Baby Ultrasound Clinic Macclesfield

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?	Good
Are services well-led?	Requires improvement

Overall summary

Baby Ultrasound Clinic Macclesfield (The clinic) is operated by Baby Ultrasound Clinic Limited. The Clinic provides self-elected, privately funded pregnancy scans including 2D, 3D and 4D keepsake scans and gender scans. All scans are abdominal. The Clinic does not provide diagnostic scans. The Clinic had a scanning room, a waiting/reception area, a kitchen and a toilet. There is also another room available for staff to talk to woman and their families if necessary.

The clinic is based in Macclesfield, and there are three other locations in the North of England.

Summary of findings

The clinic provides baby keepsake scans to women. It employed a sonographer and a receptionist at the location, and a manager spent time at the clinic and as well as its three other locations.

We inspected this service using our comprehensive inspection methodology. We carried out the inspection on 12 December 2018. The inspection was unannounced.

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.

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

Services we rate

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

- We were not assured that the clinic provided mandatory training to staff or that staff were fully engaged with it.
- The clinic did not ensure that staff received appropriate safeguarding training.
- The clinic did not always control infection risk well.
- The clinic had suitable equipment but its premises were not always looked after.
- The clinic did not store patient records securely.
- It was not clear that staff had had appropriate training in the Mental Capacity Act.
- The clinic did not always plan and provide a service that met the needs of local people.
- The clinic did not consistently take account of individual needs.
- The clinic did not operate effective systems or processes to ensure that it kept service users' records secure.
- Not all the clinic's policies referenced up to date guidelines.

However, we found that:

- The clinic completed risk assessments for each patient.
- The clinic had a comprehensive incident reporting policy and procedure.
- The clinic provided evidence-based care and treatment.
- Managers monitored the effectiveness of its services.
- Staff were competent for their roles.
- The clinic consent form was appropriate.
- The clinic provided compassionate care, emotional support and involved patients and those close to them in decisions about their care.
- People could access the service when they needed it.
- The clinic investigated complaints and learned lessons from them.
- The manager had the right skills and experience to run the service.
- The clinic had a vision for what it wanted to achieve.
- There was a positive culture in the organisation.
- The clinic had systems to identify risk and reduce them.
- The service engaged with customers effectively and used patient surveys to improve.

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 notice(s). Details are at the end of the report.

Ellen Armistead

Deputy Chief Inspector of Hospitals (North Region)

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 to protect service users from abuse or harm. It also did not have effective governance systems in place to ensure that patient records were secure. However, we found that the clinic services were effective, and that it was caring and responsive.

Summary of findings

Contents

Requires improvement

Baby Ultrasound Clinic Macclesfield

Services we looked at
Diagnostic imaging

Summary of this inspection

Background to Baby Ultrasound Clinic Macclesfield

Baby Ultrasound Clinic Macclesfield is a private clinic operated by Baby Ultrasound Clinic Limited. The clinic opened in January 2018 and is based in Macclesfield, Cheshire. It serves the local population but will also accept customers from outside the area. There are two other established clinics in Huddersfield and Bolton, and another clinic is due to open in Chester.

The clinic provides 2D, 3D and 4D scanning, and produces keepsakes including DVDs, photographs and key rings. It carries out approximately 40 to 50 scans per month.

The location is open two days a week: Wednesday (1pm to 8pm) and Saturday (11am to 7pm).

The clinic has had a registered manager in post since it opened in January 2018.

Our inspection team

The team that inspected the service comprised a CQC lead inspector, and a second CQC inspector. The inspection team was overseen by Nicholas Smith, Head of Hospital Inspection.

Information about Baby Ultrasound Clinic Macclesfield

The clinic had one ultrasound machine 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, second consultation room, kitchen and toilet facilities. We spoke with two staff including the registered manager and a sonographer. We observed one ultrasound scan and reviewed 20 customer feedback surveys completed by the clinic.

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

Activity (January 2018 to October 2018)

- In the reporting period January 2018 to October 2018 there were 504 scans completed by the clinic, all of which were privately funded.

One receptionist and one sonographer worked at the clinic, with the registered manager providing additional support when necessary.

Track record on safety:

- No never events
- No clinical incidents or serious injuries
- 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
- Four complaints

Services provided at the hospital 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 clinic provided appropriate mandatory training to staff or that staff were fully engaged with training.
- The clinic did not ensure that staff received appropriate safeguarding training.
- The clinic did not always control infection risk well.
- The clinic had suitable equipment but its premises were not always looked after.

However:

- The clinic had a comprehensive incident reporting policy and procedure.

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:

- Managers monitored the effectiveness of its services.
- Staff were competent for their roles.
- The clinic consent form was appropriate.

However:

- It was not clear that staff had had appropriate training in the Mental Capacity Act.

Are services caring?

Good

We rated it as **Good** because:

- The clinic provided compassionate care, emotional support and involved patients and those close to them in decisions about their care.

Are services responsive?

Good

- People could access the service when they needed it.
- The clinic investigated complaints and learned lessons from them.

However:

- The clinic did not consistently provide a service that met the needs of local people.

Summary of this inspection

Are services well-led?

Requires improvement 

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

- The clinic did not operate effective systems or processes to ensure that it kept service users records secure.
- Not all the clinic's policies referenced up to date guidelines.

However,

- The manager had the right skills and experience to run the service.
- The clinic had a vision for what it wanted to achieve.
- There was a positive culture in the organisations.
- The clinic had systems to identify risk and reduce them.
- The service engaged with customers effectively and used patient surveys to improve.

Detailed findings from this inspection

Overview of ratings

Our ratings for this location are:

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

Requires improvement

Diagnostic imaging

Safe	Requires improvement
Effective	Not sufficient evidence to rate
Caring	Good
Responsive	Good
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.
- The clinic's training register showed that mandatory training was provided to, and completed by, all staff. Training included basic life support training, infection prevention and control, child protection, data protection, diversity, manual handling, fire safety and Mental Capacity Act training. However, of the two members of staff that worked at the clinic one staff member told us that they had not received any training in infection prevention and control or manual handling. The other member of staff was not present to speak to. Due to this discrepancy, we were not assured that either staff had received relevant mandatory training or that they fully engaged with it.

Safeguarding

- Staff did not understand how to protect patients from abuse.
- The registered manager told us she had been trained to safeguarding level three by an external company. The registered manager delivered the same training to staff.
- The clinic provided us with a copy of the training module delivered to staff. The module did not reference up to date guidance, including Safeguarding children and young adults: roles and competencies for health care staff – Intercollegiate Document – March 2014), The Care Act 2014, and the updated Working Together To Safeguard Children (July 2018). The training did not consider current safeguarding issues or how the Mental Capacity Act applied to 16 and 17 year olds.
- The clinic's safeguarding policy did not reference up to date guidance, including Safeguarding children and young adults: roles and competencies for health care staff – Intercollegiate Document – March 2014).
- A member of staff told us that they would speak to the manager if they were alerted to a safeguarding incident. However, they could not describe what a safeguarding incident was; they referred to the location of fire exits. Therefore, we were not assured that the safeguarding training provided for staff was sufficient to protect service users from abuse.
- After the inspection, the registered manager sent us a training certificate demonstrating that a member of staff had completed adult safeguarding training with an online training company. However, despite the clinic providing scans for 16 and 17 year olds, staff had not been provided with appropriate children's safeguarding training.
- We saw evidence that staff had had up to date disclosure and barring service checks.

Cleanliness, infection control and hygiene

- The clinic did not always control infection risk well.

Requires improvement

Diagnostic imaging

- The public and staff toilet did not have soap in it to wash hands. The adjacent kitchen area (which people walked through to get to the toilets) did have hand wash basin and soap, as well as a poster for hand wash techniques.
- The ultrasound room had a sink to wash hands, but no soap. We observed the sonographer putting gloves on prior to scanning a woman, but they did not wash their hands either before or after.
- The ultrasound room was visibly clean and tidy.
- We saw the sonographer cleaning the ultrasound probe with a disinfectant gel.
- The registered manager was the infection control lead for the service.
- The sonographer and receptionist were responsible for cleaning the premises. An external company would be called as required (there was no contract) to clear any spillages of bodily fluids.

Environment and equipment

- The clinic had suitable equipment, but its premises were not always looked after well.
- The weather was very cold on the day we inspected the clinic and one of two electric heaters in the waiting area did not work and had not done so for a few weeks. This could potentially make it uncomfortable for pregnant women and those accompanying them. The registered manager told us that they had reported the issue to the landlord.
- The clinic had a separate room it told us it could use if it needed to tell women about that they had concerns about the scan. However, the room seemed to be primarily used as a storage area. It contained only one chair, there were two bins bags full of paper, and assorted leaflets stacked in piles on the floor.
- We saw bleach and other cleaning liquids stored in a floor level kitchen cupboard. This was in the same area as the baby changing and toilet facilities and could be easily accessed by children. We raised this with the registered manager who immediately moved the items to a high shelf that could not be reached by children. There was no cupboard for the storage of chemicals hazardous to health.
- The toilet was clean, but a lightbulb was missing from the light fixture in the adjoining sink area.
- The ultrasound machine was visibly clean.We saw completed inspection and cleaning charts, and there was an operating manual.It was due to be serviced annually by a third party (albeit it had not yet been a year since the equipment had been installed).The same third party could provide training should staff need it.
- The reception area was large enough to allow up to six people to wait. The clinic's website stated that up to five family members or friends could accompany the woman.
- The clinic had two first aid kits. One was new and sealed. The other was open and all items within it were within their expiry date.
- The room contained gloves and ultrasound gel, both of which were in date.
- The premises had clearly marked fire exists, alarm points and extinguishers.

Assessing and responding to patient risk

- The clinic did not offer diagnostic imaging services. Its website stated that the scans were not intended to be diagnostic and did not replace routine hospital scans. Women were asked to bring their medical notes so in the rare circumstance something was picked up their doctor or midwife was contacted.
- Women were informed of the process and sonographers discussed further options. Women were provided a report to be taken to the appropriate healthcare professional as advised by the sonographer. Details for the woman's GP and or midwife were recorded and women were given the option of staff getting in touch with them.
- The consent form required women to acknowledge that the clinic did not provide my obstetric care and that the ultrasound scan was purely for personal non-medical reasons. The procedure did not replace scans with the NHS.
- If the sonographer had concerns about a scan, they could email colleagues in other clinic locations to discuss this in more detail.

Requires improvement

Diagnostic imaging

- The clinic scanned women aged 16 and over.
- The clinic informed patients that they should be at least seven weeks pregnant for a keepsake scan, and 16 weeks for a gender scan.
- The clinic had a policy for what steps to take should a customer of visitor have a medical emergency. This included attempting resuscitation where appropriate, and calling 999.
- The clinic's consent letter, and part of its website, referenced guidelines from Public Health England (previously the Health Protection Agency). It informed women that "there is no evidence to suggest that the scans are harmful in any way. However, it is vital that you are aware of the risks associated with the procedure before coming to any decision on the matter". The Clinic provided links to relevant government websites and the British Medical Ultrasound Society.
- The registered manager told us that to minimise any potential risk to women, it limited scans to 30 minutes in length and recommended that women did not have more than three keepsake scans during their pregnancy. However, this information was not included on its website and staff did not proactively talk to women about this issue. Following the inspection, the clinic showed us evidence of an updated checklist where women were asked how many scans they had had previously.
- Despite the clinic advertising itself as a keepsake service only (rather than diagnostic), we heard a member of staff tell a woman that the foetal heart rate was "normal". This would be considered making a diagnosis and may provide a false level of reassurance for women.

Staffing

- The clinic had enough staff with the right qualifications, skills, training and experience to provide the right care and treatment.
- The clinic did not use any agency staff; all staff were directly employed.
- The clinic had a lone working policy. The clinic was staffed by at least two people, including the sonographer, and/or the receptionist or manager.
- No staff had time off sick in the three months prior to the inspection.
- All new starters received a formal induction to the business which included mandatory training, shadowing and practical experience relevant to the staff member's role.
- Staff underwent health and safety training, including being aware of posture issues when using the ultrasound machine for long periods of time.

Records

- Staff kept detailed records of patient care, but these were not always stored securely.
- Staff updated details of appointments onto a computer system. This included the woman's name, time and date of scan, and what type of scan had been undertaken.
- The clinic obtained consent to share reports with women's midwives or GPs.
- We were told that paper records and reports were locked away in secure cabinets. However, we saw patient identifiable information kept in a plastic storage box within the ultrasound room. The clinic subsequently told us that the records had been moved to a secure filing cabinet.

Incidents

- The clinic had not reported any incidents since it opened in January 2018, so we could not conclude whether it managed safety incidents well. However, it did have a comprehensive incident reporting policy.
- The clinic had a Duty of Candour policy. Whilst it was not certain that staff fully understood the term, they could describe that it meant to be open and honest when things went wrong.

Are diagnostic imaging services effective?

Not sufficient evidence to rate

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

Requires improvement

Diagnostic imaging

Evidence-based care and treatment

- Staff booking appointments completed a checklist, with some of the questioned asked designed to assess the needs of the woman. Questions included the purpose of the scan, whether there was an anterior placenta (which can affect the quality of the scan), and whether it was a multiple pregnancy.
- The clinic had an up to date equality and diversity training policy.
- The service completed an annual audit. This showed that all staff had adhered to clinical procedures and that there were no clinical errors.

Nutrition and hydration

- The clinic provided water bottles for women and those accompanying them to drink.
- The clinic's website advised women that it was helpful to have full bladders if they were having an early scan. It said it was not necessary to have a full bladder for "other scans".

Patient outcomes

- Managers monitored the effectiveness of care and treatment and used the findings to improve them.
- The clinic asked women to complete feedback forms so it could monitor the service. Of the 20forms the service had collected since the service opened in January all were positive.
- The clinic also monitored complaints, to check why those customs were not happy with the outcome they had received.

Competent staff

- The clinic made sure that staff were competent for their roles.
- The clinic had a formal induction policy that set out the process for people joining the business. All new starters underwent a four week long corporate induction which included mandatory training.
- Sonographers shadowed more experienced peers until confident and were then observed conducting their own scans until they were proficient. The registered manager would conduct monthly reviews during the probation period. This changed to quarterly reviews after staff passed their probation.
- The clinic told us that it carried out appraisals every month during the probation period, and them quarterly thereafter. However, a member of staff told us that they had not had an appraisal.
- We saw the staff files for the sonographer and the receptionist. These contained references from previous employments. The sonographer's files also included details of training, qualifications and membership of the Society of Radiographers. We noted that the sonographer's membership of the Society of Radiographers ended in September 2018.We were told that this had been renewed but the clinic did not provide evidence of this.
- The clinic told us that team meetings were held every six months. We saw minutes for meetings in April and August 2018 that included very brief minutes. Topics for discussion included the complaints policy, and training about different customer types. However, a member of staff told us that they had not attended a team meeting, despite being on the attendee list. We were therefore not assured staff were actively engaged with team meetings.

Multidisciplinary working

- The registered manager was responsible for the three sites (soon to be four) and visited these regularly.
- New staff often shadowed more experienced staff at other locations.

Seven-day services

- The service was open two days a week on a Wednesday (1pm to 8pm) and a Saturday (11am to 7pm).

Consent and Mental Capacity Act

- The clinic had developed a consent form that highlighted information described by Public Health England which staff asked customers to sign. However, the form was not available in other languages. Whilst

Diagnostic imaging

the clinic said that family members could usually translate for women, the clinic could not be assured that all relevant information was being given to the woman or that they understood it.

- The sonographer told us that they were not involved in taking consent which was completed by the receptionist or manager.They told us that they were not told whether the women had signed the consent form and did not see it. However, we observed the manager bringing a woman into the ultrasound room and handing the consent form to the sonographer for them to check.
- The clinic had a Mental Capacity Act policy. It also sent us a copy of the training staff had in consent and capacity training during induction. However, a member of staff told us that they had not had training in the Mental Capacity Act.
- The registered manager told us that they would spend longer with younger women to check they understood the scan they were having. The manager told us that if they were concerned that a person did not have capacity to understand the procedure, they would not perform the scan and refer them to their midwife.

Are diagnostic imaging services caring?

Good

We rated it as **good.**

Compassionate care

- Staff cared for patients with compassion. Feedback from patients 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 unless someone talked loudly.
- We observed staff providing compassionate care. They spoke to women and their families in a friendly manner.
- We observed the sonographer clearly explaining to a woman what she was doing. She also asked whether the room was a comfortable temperature.
- We reviewed feedback from 20 patient surveys. Women were positive about the service they had received.

Emotional support

- Staff provided emotional support for patients to minimise their distress.
- A customer survey had recorded that the "sonographer took time to explain [what was happening] and was very reassuring".
- The clinic provided information about miscarriages to women that might have had previous difficulties. It also provided information about local advocacy groups.

Understanding and involvement of patients and those close to them

- Staff involved patients and those close to them in decisions about their care.
- We observed the sonographer asking one women whether she had any questions about the scan. The sonographer did not rush and allowed the woman and her family sufficient time in the ultrasound scan room.
- The clinic displayed information in its waiting area and ultrasound room about how to report allegations of abuse; details included the various types of abuse people could suffer. It also included contact information for the local authority safeguarding team.
- The service did not provide information in a child friendly format for 16 and 17 year olds.
- The pre-appointment checklist reminded staff to confirm the purpose of the scan, the length of time it would take, and the cost.

Are diagnostic imaging services responsive?

Good

We rated it as **good.**

Service delivery to meet the needs of local people

- Information was not provided in accessible formats, and the consent form highlighting information from Public Health England was only available in English.
- There was an area for women and the family and friends to wait.
- The service offered appointments in the afternoon and evenings, and at weekends, to make it more accessible to working mothers.
- The waiting area contained details of local advocacy services.

Meeting people's individual needs

- The clinic did not routinely take account of patient's individual needs.
- The clinic website highlighted that the location did not have disability access due to property restrictions. However, the clinic did not routinely ask women whether they had any disabilities when they booked their appointment and so it was incumbent on the customer to ask the right questions or ensure they had adequately searched for the information on the clinic's website. The clinic told us it had not had to turn away any women due to this point. It also sent us evidence that, following our inspection, it had updated the checklist to ensure staff asked about disabilities prior to booking appointments.
- The clinic did not have access to any translation services for those patients that did not speak English as a first language, or who were deaf.
- The service did not provide any learning disability training to staff. However, it did have a Service Users with a Disability or 'Specials Needs' policy which staff were expected to read. The purpose of the policy was, amongst other things, to "ensure all staff were provided with information regarding the minimum requirements needed to respond to the needs of service users presenting with disabilities/special needs". The policy referenced the Disability Discrimination Act 1995 this act was repealed in 2010, when it was replaced by the Equality Act and was therefore reference out of date guidance.Appointments were also sufficiently long enough to allow extra time for those women that needed it.
- The clinic allocated sufficient time to each appointment to allow mothers or friends and families to ask questions. We observed two women attend the clinic and they were not rushed.
- The clinic's consent letter clearly advised woman that it was not always possible to identify the gender of the foetus.
- The clinic had literature available for women that had previously suffered pregnancy complications.
- The scan image was projected onto a television screen to make it easy for the women and their friends or family to view.

Access and flow

- People could access the service when the needed it.
- Women were booked for set appointments. We observed two women attend for scans whilst we were on site. They did not have to wait to see the sonographer.
- Customers paid a deposit which the clinic told us that this helped ensure that all women arrived for their scan.
- Keepsakes were created whilst women waited.

Learning from complaints and concerns

- The clinic treated concerns and complaints seriously, investigated them, and learned lessons from the results.
- The clinic tried to resolve complaints quickly and informally at first.
- The clinic had a clear complaint policy that set out the process for how formal complaints would be dealt with. Complaints would be acknowledged within two days and a written response would be sent within 14days. It confirmed that complainants would be advised, in advance, of any delays in the investigation. The complaints process was also displayed on the wall in the waiting area.
- There was evidence that the clinic learned from complaints. Following one complaint about the quality of the scanned image (at another location), the

clinic changed its processes so that those women who knew they had an anterior placenta were informed that it would be difficult to obtain an image of the foetus.

- The clinic kept a high level record of the complaints it had received. This included the complaint reference, name of complainant and date received, very brief details of the complaint, the outcome and any recommendations. Whilst a detailed file was not kept for each complaint, this was not necessarily proportionate given the types of complaints the service received; three complaints related to the quality of scan image, whilst the other related to a delay in the appointment.
- The clinic had a three stage complaints process. Stage one involved a review by the registered manager, stage two involved a review by "the Board". However, when we spoke with the registered manager, she confirmed that due to the size of the organisation, they would also carry out the second review.
- The third stage of the clinic's complaints process informed complainants to contact the Care Quality Commission. However, the Care Quality Commissioner was not a complaints adjudicator and was incorrectly referenced in the complaints policy.

Are diagnostic imaging services well-led?

Requires improvement

We rated it as **requires improvement.**

Leadership

- Managers had the right skills and experience to run the service.
- The registered manager told us she kept up to date with the industry and regularly reviewed the British Medical Ultrasound Society's website for new articles.
- The registered manager told us that she planned to undertake a sonographer course so she could provide additional support to the business. They had not yet booked on to the course.

Vision and strategy

- The clinic had a vision for what it wanted to achieve.
- The clinic had a business plan that set out what it wanted to achieve, including ensuring the relatively new location established itself and could open additional days.
- The clinic wanted to "build a brand that is recognised and trusted".
- The business plan included an analysis of strengths, weaknesses, opportunities and threats. It included an advertising strategy and pricing policy.
- Whilst the business plan did not include feedback from customers to shape the service, we saw evidence of complaints leading to changes to practice.

Culture

- Managers promoted a positive culture that supported and valued staff.
- The staff we spoke with appeared happy, and they told us they enjoyed working at the clinic.
- Whilst it was not clear whether staff fully understood their role under the Duty of Candour, they knew to be open and honest with customers should an incident occur.
- Due to the small size of the business, there were limited opportunities for staff development.
- The clinic did not currently operate a chaperone scheme, but was considering training staff and offering this service in the future.
- The clinic kept a risk register which included the risk of staff developing back problems from improper use of the work station. The clinic had controls in place including ensuring staff had regular breaks, sufficient lighting, and informing managers if they developed back pain.

Governance

- The clinic did not have systems or procedures in place to ensure that its policies were up to date, regularly reviewed and referenced current guidelines.
- The clinic told us that there were meetings with the receptionist and sonographer every six months which we saw (brief) minutes for.

Requires improvement

Diagnostic imaging

- New employees had a disclosure and barring service check. They provided references and a curriculum vitae. Staff files also included a job description and a signed employment contract. The sonographer had also provided evidence of her qualifications and training. We saw the relevant staff files and these documents were in order.

Managing risks, issues and performance

- The clinic had good systems to identify risks, and planned to eliminate or reduce them
- The clinic had a risk register which was reviewed and updated every six months. The register described the risk/hazard who might suffer harm and why, and what actions were already in place to minimise risk. The register also described what further action was necessary to reduce risk further, as well as an action owner, deadline and whether the action had been completed.
- The risks that were monitored included the use of display screen equipment, lone working, privacy in treatment rooms, and a faulty ultrasound machine. All risks were up to date.
- The registered manager completed an annual audit. We were sent this information prior to the inspection. Although the date of the audit was not recorded, it covered points such as staff adherence to clinical and governance procedures, and clinical errors.
- The clinic's policies were kept in a folder in the reception area. Not all policies were within their review date (for example the Data Protection Policy and the Complaints Procedure Policy should have been reviewed in August 2017). Those that were within their review date did not always reference up to date guidance. For example, the clinic's safeguarding document did not reference the Safeguarding children and young adults: roles and competencies for health care staff – Intercollegiate Document – March 2014).

Managing information

- Whilst the clinic collected, analysed and used information well to support its activities, it did not use security safeguards.
- Scans were emailed between locations if a sonographer needed advice from a colleague. However, the clinic did not use a secure email system.
- The ultrasound computer was not password protected.
- Paper records were shredded but this was done on an "as required" basis. The clinic's Data Protection Policy stated that: "all records should be retained and disposed of according to the Baby Ultrasound clinic's Records Management Policy". However, the clinic's Record Management Policy did not contain any reference to the disposal of patient sensitive information. Therefore, there was a risk that the clinic was keeping patient information longer than necessary.
- The clinic's consent form had been updated to reference the General Data Protection Regulations.
- The clinic primarily advertised via online services. It had a contract with a third party advertising company which managed these services.
- The clinic's website clearly set out the price for the services they offered.
- The registered manager told us that the computers used in the reception area were password protected and these passwords were changed monthly.
- It was the registered manager's responsibility to submit statutory notifications to regulatory bodies, including the Care Quality Commission, and we saw evidence that this had happened.

Engagement

- The clinic asked patients to complete a survey so it could monitor patient experience. It had collected 20 surveys in the 11 months it had been open. Blank patient surveys were kept on the reception desk.

Learning, continuous improvement and innovation

- The clinic used complaints and patient surveys to improve its service and we saw evidence of this.

Outstanding practice and areas for improvement

Areas for improvement

Action the provider MUST take to improve

- The provider must ensure that it maintains securely records in respect of each service user.
- The provider must ensure that staff receive appropriate children's and adults safeguarding training that takes account of current guidelines.

Action the provider SHOULD take to improve

- The provider should have assurance that staff are completing mandatory training modules and understand them.
- The provider should consider taking steps to improve is infection prevention and control practices.
- The provider should consider improving its premises and environment to make it more comfortable for women, including tidying the second 'consultation room'.
- The provider should ensure that it does not provide diagnostic information to women and continues to refer them to their midwives and GPs if they have concerns.
- The provider should consider changing its policies so they better reference how complaints are investigated. This should include removing reference to the Care Quality Commission as a third stage complaints handler from its policies and website.
- The service should consider providing formal translation services for its customer so it has assurance they understand the procedure they are paying for.
- The provider should ensure it has systems to review internal policies and confirm they reference up to date guidelines.

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 17 HSCA (RA) Regulations 2014 Good governance Regulation 17 HSCA 2008 (Regulated Activities) Regulations 2014 Good Governance The clinic must ensure that systems or process must be established and operated effectively to ensure compliance with the requirements in this part. Such systems and processes must enable the registered person, in particular to maintain securely an accurate, complete and contemporaneous record in respect of each service user. Regulation 17(2)(c)

Regulated activity	Regulation
Diagnostic and screening procedures	Regulation 18 HSCA (RA) Regulations 2014 Staffing Regulation 18 HSCA 2008 (Regulated Activities) Regulations 2014 Staffing The clinic 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)