Bradley Street

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	**Requires improvement**
Are services safe?	**Requires improvement**
Are services effective?	**Not sufficient evidence to rate**
Are services caring?	**Good**
Are services responsive?	**Requires improvement**
Are services well-led?	**Requires improvement**

Overall summary

Bradley Street (the clinic location) is operated by Betsy Blossom Limited T/A Lollipop 4D Baby Scans. The clinic provides self-referred, privately funded pregnancy scans in 2D, 3D and 4D, including early reassurance scans, genders scans and baby bonding scans. The service provides keepsake pictures and DVDs to people who used the service as well as keepsakes such as heartbeat bears and gender reveal balloons and cannons.

The clinic is based in Manchester city centre in the Northern Quarter.

The clinic employs a manager who is also an ultrasound technician, two receptionists and a sonographer who is able to carry out early reassurance scans as well as gender identification and bonding scans.

We inspected this service using our comprehensive inspection methodology. We carried out the inspection on 27 and 28 February 2019. The inspection was unannounced.

To get to the heart of peoples' experiences of care and treatment, we ask the same five questions of all services:

Summary of findings

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.

The main service provided by this provider was baby keepsake scanning.

Services we rate

This is the first time that we have rated this service. We rated it as **Requires improvement** overall because:

- We were not assured that the service provided mandatory training in key skills to all staff and made sure that everyone completed it.
- Staff had received training on how to recognise and report abuse, but we were not assured that there were effective systems and processes in place to support them to apply it. The safeguarding policy was lacking in detail that would enable staff to know what types of abuse should be reported, how to report it and who to.
- The service did not assess and respond to patient risk well and did not inform women of guidance relating to the risks of souvenir scans. The provider's consent form did not reference national guidelines that would allow women to make an informed decision about undergoing non-medical souvenir scans and women were not given any informative information to take away with them. The service acceptance criteria did not define women who should be excluded from receiving a scan.
- There was no mention of duty of candour in the incident reporting policy and we could not be assured that there was a full understanding of when it must be applied.
- We could not be assured that incidents were being recorded appropriately. During the inspection, one of the team was involved in an incident with an unsafe chair and this was not reported in the accident book or recorded as an incident.
- The service did not ensure that all staff remained competent for their roles by maintaining up to date employee records.
- There was no routine contact with GPs or acute trusts as part of the woman's care when possible anomalies or concerns were detected.
- Staff had not received training in the Mental Capacity Act to deal with people who lacked mental capacity.
- Information was not provided in a range of accessible formats in line with accessible information standards.
- The service did not routinely take account of people's individual needs.
- We could not be assured that people who used the service knew how to make a complaint as there was no information in the clinic about this and the policy was not on the website at the time of our inspection.
- The CQC registered manager monitored customer feedback and carried out audits.
- The service did not have systems or procedures in place to ensure that its policies were up to date, regularly reviewed and referenced current guidelines.
- There was a risk that the clinic was keeping patient information longer than necessary.

However:

- The service controlled infection risk and kept equipment and the premises clean.
- The service had suitable premises and equipment and mainly looked after them well.
- Staff kept records of patient care and these were kept securely.
- Managers monitored the effectiveness of care and used the findings to improve them.
- Staff cared for people who used the service with compassion. Feedback from people who used the service confirmed that staff treated them well and with kindness.

Summary of findings

- We saw that staff provided emotional support to people who used the service to minimise their distress.
- Staff involved people who used the service and those close to them in decisions about their care.
- The service planned and provided services in a way that met the needs of local people.
- People could access the service when they needed it.
- The clinic had a vision for what it wanted to achieve.
- Managers promoted a positive culture that supported and valued staff.
- The service had systems in place to identify risks and coping with both the expected and unexpected.
- The service collected, analysed and used information to support its activities.
- The service engaged well with people who used the service and staff to plan and manage the service and collaborated with partner organisations. Customer satisfaction remained high.
- The clinic used customer feedback to improve the service and introduced new keepsakes or gender reveal ideas as they came onto the market.

Following this inspection, we told the provider that it must take some actions to comply with the regulations and that it should make other improvements, even though a regulation had not been breached, to help the service improve. We also issued the provider with two requirement notices. Details are at the end of the report.

Ann Ford

Interim Deputy Chief Inspector of Hospitals (North)

Summary of findings

Our judgements about each of the main services

Service	Rating	Summary of each main service
Diagnostic imaging	Requires improvement 	We rated this service as requires improvement because it did not ensure that its staff were sufficiently trained in key skills and knowledge. It also did not have effective governance systems in place to ensure that comprehensive policies and procedures were in place and staff records were up to date. However, we found that the clinic services were effective, and that it was caring and responsive.

Summary of findings

Contents

Requires improvement

Bradley Street (the clinic location)

Services we looked at
Diagnostic imaging

Summary of this inspection

Background to Bradley Street

Bradley Street (the clinic location) is operated by Betsy Blossom Limited T/A Lollipop 4D Baby Scans. The service opened in August 2014. It is a private facility in Manchester, Greater Manchester. The service primarily serves the communities of Greater Manchester. It also accepts service users from outside this area.

The clinic has had a registered manager in post since it opened in August 2014.

The clinic provides 2D, 3D and 4D scanning, and produces keepsakes including DVDs, photographs and heartbeat bears. It carries out approximately 350 scans per month.

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 Judith Connor, Head of Hospital Inspection.

Information about Bradley Street

The service has one ultrasound scanning room and is registered to provide the following regulated activities:

- Diagnostic and screening procedures.

During the inspection we viewed all parts of the clinic, including the waiting area, scanning room, kitchen and toilet facilities. We spoke with three staff including the manager (an ultrasound technician) and two reception staff. We spoke with three people who used the service and two relatives. We also reviewed policies and procedures, appointment records, customer feedback reviews and one adverse outcome form.

There were no special reviews or investigations of the service ongoing by the CQC at any time during the 12 months before this inspection. The clinic had not previously been inspected.

Activity (February 2018 to January 2019)

- In the reporting period February 2018 to January 2019 There were approximately 4000 scans completed by the clinic, all of which were privately funded.

One sonographer, one ultrasound technician (the clinic manager) and two receptionists worked at the clinic. The registered manager provided additional support.

Track record on safety:

- No “never events”
- No clinical incidents or serious incidents
- Zero incidences of hospital acquired Meticillin-resistant Staphylococcus aureus (MRSA),
- Zero incidences of hospital acquired Meticillin-sensitive staphylococcus aureus (MSSA)
- Zero incidences of hospital acquired Clostridium difficile (c.diff)
- Zero incidences of hospital acquired E-Coli
- One complaint.

Services provided at the provider under service level agreement:

- Maintenance of the ultrasound equipment.
- Social media advertising.

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?

Requires improvement

We rated it as **Requires improvement** because:

- We were not assured that the service provided mandatory training in key skills to all staff and made sure that everyone completed it.
- Staff had received training on how to recognise and report abuse, but we were not assured that there were effective systems and processes in place to support them to apply it. The safeguarding policy was lacking in detail that would enable staff to know what types of abuse should be reported, how to report it and who to.
- The service did not assess and respond to patient risk well and did not inform women of guidance relating to the risks of souvenir scans. The provider's consent form did not reference national guidelines that would allow women to make an informed decision about undergoing non-medical souvenir scans and women were not given any informative information to take away with them. The service acceptance criteria did not define women who should be excluded from receiving a scan.
- There was no mention of duty of candour in the incident reporting policy and we could not be assured that there was a full understanding of when it must be applied.
- We could not be assured that incidents were being recorded appropriately. During the inspection, one of the team was involved in an incident with an unsafe chair and this was not reported in the accident book or recorded as an incident.

However:

- The service controlled infection risk and kept equipment and the premises clean.
- The service had suitable premises and equipment and mainly looked after them well.
- The clinic had enough staff to provide the right care and treatment.
- Staff kept records of patient care and these were kept securely.

Are services effective?

Not sufficient evidence to rate

We inspected but did not rate the Effective domain as we do not collect enough information to rate. During our inspection we saw:

- The service did not ensure that all staff remained competent for their roles by maintaining up to date employee records.

Summary of this inspection

- There was no routine contact with GPs or acute trusts as part of the woman's care when possible anomalies or concerns were detected.
- Consent forms did not provide information to allow women to make a fully informed decision on receiving a scan for souvenir purposes.
- Staff had not received training in the Mental Capacity Act to deal with people who lacked mental capacity.

However:

- The clinic provided evidence-based care and treatment.
- Managers monitored the effectiveness of care and used the findings to improve them.

Are services caring?

Good

- Staff cared for people who used the service with compassion. Feedback from people who used the service confirmed that staff treated them well and with kindness.
- We saw that staff provided emotional support to people who used the service to minimise their distress.
- Staff involved people who used the service and those close to them in decisions about their care.

Are services responsive?

Requires improvement

We rated it as **Requires improvement** because:

- Information was not provided in a range of accessible formats in line with accessible information standards.
- The service did not routinely take account of people's individual needs.
- We could not be assured that people who used the service knew how to make a complaint as there was no information in the clinic about this and the policy was not on the website at the time of our inspection.

However:

- The service planned and provided services in a way that met the needs of local people.
- People could access the service when they needed it.
- The service had a policy in place for dealing with complaints and concerns.

Are services well-led?

Requires improvement

We rated it as **Requires improvement** because:

Summary of this inspection

- The service did not have systems or procedures in place to ensure that its policies were up to date, regularly reviewed and referenced current guidelines.
- There was a risk that the clinic was keeping patient information longer than necessary.

However:

- The clinic had a vision for what it wanted to achieve.
- Managers promoted a positive culture that supported and valued staff.
- The service had systems in place to identify risks and coping with both the expected and unexpected.
- The service collected, analysed and used information to support its activities.
- The service engaged well with people who used the service and staff to plan and manage the service and collaborated with partner organisations. Customer satisfaction remained high.
- The clinic used customer feedback to improve the service and introduced new keepsakes or gender reveal ideas as they came onto the market.

Detailed findings from this inspection

Mental Health Act responsibilities

Start here...

Mental Capacity Act and Deprivation of Liberty Safeguards

Start here...

Overview of ratings

Our ratings for this location are:

	Safe	Effective	Caring	Responsive	Well-led	Overall
Diagnostic imaging	Requires improvement	N/A	Good	Requires improvement	Requires improvement	Requires improvement
Overall	Requires improvement	Not rated	Good	Requires improvement	Requires improvement	Requires improvement

Notes

Requires improvement

Diagnostic imaging

Safe	Requires improvement
Effective	
Caring	Good
Responsive	Requires improvement
Well-led	Requires improvement

Are diagnostic imaging services safe?

Requires improvement

We rated it as **requires improvement.**

Mandatory training

- We were not assured that the service provided mandatory training in key skills to all staff and made sure that everyone completed it. There was no evidence that any staff had received up to date training in basic life support, infection prevention and control or manual handling.
- There was a staff file which contained records supplied by the sonographer about their mandatory training undertaken at a local acute NHS trust. This training included such courses as basic life support training, fire safety, manual handling, information governance, infection prevention control, equality and diversity and mental capacity act. However, most of the courses were shown to have expired three years previously and no evidence of up to date mandatory training had been sought on an annual basis.
- Since our inspection, the clinic manager had sought evidence of up to date mandatory training from the sonographer in their substantive post and this was provided to us. It included equality, diversity and human rights; health, safety and welfare and infection prevention and control.
- The receptionists told us that they had received training in fire safety though we did not see evidence of this.
- Staff were required to sign a confidentiality notice, agreeing not to reveal the details of any people who used the service. However, staff had not received any information governance or data protection training.

Safeguarding

- Staff had received training on how to recognise and report abuse but we were not assured that there were effective systems and processes in place to support them to apply it.
- All staff had undertaken an online safeguarding course from an external company in January or February 2019.The manager told us that this was approved by the Royal Society for the Prevention of Accidents and that it covered safeguarding of adults and children. However, staff were unable to describe to what level they were trained. The provider did not know what level of training the staff needed and had not benchmarked either adult or children's safeguarding against the intercollegiate document. The clinic manager had the name of a safeguarding contact at the local authority though it was not clear whether this had been disseminated to the rest of the staff as a named contact.
- The training had not covered female genital mutilation, child sexual exploitation or the government PREVENT strategy to protect vulnerable people from the threat of terrorism and radicalisation.
- The clinic had a policy about care of vulnerable adults but this only included advising staff to call the police if there was immediate danger or to otherwise raise the

issue with a manager. The policy did not reference up to date guidance, including Safeguarding children and young adults: roles and competencies for health care staff – Intercollegiate Document – 2019).

- It did not describe the different types of abuse for children and adults and did not give details of the local authority safeguarding team where referrals should be made. The policy also did not cover child sexual exploitation or female genital mutilation where it is the sonographer's duty to report any suspicions rather than the provider.
- Since our inspection, the manager had drafted a new safeguarding policy, but this did not set out the different forms of abuse that may be identified and did not give the contact details for the local authority safeguarding team.
- We saw evidence that disclosure and barring service checks had been undertaken for staff currently working in the clinic.
- The clinic did not display any information in the waiting area or ultrasound room about safeguarding from abuse or how to report allegations of abuse.

Cleanliness, infection control and hygiene

- The service controlled infection risk and kept equipment and the premises clean. They used control measures to prevent the spread of any infection.
- All staff were responsible for cleaning the premises. There was a cleaning schedule for the toilet that was up to date but none for the rest of the premises. The manager introduced a cleaning schedule for the whole premises during our inspection.
- The premises were visibly clean and tidy. Chairs at the reception desk and in the ultrasound room were wipeable, although they were not wipeable in the waiting room.
- The ultrasound room was visibly clean. We saw that the ultrasound probe was cleaned with antiseptic wipes between each client and the manager signed the appointment list by the name of the client to indicate that the probe had been cleaned before the next client was scanned.
- The manager used hand gel before scanning a client and wore gloves. There was no hand washing sink in the ultrasound room.
- Blue roll was used on the ultrasound couch and was disposed of between clients.
- Clinical waste bags were not in use in the service and the manager told us that they did not produce any clinical waste.

Environment and equipment

- The service had suitable premises and equipment and mainly looked after them well.
- The premises were large enough to accommodate the business with an ultrasound room, reception and waiting area. There was also a staff room which contained drink-making facilities and also doubled as a storage area for confetti balloons and cannons, cleaning equipment and the printer.
- The waiting area was large enough for five or six family members to wait with the woman having a scan and there was an additional couch in the lobby area. However, there was a chair behind the reception desk that was defective and had not been removed or labelled as defective.
- The ultrasound machine had been purchased in mid-2018.The manager told us that relevant staff had been trained to use the machine although there were no training records available for us to look at. The machine was due to be serviced annually by a third-party company. There were no maintenance records held yet.
- The manager told us that they had access to a replacement machine if the main machine broke down and this could be obtained within an hour.
- There was a backup photo printer available in the premises.
- There was a first aid kit held in the stock room and staff knew where to find this. Items that we checked were in date.
- The provider had an accident book to record any incidents and accidents, although this had not been used and was still sealed.

Assessing and responding to patient risk

Requires improvement

Diagnostic imaging

- The clinic did not offer diagnostic imaging services. The consent form stated that the scans were for entertainment only, not for diagnostic purposes and did not provide antenatal care or medical advice.
- The consent form referred women to the British Medical Ultrasound Society if they wanted to find out more information about ultrasound scanning. However, it did not reference the Public Health England guidelines on ultrasound (What it is, how it works and the impact of exposure).These guidelines allow women to make an informed decision about undergoing souvenir scans by detailing any known risks, however small with frequent scanning. There was no reference to the Public Health England guidance or British Medical Ultrasound Society guidelines on the clinic website.
- Women were not given a copy of their consent form or any other informative information to take away with them.
- Women were asked to bring their medical notes to their scan so that their identity could be checked and the number of weeks they were pregnant.
- The clinic had a clinical admission/acceptance criteria document. However, this only documented that bookings could be made via Facebook, Instagram, email and telephone with a £20 deposit taken to secure the booking. They ensured the customer was aware that they were booking an entertainment scan, were aware of the British Medical Ultrasound guidelines and were asked to sign a consent form to confirm this. The acceptance criteria did not define women who would be excluded from receiving a scan, for example, based on age, known abnormalities or problems with the pregnancy, or number of weeks pregnant.
- Women were not asked how many scans they had had previously had during their pregnancy to allow the clinic to advise them of available guidelines and making informed decisions.
- The manager told us that they did not perform scans on anyone under 18 years of age. However, the clinic had a consent form for under 18-year olds that asked for a relative to sign consent on behalf of the customer. We did not hear the age of the woman wanting the scan being asked for when scans were booked by telephone.
- The clinic had an adverse outcome procedure in the rare event that a foetal abnormality or other concerns such as no heartbeat were suspected. In such an event, an “adverse outcome form” was completed by the person conducting the scan. A copy was given to the woman and an explanation that they should attend an early pregnancy unit at the earliest opportunity for further obstetric checks to be completed.
- We were shown a completed adverse outcome form and this contained full information about the concerns of the sonographer.
- In the event of a medical emergency happening at the premises we were told that staff would call for an ambulance. The clinic had guidance on how to perform cardiopulmonary resuscitation on children and adults.
- Despite the clinic advertising itself as a keepsake service only (rather than diagnostic), the website described the eight benefits of 4D ultrasounds during pregnancy, one of which was the early detection of pregnancy issues, abnormalities or malformations. This could lead to false reassurance in women if the clinic did not detect any issues.

Staffing

- The clinic had enough staff to provide the right care and treatment.
- The clinic did not employ any agency staff. Reception staff and the manager were directly employed. The two reception staff were both recently employed by the clinic and were covering maternity leave for two permanently employed receptionists.Both worked for three days a week.
- The manager was employed as an ultrasound technician and worked for the four days a week that the clinic was open.

Requires improvement

Diagnostic imaging

- The sonographer worked on a self-employed basis and invoiced for their time. They generally worked in the clinic for two days a week. They held a substantive position as a diagnostic radiographer in a local NHS acute trust.
- The manager (ultrasound technician) only carried out scans on women who were more than 15 weeks pregnant whilst the sonographer would also carry out early pregnancy scans on women from seven weeks pregnant. Early pregnancy scans were booked in on a day that the sonographer was working.
- The manager told us that they had used two other sonographers for ad hoc shifts at the clinic who worked with the main sonographer in the acute trust, however, there were no references or qualifications for these people on the staffing file.The manager said that they had not done any work in the clinic for some time.
- The clinic was staffed by at least two people whenever open to avoid any lone working.
- The clinic had a document relating to how staffing levels are determined. This stated that the needs of the customer should be met so that phone calls, emails and messages were responded to in a timely manner, everyone was greeted quickly when they arrived and that they received their photographs and keepsakes as quickly as possible after their scan.
- The clinic had a staff handbook that was available to all staff and covered all aspects of human resources relating to their role, including employment terms and conditions, data protection, equality and diversity, dignity at work, training and development and fire safety.

Records

- Staff kept records of patient care and these were kept securely.
- Consent forms were kept in a secure storage file. No records of appointment details were kept on computer.
- The images and records held on the ultrasound scanning machine were wiped after approximately two months.
- The clinic obtained consent to share information about any adverse findings with the woman's GP.
- The clinic took consent for women to share their details with a third party photographer where they could receive a free photo shoot. Details of people who used the service who had consented to this were added to a secure spreadsheet that was sent to the photographer by zip file.
- Appointments made by people who used the service were recorded on a daily sheet in an appointment file. Details recorded were the customer name, how many weeks pregnant, their telephone number and whether a deposit had been paid.

Incidents

- The clinic had not reported any incidents or near misses since it opened in 2014 so we could not conclude whether it managed safety incidents well.
- We could not be assured that incidents were being recorded appropriately. During the inspection, one of the team was involved in an incident with an unsafe chair and this was not reported in the accident book or recorded as an incident.
- The service did have an incident reporting policy that stated that all incidents involving staff, people who used the service, guests of people who used the service and anyone else who entered the building must be informed immediately to the manager and an incident report form completed. The policy did not set out how incidents would be investigated or within what time frame and how lessons would be learned from incidents.
- There was no mention of duty of candour in the incident reporting policy. 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) as soon as reasonably practicable, of 'notifiable safety incidents' and provide reasonable support to that person and offer an apology.
- The manager told us that they were aware of duty of candour and they had spoken to staff about it but we could not be assured that there was a full understanding of when it must be applied.

Diagnostic imaging

- The manager told us that if an incident occurred they would have a meeting and put things in place to ensure that it did not happen again.
- The clinic had a major incident policy for guidance on how to maintain business continuity in the aftermath of an emergency or major incident. The policy did not define what a major incident may be or how business continuity may be maintained. However, it stated that management must be notified and management would decide whether they could continue to see people who used the service and a major incident form would be completed.

Are diagnostic imaging services effective?

We inspected but did not rate the Effective domain as we do not collect enough information.

Evidence-based care and treatment

- The service provided care based on national guidance and referred people who used the service to the British Medical Ultrasound Society (Guidelines for Professional Ultrasound Practice) for further information on ultrasound. These guidelines state that scans in pregnancy should not be carried out for the sole purpose of producing souvenir videos or photographs.
- The manager was unaware of Public Health England guidelines on ultrasound scanning and the impact of exposure and people who used the service had not been signposted to this to inform their decision as to whether to receive an ultrasound scan.

Nutrition and hydration

- The clinic could provide water to drink for women attending for a scan.
- The service advised women to attend with a full bladder when they telephoned to make an appointment. This advice was also given on the clinic website.
- For those receiving a gender scan, people who used the service were also advised to eat before attending their scan so that the baby was active.

Patient outcomes

- Managers monitored the effectiveness of care and used the findings to improve them.
- The clinic sent an email to as many people who used the service as possible to receive feedback on their experience. They were asked to provide data on how many weeks pregnant they were, whether they had used the service before, service received from the receptionist and sonographer and their overall experience.
- The registered manager collated comments received via the website and Facebook page Comments received from July 2018 to January 2019 were predominantly positive feedback.
- The service had carried out audits each month during 2018.These audits covered waiting times; image quality satisfaction; complaints received and incorrect genders identified.
- Audits on waiting times showed the percentage of women who waited for more than five minutes after their original appointment times. These showed that between 0 and 10% of women waited more than five minutes past their appointment times during 2018.
- Image quality satisfaction was 100% for seven months during 2018 and the lowest satisfaction rate was 97% in November 2018.
- There was one instance of incorrect gender identification during 2018.

Competent staff

- The service did not ensure that all staff remained competent for their roles by maintaining up to date employee records.
- The clinic had a formal induction training for reception staff to undertake all aspects of their job but there was no timescale on the document by which time all the aspects had to be taught and achieved. The training did not include any mandatory training.
- We saw evidence that the receptionists who were on maternity leave had received an appraisal in 2018.The two receptionists who were covering maternity leave for the two substantive receptionists had not been employed long enough to receive an appraisal.

Requires improvement

Diagnostic imaging

- We saw the staff file for employees. The sonographer's file held their NHS mandatory training, disclosure and barring service checks and British Medical Ultrasound registration. All were out of date and had not been updated on an annual basis.
- The ultrasound technician (clinic manager) told us that they had received their training by arranging for a trainer to come from America for a one-week training course for her to become an ultrasound technician. However, she was unable to provide us with a certificate to show that she had received any qualification following the one-week training course.
- There were no equipment training records available for the new ultrasound machine for either the ultrasound technician (clinic manager) or sonographer who were the two staff who operated the machine.

Multidisciplinary working

- There was no routine contact with GPs or acute trusts as part of the woman's care when possible anomalies or concerns were detected. If there were possible anomalies or concerns the customer was given a report to pass on to the customer's early pregnancy unit.

Seven-day services

- The service was open for four days a week on a Wednesday, Friday, Saturday and Sunday from around 10am to around 8pm.

Consent and Mental Capacity Act

- The clinic had a consent form but this did not highlight information produced by Public Health England to inform women about making an informed decision on receiving a scan based on national guidance.
- People who used the service were handed a consent form to read and sign as soon as they checked in. The consent form was not available in other languages. The sonographer was not involved in taking consent from a customer.
- No staff had received training in the Mental Capacity Act to deal with people who lacked mental capacity.
- People who used the service who purchased a confetti cannon were given information about using it safely and asked to sign a consent form to say that they understood that it contained explosives and would be fired in accordance with the recommended safety instructions.

Are diagnostic imaging services caring?

Good

We rated it as **good.**

Compassionate care

- Staff cared for people who used the service with compassion. Feedback from people who used the service confirmed that staff treated them well and with kindness.
- Ultrasounds were carried out in a separate room. It was not possible to hear general conversation from the room.
- We observed staff providing compassionate care. They spoke to women and their families in a friendly manner.
- We reviewed feedback from many people who use the service. Women were positive about the service they had received.

Emotional support

- We saw that staff provided emotional support to people who used the service to minimise their distress.
- The manager told us that, if a potential concern was detected during the scan, then this was fully explained to the woman who was kept in the scanning room whilst the form was completed for them to take to an early pregnancy unit. When the woman was ready they would be escorted to the door.
- We saw that scans were not rushed and that if good images could not be obtained the woman was advised to go for a walk and then come back for a further attempt. Free rescans were offered where images could not be obtained or the gender of the baby could not be seen.

Understanding and involvement of patients and those close to them

Requires improvement

Diagnostic imaging

- Staff involved people who used the service and those close to them in decisions about their care.
- People who used the service were given full information on the cost of their scan, packages available and the cost of added extras, such as confetti cannons or balloons.
- The clinic website showed the scan packages that were available along with the cost so people who used the service could make a choice about what they wanted. People who used the service were able to choose the photographs they received from all the available computerised images. People who used the service were able to change their mind about the package they received and pay the balance outstanding.
- We observed that information was given to women phoning to book an appointment about the best time to have the scan based on the number of weeks pregnant and appointments were made during the optimum window when the best images were likely to be obtained.

Are diagnostic imaging services responsive?

Requires improvement

We rated it as **requires improvement.**

Service delivery to meet the needs of local people

- The service planned and provided services in a way that met the needs of local people.
- The clinic was located in Manchester city centre and was easily accessible by public transport and by car. It was located within walking distance of two major train stations and tram stops.
- The waiting area had comfortable and sufficient seating for women and their families and friends. There was a toilet available for customer and staff use that was regularly cleaned.
- The service was flexible and offered appointments up to 8pm and at weekends. Women were advised if they wanted to book an appointment outside the optimum time to obtain good images, for example, if they were more than 30 weeks pregnant.
- The service did not have any information leaflets but information about the different types of scans (2D,3D or 4D) was on the clinic website.
- Information was not provided in a range of accessible formats. Information about the scans was only available on the website and appointments could only be booked by telephone. If the service received an email enquiry the enquirer was telephoned to book the appointment and deposits were taken over the telephone.

Meeting people's individual needs

- The service did not routinely take account of people's individual needs.
- The clinic was wheelchair accessible. The clinic did not routinely ask women whether they had any disabilities or additional needs that may affect their ability to receive an ultrasound scan. The clinic manager told us that they had never had a customer who was a wheelchair user.
- The clinic did not have access to an interpreter service for those people who used the service that did not speak English as a first language or who were deaf. The manager told us that they had never had a non-English speaking customer.
- Information was not available in any other language than English and there was nothing available in an easy-read format.
- Staff had not received any disability awareness or Equality Act training. The clinic did not have a policy in place around making reasonable adjustments for people with a protected characteristic, for example, people with a learning disability or autism.
- The service made appointments sufficiently long enough for women and their families to ask any questions and to complete the consent form before their scan. They were advised to turn up 15 minutes before their appointment time to avoid any delays.

Access and flow

Requires improvement

Diagnostic imaging

- People could access the service when they needed it.
- Women were offered a choice of appointment times and dates. People who used the service paid a non-refundable deposit and this reduced the number of women who did not turn up for their appointment.
- We saw that gaps were left in the appointment schedule and this allowed for women to return for a re-scan if images could not be obtained at the first attempt without delaying other appointments.
- Women did not wait a long time for their scan after arrival, five to ten minutes. They were able to choose scan images as keepsakes immediately after they returned to the waiting area. Gender reveal balloons or cannons were prepared by reception staff whilst they were still in the scanning room.
- The clinic audited the number of women who waited more than five minutes after their appointment time to be seen and the results showed that delays to appointments were low.

Learning from complaints and concerns

- The service had a policy in place for dealing with complaints and concerns but we could not be assured that people who used the service knew how to make a complaint.
- The clinic tried to resolve complaints quickly and informally wherever possible. In the last 12 months they had only received one formal complaint.
- The clinic had a complaints policy which was added to the website following our inspection.
- There were no feedback or complaints leaflets in the clinic.
- The complaints policy stated that complaints would be acknowledged within a week and should receive a definitive written reply within four weeks.
- When we reviewed the complaints policy we saw that it stated that after a stage two investigation the decision taken was final unless the director decided that it was appropriate to seek assistance from the British Medical Ultrasound Society.The policy made no mention of signposting complainants to the Independent Sector Complaints Adjudication Service (ISCAS) for an independent review of the complaint.
- The service maintained a summary of previous complaints and feedback and actions taken in response. For example, they had loosened the policy on rescans to allow two free rescans if they felt that this would be beneficial. They had responded to customer feedback about difficulties in finding the clinic by purchasing signage that was placed at the end of the street. In response to an incorrect gender scan, the customer was refunded the cost of the scan and offered a free bonding scan.

Are diagnostic imaging services well-led?

Requires improvement

We rated it as **requires improvement.**

Leadership

- The manager was in the clinic when it was open and scanned women for gender scans and baby bonding scans.
- Reception staff told us that they were happy to approach the manager with any concerns and that it was a good place to work.
- The manager told us that they had been trained to be an ultrasound technician and kept up to date with British Medical Ultrasound Society guidance.
- The CQC registered manager monitored customer feedback and carried out audits.

Vision and strategy

- The clinic had a vision for what it wanted to achieve.
- The service had a business plan that set out what it wanted to achieve and described its strengths, weaknesses, opportunities and threats. The plan forecast that they would provide 300 scans a month and offer unique products such as heartbeat bears in 2018.
- The business plan did not include feedback from people who used the service to shape the service.
- The service also had an annual strategy report for 2019 which outlined objectives for 2019 and looked back at what was achieved in 2018.

- The strategy outlined that they had invested in a new ultrasound machine in 2018 to produce high quality images. The goals for 2019 were to provide over 350 scans per month; invest in further technology to enable sending images direct to the customer; evolving the current site or opening a new branch and improving social media ratings.

Culture

- Managers promoted a positive culture that supported and valued staff.
- Staff told us that they enjoyed working there and one staff member said it was the best place she had worked.
- The reception staff had not worked there long as they were covering maternity leave but they appeared to have settled in well in a short space of time and were confident in their roles.
- The service strategy set out the commitment of the service to put the customer first.

Governance

- The service did not have systems or procedures in place to ensure that its policies were up to date, regularly reviewed and referenced current guidelines.
- Policies and procedures were lacking in detail and did not have the date they were written, dates reviewed and amendments made. We were not assured that policies and procedures had been in place since the business had begun operating in 2014.
- Staff had not received a number of mandatory training courses that we would expect to see in an independent provider, such as, information governance, manual handling and infection prevention.
- No-one in the service had received safeguarding training at level three and there were no clear pathways for staff to be able to make a safeguarding referral to the local authority.
- The staff file for the sonographer was not up to date, certificates to demonstrate mandatory training undertaken and registration had expired.
- The service had a guidance document for dealing with third party providers that stated that the clinic managers would assess and review the due diligence of any third party suppliers and risk assess each business. Third party suppliers were stated to be the building landlords, machine suppliers, newborn photographers and stock suppliers.
- The service held team meetings when necessary and we saw brief minutes of one such meeting.

Managing risks, issues and performance

- The service had systems in place to identify risks and coping with both the expected and unexpected.
- The clinic had a risk register that described the risk, gave each risk a probability and impact rating and the owner of each risk. The register did not detail what further action was necessary to reduce the risk and a review date for each risk.
- There was a risk management policy in place that set out four steps for risk management, these being, identify the risk; analyse and evaluate the risk; treat the risk and monitor and review the risk. It was the responsibility of the managers to carry out these steps.
- The risks present on the risk register were whether a new ultrasound machine supplier would visit the site within 24 hours if the machine broke down; receptionist and sonographer sickness; bad weather; abusive customers and a broken printer.
- The manager told us that staff knew how to raise a risk.

Managing information

- The service collected, analysed and used information to support its activities but there was risk that the clinic was keeping patient information longer than necessary.
- We were told that the images stored on the ultrasound scanner were wiped off after around two months but the manager could not give exact timescales that they were stored for but believed that they were deleted automatically.
- The customer consent forms and daily appointment lists were stored in secure boxes. The manager told us that no patient identifiable information was stored on the clinic computer.

Requires improvement

Diagnostic imaging

- The clinic had a records policy but this made no mention of retention timescales and disposal of paper records and patient sensitive information. This presented a risk that patient information was being kept for longer than is necessary.
- The service did not send marketing emails or texts to people who used the service.
- Full terms and conditions of the services and price packages were clearly defined on the company website.

Engagement

- The service engaged well with people who used the service and staff to plan and manage the service and collaborated with partner organisations.
- The service sought feedback from people who used the service via surveys or on social media. Feedback was predominantly positive and we noted that many of the women who attended for a gender scan booked a further appointment for a baby bonding scan further into their pregnancy.
- The service collaborated with a local photographer who offered a free photo session for people who used the service.
- People who used the service were encouraged to upload videos of gender reveals onto the clinic Facebook page.

Learning, continuous improvement and innovation

- The clinic used customer feedback to improve the service and introduced new keepsakes or gender reveal ideas as they came onto the market.
- The clinic had invested in high quality scanning equipment to ensure that they were competitive in the market and customer satisfaction remained high.

Outstanding practice and areas for improvement

Areas for improvement

Action the provider MUST take to improve

- The provider must ensure that at least one member of staff was appropriately trained to level three in safeguarding, that takes account of current guidelines, and that staff have access to documentation about types of abuse and appropriate escalation pathways for safeguarding concerns.
- The provider must ensure that qualified staff employed by them have the qualifications, competence, skills and experience which are necessary for the work to be performed by them and that these are checked on an annual basis.
- The provider must take action to address a number of concerns identified during the inspection in relation to the governance of the service, including policies being regularly reviewed and referencing current guidelines, staff receiving appropriate mandatory training and staff records being kept up to date.

Action the provider SHOULD take to improve

- The provider should ensure that appropriate mandatory training modules are identified, that staff complete them and understand them.
- The provider should ensure that women using the service are informed of Public Health England Guidelines on souvenir ultrasound scans.
- The provider should ensure that acceptance criteria defined women who were excluded from receiving a scan.
- The provider should ensure that the information on the website around the benefits of 4D ultrasounds does not lead to the false reassurance in women if the clinic did not detect any issues.
- The manager should ensure that they keep records or their own training in ultrasound and that these are available for inspection.
- The provider should consider involving other healthcare professions in the care of the women using the service by liaising with their GP or early pregnancy unit when possible anomalies were detected during an ultrasound scan.
- The provider should consider training staff in the Mental Capacity Act.
- The provider should have access to an interpreter service to assist those people who used the service whose first language was not English and to ensure that they have understood the consent form.
- The provider should consider offering disability awareness and Equality Act training to staff and having a policy in place around making reasonable adjustments for people with a protected characteristic.
- The provider should consider displaying information on how to give feedback or complain in the clinic for those people without access to the clinic website.
- The provider should consider carrying out a risk assessment on the length of time that images are kept for and producing a policy on the storage and destruction of customer information.

This section is primarily information for the provider

Requirement notices

Action we have told the provider to take

The table below shows the legal requirements that were not being met. The provider must send CQC a report that says what action they are going to take to meet these requirements.

Regulated activity	Regulation
Diagnostic and screening procedures	Regulation 13 HSCA (RA) Regulations 2014 Safeguarding service users from abuse and improper treatment Service users must be protected from abuse and improper treatment in accordance with this regulation. Systems and processes must be established and operated effectively to prevent abuse of service users. Systems and processes must be established and operated effectively to investigate, immediately upon becoming aware of, any allegation or evidence of such abuse. Regulation 13(1)(2)(3)

Regulated activity	Regulation
Diagnostic and screening procedures	Regulation 18 HSCA (RA) Regulations 2014 Staffing The provider must ensure that persons employed by the service provider in the provision of a regulated activity must receive such appropriate support, training, professional development, supervision and appraisal as is necessary to enable them to carry out the duties they are employed to do. Regulation 18(1)(2)(a)

Regulated activity	Regulation

This section is primarily information for the provider

Requirement notices

Diagnostic and screening procedures

Regulation 17 HSCA (RA) Regulations 2014 Good governance

Systems and processes must be established and operated effectively to ensure the requirements of this part.

Maintain securely such other records as are necessary to be kept in relation to persons employed in the carrying on of the regulated activity and the management of the regulated activity.

Regulation 17(1)(2)(d)(i)(ii)