were coming to inspect to ensure the availability of senior staff 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. 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 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. If a complaint received the registered manager would complete a comprehensive investigation and share 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.

Summary of findings

- 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.
- 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.

Dr Nigel Acheson

Deputy 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 	**Diagnostics was the only activity the service provided. We rated the safe as good because it was safe, effective, caring, responsive and well led.**

Summary of findings

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Good

Window to the Womb Southampton

Services we looked at
Diagnostic imaging

Summary of this inspection

Background to Baby Bonding Limited Window to the Womb Southampton

Window to the Womb Southampton is operated by Baby Bonding Limited.

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

Window to the Womb Southampton opened in 2016 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 was registered with the CQC to undertake the regulated activity of diagnostic and screening procedures.

We have not previously inspected this service.

The service did not use or store any medications.

The group clinic manager was training a senior scan assistant to become the registered manager for the Window to the Womb Southampton location. The group clinic manager was responsible for overseeing seven Window to the Womb locations. At the time of our inspection the group clinic manager was managing the Window to the Womb Southampton.

Our inspection team

The inspection team was formed of one CQC inspector. The inspection team was overseen by Catherine Campbell, Head of Hospital Inspection for South East region.

Information about Baby Bonding Limited Window to the Womb Southampton

The service provides diagnostic imaging service (ultrasound scans) to self-funding pregnant women aged 16 and above across Southampton. The service is single storey clinic with driveway access from main the road to a car park. The service was a stand-alone purpose built diagnostic and screening facility.

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 weeks to 10+6 weeks gestation
- Dating scans from eight to 12+6 weeks gestation
- Reassurance scan 12 to 15+6 weeks gestation.

The Window to the Womb clinic offers the following scans:

- Wellbeing and Gender scans 16-22 weeks
- Wellbeing and 4D scans 24-34 weeks
- Wellbeing and Growth scans 26-42 weeks

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 the CQC in 2015.

The service runs eight clinics a week. Monday, Wednesday and Thursday afternoons and evenings and all-day Saturday and Sundays.

At the time of our inspection, Window to the Womb employed a full-time sonographer. There were nine scan assistants who were on zero-hour contracts. The group clinic manager was acting as the clinic manager.

During the inspection, we visited the registered location in Southampton. We spoke with five staff and four women being scanned and their partners. During our inspection, we reviewed 12 sets of patient records.

Summary of this inspection

Activity (May 2018 to April 2019)

- First Scans (6-15 weeks) 1074
- Wellbeing and gender (16-23 weeks) 1715
- 4D scans (23-34 weeks) 1950
- Growth and presentation scans (34 weeks plus) 72

Track record on safety

- No Never events
- No Clinical incidents
- No serious injuries

No incidences of healthcare acquired Meticillin-resistant Staphylococcus aureus (MRSA),

No incidences of healthcare acquired Meticillin-sensitive staphylococcus aureus (MSSA)

No incidences of healthcare acquired Clostridium difficile (c.diff)

No incidences of healthcare acquired E-Coli

No complaints

Services provided at the hospital 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?

Are services safe?

Good

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

- The service provided mandatory training in key skills to all staff and made sure everyone completed it.
- 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. Staff kept equipment and the premises visibly 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 processes for staff to raise concerns and report incidents. Staff understood their roles and responsibilities to raise concerns and record safety incidents.

Are services effective?

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.
- 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.

Summary of this inspection

- Staff worked together as a team to benefit women and their families.
- Staff provided women with information about the scan findings and health promotion information about their pregnancies.
- Staff understood how and when to assess whether a woman had the capacity to make decisions about their care.

Are services caring?

Good

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

- The service planned and provided services in a way that met the 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 five days of the week, open all day Saturday and Sunday and could accommodate same day appointment requests.
- The service had a complaints policy and treated concerns and complaints seriously. The manager would investigate any complaints received and any lessons would be shared.

Are services well-led?

Good

We have not previously rated well led. 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.

Summary of this inspection

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

Detailed findings from this inspection

Overview of ratings

Our ratings for this location are:

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

Good

Diagnostic imaging

Safe	Good
Effective	
Caring	Good
Responsive	Good
Well-led	Good

Are diagnostic imaging services safe?

Good

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.
- 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.
- Four staff we spoke with had completed mandatory training. This included two scan assistants, a bank sonographer and the group clinic manager. Staff we spoke with said their mandatory training was easily accessible. At the time of our inspection the group clinic manager at the location oversaw mandatory training requirements and gave time for staff to complete their mandatory training. Staff compliance with mandatory training was 100% other than for a new member of staff, and the Mental Capacity Act (2005) e learning course which the service launched in June 2019.
- The group clinic manager and registered managers for a location 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, the sonographer and eight of the nine scan assistants were compliant with safeguarding training. The scan assistant who was not compliant was new in post. All staff we spoke with had received training in levels two or three for children's safeguarding as needed for their role. The group clinic manager was trained to level three and could access advice from the local council safeguarding teams if needed.
- 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 had 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.

Cleanliness, infection control and hygiene

The service controlled infection risk well.

Good

Diagnostic imaging

- Staff kept the equipment and premises visibly clean. They used control measures to control and prevent the spread of infection.
- During inspection we saw staff were 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 use of gloves when staff cleaned couches and equipment after patient use. We saw 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 told us the probes were covered during investigations and and then cleaned 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 saw staff use the hand sanitiser appropriately.
- We saw staff washed 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.
- We saw signed records to show monthly deep cleaning of the location had taken place, which included the scan room, printing area, reception area, toilets and kitchen.
- 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 three large sofas' and many examples of scan pictures at different stages of pregnancy on the walls.
- 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 320 kg. This meant they were suitable for bariatric women.
- 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 promptly, when needed. This ensured women would not experience prolonged delays to their care and treatment due to broken and out of use equipment.
- The fulltime sonographer and bank sonographer were registered with the Health and Care Professionals Council (HCPC) and trained to use the ultrasound machine at the location.
- Due to the nature of the service they did not need 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 a store cupboard in line with the Control of Substances Hazardous to Health Regulations 2002 (COSHH). COSHH is the legislation which requires employers to control substances which are hazardous to health.

Assessing and responding to patient risk

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

Good

Diagnostic imaging

- Staff told us the 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 the right 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 on the evening before our inspection a referral had been made to the early pregnancy unit at their local NHS trusts as per the pathways. Staff had had made three unplanned transfers of patients from May 2018 to April 2019, for women with ectopic pregnancies.
- Staff documented referrals on dedicated referral forms which the registered manager reviewed for completeness.
- 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. We saw four patient scans, and the four patients all had their NHS records with them.
- For women aged 16 to 17 years the service would not perform the scan without their pregnancy records and the service requested that a responsible adult must go with them to the appointment. The service defined a responsible adult as a person over the age of 18 years and a parent, step parent, legal guardian, grandparent or a person who was acting in place of your parent and could reasonably be expected to exercise responsible supervision of them. The service did not scan anyone under the age of 16. From May 2018 to April 2019 there were eight 16-17 year olds scanned.
- Staff told 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.

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 nine scan assistants on zero hours contracts. There was one full time sonographer and a bank sonographer who was employed on a zero hours contract and held a substantive post in an NHS trust. If needed to cover unexpected absence, a sonographer would be brought over from another location in the franchise, to prevent the cancellation of a clinic.
- 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 at the time of our inspection, and the group clinic manager took on the role as part of their day to day role which was effective for the everyday running of the clinic. The group clinic manager was training a senior scan assistant to be the registered manager and undertake the role of clinic manager.
- 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'.
- If a staff member went 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 group clinic manager covered the scan assistant role. This helped to prevent clinic cancellations.
- All staff including sonographers employed by Window to the Womb underwent a local induction over a three-day period which covered 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.

Good

Diagnostic imaging

- 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 needed, 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.
- Staff saved the ultrasound images onto a memory stick, which they uploaded to Window to The Womb's 'Bumpies' mobile phone application ('app'), which was a free application for the women. The Bumpies 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 12 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.
- 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 buy the recording it was deleted after 24-hours.
- 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.
- Staff we spoke with knew how to report incidents and could give examples of when they would do this. If an incident should occur, managers told us they would investigate them and share lessons learned with the whole team and the wider service. If things should go wrong, staff would apologise and give patients honest information and suitable support.
- The service did not report any clinical incidents from May 2018 to April 2019. They had reported three accidents in the accident book at the location from December 2018 to May 2019. One was where a woman stumbled over their daughter's foot with no injury sustained, a second a boy who fell in the car park with no injury sustained and a third a staff member who slipped whilst mopping the floor. Staff reported these incidents in the accident book with all details fully completed.
- 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 May 2018 to April 2019, 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 May 2018 to April 2019.
- 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 needed 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). All policies and protocols had a next renewal date, which ensured the service reviewed them in a timely manner.
- Staff showed 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 found a foetus did not have a visible heartbeat and measured less than 7.0 mm.
- The service followed as low as reasonably achievable (ALARA) principles outlined by the British Medical Ultrasound Society (BMUS). The service kept scanning times to a minimum and did not offer scans that lasted longer than 10 minutes.
- 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 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

Staff gave patients enough food and drink to meet their needs.

- Staff gave women 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.
- Women had access to water in the reception area whilst awaiting their scan. There was also a small choice of snacks and drinks available for purchase.

Pain relief

Staff assessed and monitored patients regularly to see if they were comfortable.

- 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 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 Baby Bonding achieved 9% which was slightly above the brand average of 6%. The group clinic manager told us that since 1 July 2019 the number of re-scans had reduced to 8%.
- From 14 January 2019 to 11 August 2019 there were 40 referrals following first scans, and from 9 January 2019 to 14 July 2019 there were eight referrals following foetal wellbeing scans to the local NHS due to the detection of potential concerns.
- 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, who had been in post until May 2019 had appraised all scan assistants and we saw 100% of eligible staff had received an appraisal. The group clinic manager was training a new clinic manager to undertake staff annual appraisals.
- 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 Health and Care Professions Council (HCPC) registrations. The sonographers also belonged to the Society and College of Radiogaphers.

Multidisciplinary working

Staff 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.
- Staff ensured before scans were undertaken patients had signed to confirm they agreed to the terms and conditions. This included patients giving consent for medical information relating to their pregnancy being passed on to their NHS provider.

Seven-day services

- The service ran eight clinics a week. Monday, Wednesday and Thursday afternoons and evenings and all-day Saturday and Sundays. The service designed clinic sessions 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.

Health promotion

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

- The service provided families with information about pregnancy specific issues or concerns, for example morning sickness, keeping healthy, foods to avoid and complications in pregnancy and what to do.

Consent and Mental Capacity Act

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

- 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 pregnancy care and consent to share information with the NHS. We saw clear signed consent in 12 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 patient details prior to the scan and obtained verbal consent to begin.

Good

Diagnostic imaging

- 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 had designed a bespoke Mental Capacity Act online training course which had started at the end of June 2019. Five of the 10 staff working at the service had completed the mental capacity e learning course when we inspected on 12 August 2019.

Are diagnostic imaging services caring?

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 saw staff did not rush women through their scans, checked they were comfortable throughout and spent time explaining their findings from the ultrasound scans.
- Staff showed a kind and caring attitude to women and their partners. This was evident from the interactions we saw 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 kept 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:

"Excellent service. Welcoming and caring. Really enjoyed our experience"

"Staff our lovely. We are so pleased with our photos"

"Lovely experience. Friendly staff"

- We saw 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 'Bumpies' mobile phone application.

Emotional support

Staff provided emotional support to patients to minimise their distress.

- 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 Window to the Womb appointment. Staff showed a calming and reassuring demeanour so as not to increase anxiety for women and their partners.
- Staff informed us that 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 needed and were able to exit the clinic via an alternative exit to prevent them having to pass waiting pregnant women.
- We saw the sonographer providing reassurance throughout an ultrasound scan because the woman was anxious about the gender of their baby. Both the scan assistant and the sonographer offered kind words of reassurance to both the woman and her partner.

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 saw 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 everyday 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.

Good

Diagnostic imaging

- 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 'Bumpies' mobile phone application, so the women could choose who to share the images with.
- The service collected feedback from an internet site and we saw wholly positive feedback. The service scored 4.9 out of 5 for the services on an internet rating site.

Are diagnostic imaging services responsive?

Good

Service delivery to meet the needs of local people

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

- The service provided information on travelling to the clinic on their website. Parking was free at the service.
- The service had developed an innovative mobile phone application called 'Bumpies' The 'Bumpies' 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 Bumpies 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 toilets were 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 service had a policy on the provision of key information which told staff the steps they should take to provide key information to women where English was not their first language, had sight or hearing impairments. The franchise had recently introduced a new online translation service where written information could be translated into any recognised world language. Staff could access a read aloud service for women with sight impairment. Staff would read key documents where patients had a hearing impairment, and use a pad and paper to communicate as required.
- The ultrasound scan room provided a calm and relaxing atmosphere with relaxing music playing in the background and dimmed lighting.
- The service had separated the Window to the Womb sessions from the Firstscan early pregnancy scans. Staff removed all soft toys and keepsakes for the Firstscan sessions to be sensitive to the needs of women and families who may have needed 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 had a description of what the sonographer had found, advice, and the next steps they should take.

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 following the scan. The sonographer produced a report whilst the women and their partner were choosing the pictures they would like to keep.
- We saw women and their families arrive in the reception area and wait. During our inspection towards the end of the clinic there was about a thirty-minute delay. This was due to the need for some re-scans, due to the position the babies were lying in. The women were re-scanned after they had walked around for a short while. The group clinic manager kept women and their partners updated about the waiting times. The service did not audit the patient waiting times for staff to call them through. This would help identify any areas for service improvement.
- The group clinic 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 May 2018 to April 2019 the service had not cancelled any planned ultrasound scans.

Learning from complaints and concerns

The service had a complaints policy and treated concerns and complaints seriously.

- The service had not receive any complaints from May 2019 to April 2018.
- There was information for patients within the reception areas, leaflets and website on how to make a complaint.
- Window to the Womb had a policy for managing complaints, which included timescales for acknowledging a complaint (three days) and responding within 21 days. The manager would investigate any complaints received and any lessons would be shared.
- All four 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 a regular agenda item to ensure if there was a need to improve their service, this was discussed.

Are diagnostic imaging services well-led?

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 group clinic manager was currently acting as the clinic manager. The group clinic manager was training a member of staff in the role of a scan assistant to be the registered manager for the location. Senior staff explained to us the organisation prided itself on having a management and development programme, which gave staff a career development pathway.
- The group clinic manager currently managing the location shared business information with the directors of the franchise Window to the Womb Ltd. We observed clear management and reporting arrangements.
- The group clinic 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 saw positive working relationships between the group clinic and the Window to the Womb Ltd franchise director. There was also a monthly meeting which the clinic managers attended, chaired by the group clinic manager and attended by the group clinic director and their general manager. The Window to the Womb Southampton clinic was one of seven in the group.
- Staff told us the group clinic manager was accessible and approachable if they wanted advice or to make suggestions. The group clinic manager kept staff informed of any developments for the service.
- Staff told us the group clinic 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.

- Baby Bonding Limited 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".
- 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 Southampton shared. Staff worked within these values and told us they aimed 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 the registered manager, who had been in post until May 2019, had 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. The group clinic manager told us that duty of candour training was included when new staff received their induction, to the Window to the Womb organisation.
- Throughout our inspection, the group clinic 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 showed 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.
- Window to the Womb (Franchise) Ltd had indemnity and medical liability insurance which covered all staff working for the franchise, in 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.
- The audit programme included monthly local audits, annual audits and peer review audits. Annula compliance audits included premises checks, health and safety, emergency planning, accuracy and completion of scan reports, completion of pre-san questionnaires, professional registration and staff records. We saw clear actions were identified and agreed with the clinic.
- Baby Bonding Limited 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.

Good

Diagnostic imaging

- 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. 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 manager asked them to sign a printed version of the minutes to confirm they had read them.
- The location also used a closed text message group using an App to communicate updates to the team. Staff we spoke with at the inspection told us they found this system worked well for the team.
- 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 about the business's overall performance.

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 service did not have a risk register however, we saw evidence the registered manager reviewed all risk assessments records monthly to ensure they documented any changes or identified new risks.
- 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.
- 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 team meeting held on 25 April 2019, the registered manager noted how for feedback and performance the clinic was in the upper part of the group.
- 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 case 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 showed 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.
- 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 location had increased the number of early pregnancy scan appointments to reflect demand. The service now provided more weekday evening appointments for both early pregnancy and 16 weeks plus to suit demand.
- The Window to the Womb franchise undertook a national staff survey in 2019. Overall the results were positive. Where there were concerns identified, actions were put in place to address the concerns. The franchise was planning to undertake annual staff surveys.

Good

Diagnostic imaging

- We saw 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 had 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.

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 service had acted to address some of the concerns raised after other inspections in the franchise. This included ensuring staff were completing the newly introduced Mental Capacity act (2005) training.
- The franchisor, Window to the Womb, had developed the 'Instant Midwife' service to respond to questions and concerns women often 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.