

Show Your Bump

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?

Inadequate



Overall summary

Show Your Bump is operated by Mrs Wendy Ann Williams.

The service provides pregnancy keepsake scans to self-paying members of the public. These are trans abdominal scans, including 2D, 3D and 4D baby keepsake scans and gender scans. The clinic does not provide diagnostic scans.

The service is based in Wigan and in addition to the manager it employs one full time sonographer; one full time receptionist and three part time receptionists.

The clinic has a waiting room and reception area; a scanning room; a small private room for women to use if required; a toilet; and a small kitchen area. Souvenir items such as teddies and keyrings were displayed in the reception area.

We inspected this service using our comprehensive inspection methodology. We carried out the unannounced inspection on 1 May 2019.

To get to the heart of patients' 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 Show Your Bump was baby keepsake scanning.

Services we rate

We rated this service as **Requires improvement** overall because:

- Staff did not complete mandatory training appropriate for their roles.
- Staff did not always understand how to protect patients from abuse but they knew how to contact other agencies to raise any safeguarding issues.
- The service did not have suitable premises or use appropriate control measures to manage the risk of infection.
- The provider did not have clear operational policies for the service in place, or a system to ensure these were followed by all staff.
- The service did not have systems to identify risks, or plans to eliminate or reduce them.
- Leaders were not always aware of the risks, issues and challenges within the service and during

inspection we identified risks which had not been previously recognised. This included risks in infection prevention and control, consent and in safeguarding systems.

- There was no process to review key items and a strategy, values or governance framework was not identified.

However;

- Equipment was maintained in accordance with manufacturers' guidance.
- Staff kept appropriate records for service users and stored these securely.
- Staff treated service users with dignity and respect and involved service users and those close to them in decisions about their care.
- The service engaged with customers and staff and took action to improve the service provided.
- The manager promoted a positive culture that supported and valued staff.

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 seven requirement notices for the service. Details are at the end of the report.

Name of signatory

Ellen Armistead

Deputy Chief Inspector of Hospitals (Hospitals North)

Summary of findings

Our judgements about each of the main services

Service

Diagnostic imaging

Rating

Requires improvement



Summary of each main service

We rated this service as requires improvement because the service required improvement in safe and responsive, was inadequate in well-led, but it was good in caring.

We inspected but did not rate effective.

Summary of findings

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Requires improvement 

Show Your Bump

Services we looked at

Diagnostic imaging

Summary of this inspection

Background to Show Your Bump

Show Your Bump is operated by Mrs Wendy Ann Williams. The service opened in August 2014. It is a private clinic in Wigan, Greater Manchester. The clinic primarily serves the communities of Wigan. It also accepts service users from outside this area, across the North West.

The clinic has a Registered Manager who is registered with CQC since 2014. The legal entity is that of a sole trader.

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 Show Your Bump

The clinic had one ultrasound scanning machine and is registered to provide the following regulated activities:

- Diagnostic and Screening Procedures.

During the inspection, we inspected all areas at the clinic and observed three ultrasound scans. We spoke with the manager, sonographer and receptionist. We spoke with three service users and reviewed service user feedback. During our inspection, we reviewed 25 sets of service user records.

There were no special reviews of the clinic ongoing by the CQC at any time during the 12 months before this inspection.

Activity (May 2018 to 30 April 2019):

- 5052 client appointments for different types of scan
- No appointments were cancelled or re arranged.
- 102 women were signposted to other services for further review

Track record on safety

- No Never events
- No incidents or serious injuries
- No incidences of hospital acquired Meticillin-resistant Staphylococcus aureus (MRSA),
- No incidences of hospital acquired Meticillin-sensitive staphylococcus aureus (MSSA)
- No incidences of hospital acquired Clostridium difficile (c.diff)
- No incidences of hospital acquired E-Coli
- No complaints

Services provided at the location under service level agreement:

- Social media advertising
- Maintenance of ultrasound equipment

Summary of this inspection

The five questions we ask about services and what we found

We always ask the following five questions of services.

Are services safe?

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

- Staff had not completed mandatory training relevant for their role.
- Staff did not always understand how to protect service users from abuse.
- The service did not always control infection risk well and did not always use control measures to prevent the spread of infection.
- There was no sink within the toilet facilities or hand washing facilities in the scan room.

However;

- Ultrasound equipment was maintained in accordance with manufacturer's guidance.
- The service ensured there was always a member of staff trained in first aid available during opening hours.
- The service kept records of referrals for cases where an abnormality or concern had been identified.
- Staff kept appropriate records of care for service users, and stored records securely.

Requires improvement



Are services effective?

We did not rate effective because we do not have enough information to make a judgment. We found:

- Sonographers completed peer review of their practice.
- Women were advised about the need to drink water prior to their appointment.
- The service had a resource folder for staff containing details of early pregnancy flow charts and NHS guidance.

However:

- There was no induction process for new staff.
- The service did not have a policy and staff had not completed training regarding the Mental Capacity Act.

Not sufficient evidence to rate



Are services caring?

We rated caring as **Good** because:

- Staff cared for service users with compassion and respect.
- Staff ensured women were comfortable during their appointments and protected their privacy and dignity.

Good



Summary of this inspection

- Staff were aware of women's emotional needs and supported them professionally when they needed to communicate any concerns identified.
- Staff involved women and those close to them in decisions about their care.

Are services responsive?

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

- The service did not always take account of people's individual needs.
- The service did not have an effective and accessible system for identifying, receiving, recording, handling and responding to complaints by service users.

However

- Appointments allowed sufficient time for service users to understand information and select their scan pictures.
- People could access the services at a time convenient to them.
- The service received positive feedback from service users and any concerns were investigated.

Requires improvement



Are services well-led?

We rated well led as **Inadequate** because:

- Although there was an overall aim to develop the service, there was no strategy or plan documented to progress this.
- There were no formal governance arrangements in the service and policies related to service activities were not clearly identified.
- The service did not have effective recruitment processes.
- The service did not have arrangements in place for identifying, recording and managing risks. Leaders were not always aware of the risks, issues and challenges in the service.
- There was no process to review key items and a strategy, values or governance framework was not identified.






However;

- There was an open and transparent culture within the service; all staff we spoke with were passionate about the service and proud of their work.
- The service engaged well with service users and staff.

Inadequate



Diagnostic imaging

Safe	Requires improvement 
Effective	Not sufficient evidence to rate 
Caring	Good 
Responsive	Requires improvement 
Well-led	Inadequate 

Are diagnostic imaging services safe?

Requires improvement 

We rated safe as **requires improvement**.

Mandatory training

- The service did not provide mandatory training in key skills to all staff and did not ensure everyone completed it. Staff had only recently completed safeguarding training after we had informed the provider we would be inspecting the service, otherwise no other formal mandatory training was identified for staff to complete.
- The manager did not keep an overall record of any training staff completed, although we saw certificates of safeguarding training were held in staff files.
- The service did not have a mandatory training policy and staff had not received any training in core subjects such as health and safety, fire safety, information governance, infection prevention and control, consent or conflict resolution.
- The service had a staff handbook, providing general information about different areas applicable to the service. This information ranged from subjects such as equal opportunities, bullying, and health and safety; to complaints procedures and company policies. The handbook stated staff must sign this document on a yearly basis to ensure they were up to date and fully aware of all procedures. However, we did not see any records were kept by the manager to confirm this and staff did not tell us of any mandatory training apart from safeguarding training.

Safeguarding

- Staff did not always understand how to protect service users from abuse but they knew how to contact other agencies to raise any safeguarding issues.
- The registered manager and sonographer were the designated safeguarding leads for the service and had recently completed safeguarding adults training for this role. They had also completed level three safeguarding children training; both of these training courses were completed by e-learning. This did not fulfil training requirements for level three safeguarding, which needs to be provided in both face-to face and e-learning elements.
- All staff in the service had completed e-learning training for safeguarding children level three, although reception staff had not completed safeguarding adults training. The registered manager told us they felt it was more appropriate for the sonographer and manager to have this training, as they would be the individuals able to question service users in privacy during their scan. However, reception staff were the first point of contact for service users and would need to be aware of any potential safeguarding issues relating to adults. The manager said the reception staff would be able to observe any children attending appointments with their relative whilst waiting in the reception area. Reception staff said they had not identified any concerns to the manager regarding any such observations of children.
- Staff told us they would share any safeguarding concerns initially with the manager. The staff handbook documented contact details for the local authority safeguarding hub and the manager had

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recently had contact with the hub to confirm these processes. Staff in general were aware of this route for referral, however none had raised any concerns to date in following this procedure.

- When we asked staff, we found awareness of safeguarding issues was generally limited to concerns about possible physical signs, such as bruising. Staff frequently commented that any abdominal bruising observed during scans was often due to women having Fragmin injections during their pregnancy. There was limited awareness of the potential wider safeguarding issues that could present in the service, such as child sexual exploitation, female genital mutilation or domestic abuse.
- The service saw service users age 16 and 17 years old for pregnancy scans. Reception staff contacting service users to book appointments would ask their age and if identified as under 18, service users would be informed they needed to be accompanied by a parent or guardian.
- The service did not have a formal safeguarding policy for adults or children, although the staff handbook documented a short section on safeguarding. This highlighted the need for staff to note if service users had any suspicious bruising, or if there was a suspicion of the use of drugs or abuse to service users' unborn babies. The handbook did not reference up to date national safeguarding guidance.
- The sonographer maintained a safeguarding proforma documenting details of any safeguarding concerns. We reviewed a total of 23 completed records documented on the safeguarding proforma since July 2018. Most of these documented abdominal bruising seen, resulting from anti-clotting injections when required during pregnancy. Only one record identified any further action and contact made with social services.
- In staff files we saw evidence of up to date disclosure and barring service checks. All of these had been completed in April 2019.

Cleanliness, infection control and hygiene

- The service did not always control infection risk well and did not always use control measures to prevent the spread of infection, although staff kept themselves, equipment and the premises clean.

- The registered manager was the lead for infection control. The sonographer had completed a hand hygiene certificate of training in March 2019, but no other staff had completed training in infection prevention and control.
- The service did not have an infection prevention and control policy, but staff had access to infection control guidance contained in the staff handbook. This provided details of general cleaning tasks, detailing that all surfaces must be cleaned every day with antibacterial spray; all hard floors vacuum cleaned, swept and mopped every day. This also stated staff must use hand sanitiser to ensure hands were clean before dealing with service users and that uniforms must be washed on a daily basis.
- The service had a checklist of cleaning duties for the reception, kitchen and bathroom areas, which reception staff managed daily. Between August 2018 and March 2019, we saw the cleaning rotas were ticked as completed, with the exception of three dates not signed for as completed.
- During inspection we observed the majority of areas, including the waiting area, scan room and storage areas were visibly clean and orderly.
- Service users and staff needed to walk through a rear room to access the toilet facilities. There was a baby changing station with a mat and table in the corner of this room. Women were also directed to use a therapy ball in this room to facilitate a change of the baby's position, if this was needed for a clearer scan image.
- The toilet facilities were towards the rear of the premises, adjacent to a kitchenette area. The entrance to the kitchenette and toilet areas was through an open doorway, but with no door to enclose this area. There was no sink within the toilet facilities; service users and staff needed to use the sink in the kitchenette area opposite the toilet. The kitchen sink was next to a fridge; on top of the fridge was a microwave cooker with a kettle and toaster on top of this. This presented a potential risk to infection prevention and control and management of good hygiene.
- A notice was displayed in the toilet advising service users that the toilet area was checked during the day, but to inform staff in case of any cleaning needs. There

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was no notice displayed here to prompt staff or service users to wash their hands, but this was displayed above the kitchen sink. We observed several people did not wash their hands after using the toilet facilities. During the inspection we raised our concerns to the manager.

- Staff did not have access to hand washing facilities in the scanning room. The sonographer used gloves and gelled their hands in between service users. The sonographer told us they would wash their hands after each third client appointment, using the sink facilities in the kitchenette. We only observed one occasion where the sonographer did this during our visit.
- The sonographer wiped the ultrasound transducer head before each client's scan. A paper towel covered the treatment couch during client scans and was replaced after each client's use. The sonographer maintained the daily cleanliness of the ultrasound machine. During the scan, women were given a paper towel to help maintain their dignity. Following the scan, the towels were used to wipe the gel from the ultrasound.
- The service did not undertake non-invasive prenatal blood tests for service users.
- There had been no incidences of healthcare acquired infections at the service since it opened.

Environment and equipment

- The ultrasound scan equipment was serviced annually and maintained in accordance with the manufacturer's guidance. Arrangements were in place for supply of replacement equipment from the contractor, in the event of any emergency breakdown. The sonographer reported there had been no instances where this had occurred.
- The service maintained an inventory of all equipment items, detailing 28 items. This included domestic equipment such as kettle and vacuum cleaner, as well as television, laptop computer and scan machine. The equipment register listed the location of the equipment and was ticked for a weekly visual check. Records also identified if any equipment was faulty or removed; this documented a fan had been removed when faulty.

- Records we reviewed showed the service arrangements for electrical safety testing with an external contractor. All electrical equipment we checked, including the ultrasound scan displayed a current electrical safety testing sticker.
- The clinic had a first aid kit in the scan room and reception; all the items were within the manufacturers' expiry dates.
- A rear room next to the reception and scan room provided further seating, with shelving and a storage unit containing stock items.
- We saw bleach and other cleaning liquids stored in a cupboard underneath the kitchen sink; this had a childproof lock on it. Fortnightly removal of non-clinical waste was managed as part of the rental arrangements for the premises.
- The premises had clearly marked fire exits and fire extinguishers which were stored securely, and a smoke alarm was fitted. Fire safety checks had been completed at the time of installation and a fire regulation notice was displayed in the rear room. No smoking signs, a health and safety at work and workplace first aid guides were displayed in the premises.
- The manager and sonographer had completed fire extinguisher training in 2019 however we did not see records of fire safety training for any other staff. The staff handbook stated all staff may use the fire extinguishers in a small manageable fire, otherwise they should not attempt to put the fire out.
- We saw reference in team meeting records that there had been difficulties with environmental temperature control during periods of hot weather. There was an air conditioning unit in the scan room, not in use at the time of inspection.
- The premises had an alarm system, with door and window shutters in use when the service was closed. There was closed circuit TV monitoring, with camera recording in the reception area and a notice at the entrance to advise service users of this.

Assessing and responding to patient risk

- The service had systems in place to assess and manage risks to women and their babies.

Diagnostic imaging

- The service did not offer diagnostic imaging scans and staff told us the scans were for baby bonding and souvenir purposes, not intended to replace routine NHS maternity scans and services.
 - Information on the website stated ‘Ultrasound technology has been researched in hundreds of clinical studies over the past 30 years and it has not been shown to cause any harm to either mother or baby’, also, ‘With routine scanning in all 3D,4D and HD Live it has been proven that scanning you and your baby is perfectly safe, exactly the same type and intensity of ultrasound is used as with your hospital 2D scanning.’
 - The website also provided links to NHS information about ultrasound and an American website called ‘baby center’. There was no reference to the British Medical Ultrasound Society on the website, however this detail was included on the declaration form for service users to read and sign when attending appointments.
 - Service users booking in were asked to read a copy of the terms and conditions of the service and sign a declaration form when they had completed this. The declaration form provided information about the different types of scan available and the optimal stage of pregnancy for these to be done, in order to provide a clear image of their baby.
 - The declaration form also asked women to confirm they did not have any medical condition which could affect the scan, also to agree that the sonographer would advise them to contact their midwife, general practitioner or hospital in the event of any abnormality being detected. The form also stated that in cases where a possible abnormality was identified, Show Your Bump would share the client’s personal information and provide a report to the healthcare professional.
 - Women were not routinely asked to bring their maternity notes and for early pregnancy reassurance scans medical records would not generally be available.. Staff told us if further assessment or opinion was required the sonographer would explain the findings and provide information for the woman to take to the appropriate healthcare professional. In addition, the woman would be given the option of staff also contacting the health professional.
 - The service kept records of referral for cases where they had detected an abnormality or advised the woman to seek further advice. We reviewed nine referral records completed during April 2019 and saw appropriate communications were documented regarding such cases. We saw 93 referral records had been completed between January and December 2018.
 - The manager and sonographer had completed first aid training and during opening hours at least one of these staff was always available.
- ### Staffing
- The service had enough staff with the right skills, and experience to keep people safe from avoidable harm and to provide the right care and treatment.
 - There was one permanent sonographer and the manager was also trained to undertake pregnancy scans. The manager and sonographer worked together to cover scanning service appointments through the week. There was one full time receptionist and three other part time reception staff who worked together in shifts to provide reception cover.
 - The service did not offer scan appointments during two weekdays; however, the receptionist and occasionally other staff would be at work to cover appointment bookings and website responses. At times the receptionist would be alone at work in the premises, however they would keep the doors locked and the shop blinds closed; the premises were also monitored by had closed circuit TV. The service did not have a lone working policy.
 - There were no vacancies in the service at the time of inspection. Any sickness was covered between staff, as and when it occurred.
- ### Records
- Staff kept appropriate records of service users’ care and treatment. Records were clear, up-to-date and available to all staff providing care.

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- Paper records were completed at the time of service user's attendance to confirm to the sonographer the details of which scan was requested, together with the client declaration form, which the sonographer checked through again with the client in the scan room. These paper records were destroyed after one month.
- Staff kept records of client consent forms for under 18-year olds. These were stored securely in a locked cupboard within the scan room, which was also kept locked when not in use.
- The service maintained a secure file containing copies of referral report forms for service users, where any concerns or anomalies had been detected and service users had been directed to NHS professionals.
- The sonographer maintained a list of client names in a 'safeguarding proforma', where any safeguarding concerns were identified during scan appointments. This included details of the service user's name, any unusual marks noted and the sonographer's name. The client would be asked to sign at the end of the relevant row to confirm their understanding of the sonographer's record of the safeguarding concern. As more than one record was recorded on each page, there could be potential for the client to view details of another service user's details recorded on the form whilst signing their name. The sonographer told us they would always ensure the document was covered by a blank sheet of paper to prevent this from happening.

Incidents

- Staff had a general awareness of their roles and responsibilities to raise any concerns and the service had an accident book for staff to document these.
- The service had an accident record book and a near miss record book to document any incidents. When we reviewed these during inspection, we saw nothing was recorded and staff told us there had been no formal incidents occurring in the service. We saw, however, there had been a number of incidents which had occurred in the service, such as high environmental temperatures and breakdown of fan equipment.

- The service did not have a documented incident policy or procedure and staff we spoke with said they would raise any concerns to the manager in the first instance. The manager did not tell us of any incidents requiring investigation and we did not see any discussion of incidents recorded in team meetings.
- Staff were aware of the principles of being open and honest and the duty of candour. The duty of candour is a regulatory duty that relates to openness and transparency and requires providers of health and social care services to notify patients (or other relevant persons) of certain 'notifiable safety incidents' and provide reasonable support to that person. The sonographer told us of occasions where they had communicated openly to share information with service users, after identifying a possible abnormality on their scan.

Are diagnostic imaging services effective?

Not sufficient evidence to rate 

The domain for effective was inspected but not rated

Evidence-based care and treatment

- Service users signed a declaration form at their appointment which directed them to them to the British Medical Ultrasound Society's website for further information.
- The sonographer and manager completed peer review of each other's practice of ultrasound scanning and patient care, recording these in a medical ultrasound assessment of clinical learning document. We reviewed six of these records which covered different types of scan, including checking referral details, environmental and consent procedures as well as clinical aspects. We saw, and the manager confirmed, these had been introduced since January 2019.

Nutrition and hydration

- Women were advised regarding the need to drink water prior to their scan to enable a better image of their baby. Staff provided water to women at their appointment, if this was requested or needed.

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Patient outcomes

- Staff monitored the effectiveness of care and treatment and used the findings to improve them.
- Women were asked to complete feedback forms and invited to comment on social media following their appointments to assist the service in identifying areas of improvement.
- Staff recorded information about the number and type of scan appointments each month. The service maintained a secure file containing details and numbers of referrals where any concerns or anomalies had been identified following a scan.
- The service had a resource folder providing general information for staff about ultrasound scan, early pregnancy pathways and report proformas. The information included details of the NHS fetal abnormality screening programme handbook and flow charts to follow when any abnormality was detected.
- We reviewed different report proformas and noted amongst these that the scanning protocol had no issue or review date and there were two different report forms used. When we asked the manager, we were told one was used for under 20 weeks of gestation and one for over 20 weeks of gestation. However, neither of these forms clearly indicated this.
- The sonographer demonstrated an understanding of national legislation and best practice guidance for ultrasound, including how the thermal index was recorded on scans. The ultrasound waves may cause heating in tissue and the thermal index expresses the potential rise in temperature at the ultrasound's beam focal point.

Competent staff

- The service was not able to demonstrate staff were competent for their roles due to lack of appraisals being completed.
- We saw evidence to confirm the sonographer's qualification and current registration as a radiographer with the Health and Care Professions Council. We saw evidence confirming the manager's degree qualification and training completed for practice of ultrasound scanning.

- Other staff files we reviewed showed assorted documents and certificates confirming various training completed by staff, although this was not always directly related to their current role. These included evidence of the sonographer's and manager's qualifications in sonography, as well as training completed by individual members of staff. Amongst these were certificates for training in apprenticeships in the children and young people's workforce; level three diploma children's learning and development (2018); and level three diploma in health and social care (adults) (2014).
- The service did not have a formal induction process for any new staff although new staff confirmed they would be shown the different tasks required for their role as needed, and directed to the staff handbook for further information.
- There was no formal process for staff appraisals and staff told us there was daily communication between all members of staff in the service. Any discussions and opportunities for development could be raised through this approach. We did not hear of specific examples of development that staff had been able to progress, although all said there would be support and encouragement from the manager for this.

Multidisciplinary working

- Staff of different kinds worked together as a team to support women accessing the service.
- During our inspection we observed professional communication and a positive working environment between staff and towards service users. The atmosphere was calm and friendly, allowing women to feel at ease.
- We heard that on occasions where service users had consented for staff to contact other NHS professionals, there could sometimes be difficulty or a wait to speak to the individual concerned. However, staff would persevere with attempts to make contact when needed.

Seven-day services

- The service was open seven days a week, offering scan services on five days. On Tuesdays and Thursdays staff

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covered website enquiries and appointment bookings. Opening hours varied on different days, offering flexibility with early and evening appointments, available on weekdays or weekends.

Consent and Mental Capacity Act

- The service had a declaration form for women to read and sign at the time of their appointment. This stated the scans were not diagnostic and not intended to provide obstetric care or replace scans with the NHS.
- We observed the receptionist checking service users' understanding of the declaration form during their appointment. We saw also the sonographer confirmed the procedure the client was having, asking permission before applying gel to the woman's abdomen and explaining details of the procedure throughout the scan.
- Parents or guardians attending appointments with service users under 18 years old would sign an additional consent form for the scan. This would not be required as a consent process. During inspection we reviewed 12 consent form records that had been completed for service users under 18 years old having scans, from February to May 2019. All of these service users were aged 17 years.
- At the time of our inspection staff had not completed training for Mental Capacity Act or consent. Staff perceived they had not really seen any service users who lacked mental capacity, but said if they had any concerns about an individual's capacity to consent, service users would be directed to NHS services
- The service did not have a Mental Capacity Act policy and information on consent was not detailed in the staff handbook.

- Feedback from service users confirmed that staff treated them well and with kindness. Comments included 'the staff were very friendly and professional'.
- We observed staff communicating with sensitivity and understanding when engaging with service users and their families.
- Scans were conducted in a closed room to ensure privacy and dignity was maintained. The sonographer spoke calmly to explain what was happening during the scan and what was being observed on the scan images.
- The sonographer checked women were comfortable during the scan and supported them to change their position where needed.

Emotional support

- Staff provided emotional support for service users to minimise their distress.
- Staff were aware of the emotional needs of women during their appointments and provided encouragement and reassurance to reduce any anxieties about the scan procedure.
- Reception staff supported women and their families appropriately when choosing a scan image. Staff welcomed any children and family members attending with the woman for the scan, providing a comfortable and relaxing environment.
- The sonographer described how they supported women when they had to communicate any concerns. Appointment times allowed for some flexibility for this discussion in the scan room but there was no other private area available. Reception staff said they discreetly communicated to other women who may be waiting for their appointments at such times, in case of any resulting delays.
- Reception staff offered to accompany women during their scan, if they attended on their own and were anxious.

Are diagnostic imaging services caring?

Good 

We rated caring as **good**.

Compassionate care

- Staff cared for service users with compassion and respect.

Understanding and involvement of patients and those close to them

- Staff involved service users and those close to them in decisions about their care.

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- During our inspection we observed staff involving women and their partners in discussions about the appointment, the services available, and explaining the procedure and the images taking place.
- The sonographer checked with the woman to confirm if they wished to know the baby's gender before disclosing this.
- Information regarding the different types of scans and packages available for people to purchase was clearly presented on the provider's website. Service users told us they were very happy with the service they had received and felt supported throughout.

Are diagnostic imaging services responsive?

Requires improvement 

We rated responsive as **requires improvement**.

Service delivery to meet the needs of local people

- The service was located in a parade of shops, near to the town centre and accessible by public transport, with car parking available on nearby local streets.
- The premises were located on the ground floor, with a reception area, a scanning room, a rear storage room, kitchenette area and toilet. The reception area was light and spacious, equipped with large sofas and children's seating.
- In the scan room there was an ultrasound machine, five chairs and a clinical treatment couch. In addition, there was a raised television screen on the wall for scan images to be displayed. The service provided a second computer terminal for women to choose their scan pictures.
- We saw that sufficient time was available during appointments to allow for completion of the declaration form, ask questions and for service users not to feel rushed.
- The clinic informed service users that they should be at least seven weeks pregnant for a keepsake scan, and 16 weeks for a gender scan.

Meeting people's individual needs

- The service did not always take account of service users' individual needs.
- The service could provide a ramp for access to the premises and staff confirmed they could offer scans for women, or access for family members, using a wheelchair. However, toilet facilities were not accessible for wheelchair users. Staff could not confirm whether there had been any issues regarding this.
- During inspection we saw staff supporting a client's partner who was deaf to be involved in the appointment.
- The website and other clinic information was only provided in English language format.
- The reception area had a sweets dispenser for families to access.

Access and flow

- People could access the service when they needed it.
- Women could arrange appointments according to their preference and the sonographer availability. At the time of inspection there was no waiting list for appointments and no cancellations.
- The receptionist arranged appointments for scans in response to phone or website enquires. When arranging appointments, reception staff would go through initial information with the service user, including the type of scan preferred and detail of scans available.
- Appointments were booked on an electronic system, noting the woman's details and the type of scan to be undertaken. Service users completed the declaration form and made payment at the time of attendance.
- Service users were advised of the best time during pregnancy to attend for different types of scan. The website confirmed for 4D scans this would be between 24 and 33 weeks pregnant.
- The service had a system in place for service users who required a rescan, but this data was not recorded or monitored. Rescans were provided where it had not been possible for the sonographer to obtain a clear image due to the baby's stage of gestation.

Learning from complaints and concerns

Diagnostic imaging

- The service did not have an effective and accessible system for identifying, receiving, recording, handling and responding to complaints by service users.
- Staff monitored service user feedback to identify any issues and where improvements could be made.
- Staff were directed to information in the staff handbook regarding complaints, advising staff to try and resolve any concerns with service users as they arose. The staff handbook stated 'we have a complaints procedure'; this was to raise any complaint in an email to the manager. The service did not have a formal complaints policy which included timelines for acknowledgement and response to complaints. We did not see any information provided for service users at reception regarding how to raise a complaint and there was no information on the provider's website regarding how to raise a complaint.
- Data confirmed there had been no complaints during the twelve months prior to inspection. However, we saw in team meeting minutes from August 2018 that a complaint had been discussed following a service user's dissatisfaction with the scan image. Following this, actions were identified for staff to ensure service users were made aware of the best type of scan in relation to their stage of pregnancy.
- Positive feedback was regularly received from service users, including for example '

Are diagnostic imaging services well-led?

Inadequate 

We rated well-led as **requires improvement**.

Leadership

- The service was led by the company owner and manager, who was registered as a sole trader. The manager had not completed any specific leadership training for their role.
- The manager and sonographer worked together closely in day-to-day operational matters, providing support and direction to other staff as this was needed. Staff in the service said they were well supported by the manager and sonographer.

Vision and strategy

- The service had a broad vision for what it wanted to achieve, but did not have workable plans to turn it into action.
- Whilst there was no documented strategy for the service, the aim was to expand the business over the next five years.
- The manager confirmed the focus for the business at present was to ensure the current service was providing the best care it could give. In the business plan document, provided prior to inspection, the service 'planned to maintain the good reputation we have and carry on all the good work we do'.
- The business plan document also comprised a list of current outgoings, together with statements of future intentions for the service. Included in these were 'to build the good relations we are building with the local hospitals and midwives; to ensure all staff have the adequate continuing professional development and training if needed and to keep policies up to date and revised on a regular basis.'
- Staff we spoke with expressed a general aspiration to expand the service, and to complete further sonography training, but were unaware of any further detailed plans.

Culture

- The manager promoted a positive culture across the service that supported and valued staff.
- There was an open and transparent culture within the service; all staff we spoke with were passionate about the service and proud of their work. Two members of staff were family members, and another was partner of a family member. Other members of staff described the whole service as 'like a family'.
- Staff felt able to raise concerns to the manager without any fear of retribution.
- During the inspection when we shared information about areas of the service where improvements may need to be made, the manager was positive in response to this.

Governance

Diagnostic imaging

- The service did not have systems or procedures in place to ensure that any policies were up to date, regularly reviewed, referenced current guidelines or that these were followed.
- There were no formal governance arrangements in the service. Separate policies related to service activities were not clearly identified, and there were no arrangements for oversight of the service as a whole through policy monitoring and review. There was no process to review key items and a strategy, values or governance framework was not identified.
- Key information for the service was contained in the 'staff handbook – policies and procedures'. This incorporated general information under different subject area headings, including for equal opportunities; bullying; health and safety; time keeping, sickness and holidays; patient care; complaints procedure; safeguarding; disciplinary procedures; grievances; and company policies. Information in the staff handbook was inconsistently ordered, with varying levels of content and directions for staff.
- Effective recruitment processes for employees were not in place and disclosure and barring certificates, whilst present for all staff, had only been completed in April 2019, after we had notified the provider we would be inspecting. Records in staff files were inconsistently ordered; in some these contained general training certificates, others contained different documents, including one where another member of staff's record was included. We did not see any evidence of references requested or received in staff files, or photographic ID for employees.
- Documents we reviewed also referenced the previous company name 'peek@baby'. The manager told us the name had changed four years ago.

Managing risks, issues and performance

- The service did not have systems to identify risks, plan to eliminate or reduce them.
- The service did not have arrangements in place for identifying, recording and managing risks. The service did not have a risk register or other document for

identifying any potential risks which could arise in the service. When we spoke with staff during inspection about this, they seemed unclear about what sort of issues could present as a risk in the service.

- There was little understanding of management of risks and issues, with no audit systems to monitor these. During inspection we identified key areas of risk in infection prevention and control, safeguarding systems and consent, which leaders had not been aware of.
- Staff told us they had day to day communications about any new issues that were identified and monthly team meetings to review where any changes were needed.
- We did not see any documented risk assessments that had been completed in the service, although the staff handbook stated these had been done. Following inspection we requested evidence of these but the service was unable to provide this. The manager and sonographer had completed fire extinguisher safety training and fire exits were clearly marked.

Managing information

- The service collected, analysed and used information well to support its activities using secure electronic systems and security safeguards.
- Computers used by staff and for service users choosing scan images in the reception area were password protected. Personal data was not retained by the service; after service users had selected their scan images, these were sent to the service user's email address using secure systems. The receptionist confirmed the correct email address with the service user after their appointment, turning the computer monitor discreetly to maintain privacy whilst the service user checked these details. After sending the email and attached images, we saw the receptionist deleted this permanently.
- The ultrasound scan machine was password protected and digital images were stored for twelve months before being destroyed. Paper records, including consent forms for under 18-year olds, were stored in a locked cupboard in the scan room. This was keypad locked when not in use.

Diagnostic imaging

- Information on the website was clear about services provided and the various costs of these. The client disclosure form included terms and conditions of the service.

Engagement

- The service engaged well with service users and staff.
- Women who accessed the service were given the opportunity to provide feedback relating to the service they received on the feedback form.
- Although the service did not have any specific staff engagement or staff questionnaire, we saw there was

positive and continuing engagement with staff in day to day activities. Staff team meetings were held monthly, including participation through internet access for those unable to attend in person. Staff had participated in a Christmas meal, with cost of this covered by the manager.

Learning, continuous improvement and innovation

- Staff in the service were enthusiastic about future opportunities for development. One member of staff was completing an access to health course at a local college and hoped to pursue training as a midwife following this.

Outstanding practice and areas for improvement

Areas for improvement

Action the provider **MUST** take to improve

- The provider must review policies and procedures for obtaining consent to care and treatment. The provider must ensure these reflect current legislation and guidance and that staff follow these at all times. Regulation 11(1) (2).
- The provider must review safeguarding systems and processes and operate these effectively to prevent abuse of service users. Regulation 13 (1)(2).
- The provider must ensure there are appropriate hand washing facilities available for service users and staff. Regulation 15(1)(a)(c)(f)(2)
- The provider must establish an effective and accessible system for identifying, receiving, recording, handling and responding to complaints by service users. Regulation 16 (1)(2)
- The provider must review and identify policies as appropriate for the service, including safeguarding guidance, to ensure this meets with national guidance and best practice. Regulation 17(1)(2)(a)

- The provider must have a system for identifying, managing and reducing any risks in the service. Regulation 17(1)(2)(b)
- The provider must review systems for staff mandatory training, supervision and appraisal. Regulation 18 (1)(2)(a).

Action the provider **SHOULD** take to improve

- The provider should review arrangements for recording any safeguarding concerns to ensure client confidentiality is maintained.
- The provider should consider extending audits or other measures to monitor performance and improve outcomes.
- The provider should consider developing a vision and strategy for the service.

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	<p>Regulation 11 HSCA (RA) Regulations 2014 Need for consent</p> <p>Care and treatment of service users must only be provided with the consent of the relevant person.</p> <p>If the service user is 16 or over and is unable to give such consent because they lack capacity to do so, the registered person must act in accordance with the Mental Capacity Act 2005.</p> <p>Parents or guardians of young people under the age of 18 years were asked to sign a consent form for the scan to be carried out. This would not be required.</p> <p>Staff had low awareness of the potential needs of people who lack capacity to consent.</p> <p>Staff had not completed training in consent or Mental Capacity Act.</p> <p>Regulation 11(1) (2) (3)</p>
Diagnostic and screening procedures	<p>Regulation 13 HSCA (RA) Regulations 2014 Safeguarding service users from abuse and improper treatment</p> <p>Systems and processes must be established and operated effectively to prevent abuse.</p> <p>Safeguarding systems in the service were not robust and staff awareness of potential safeguarding issues was low.</p> <p>Regulation 13(1)(2)</p>
Regulated activity	Regulation

This section is primarily information for the provider

Requirement notices

Diagnostic and screening procedures

Regulation 15 HSCA (RA) Regulations 2014 Premises and equipment

Premises and equipment should be clean and suitable for the purpose for which they are being used.

The toilet facilities available did not have a sink, requiring staff and service users to use a kitchen sink for hand washing.

The provider had a tick list for daily cleaning tasks, however there was no standardised documentation or directions for cleaning procedures.

Regulation 15 (1) (a)(c)(f)(2)

Regulated activity

Regulation

Diagnostic and screening procedures

Regulation 16 HSCA (RA) Regulations 2014 Receiving and acting on complaints

The provider did not have an effective and accessible system for identifying, receiving, recording, handling and responding to complaints by service users.

Regulation 16(1)(2)

Regulated activity

Regulation

Diagnostic and screening procedures

Regulation 17 HSCA (RA) Regulations 2014 Good governance

The provider did not have appropriate policies and procedures in place for the service.

The provider did not have a system for identifying, managing and reducing any risks in the service

This section is primarily information for the provider

Requirement notices

Regulation 17(1) (2)(a)(b)

Regulated activity

Diagnostic and screening procedures

Regulation

Regulation 18 HSCA (RA) Regulations 2014 Staffing

Sufficient numbers of suitably qualified, competent skilled and experienced persons must be deployed. They must receive such appropriate support, training, professional development, supervision and appraisal as necessary to enable them to carry out the duties they are employed to perform.

Staff did not receive mandatory training, supervision and appraisal.

Regulation 18(1)(2)(a)

Regulated activity

Diagnostic and screening procedures

Regulation

Regulation 19 HSCA (RA) Regulations 2014 Fit and proper persons employed

Persons employed must be of good character and have the qualifications, competence, skills and experience which are necessary for the work to be performed by them. Recruitment procedures must be established and operated effectively.

Staff files did not contain employee references and the provider did not have an induction procedure for staff.

All disclosure and barring checks had been completed in the month prior to the inspection

Regulation 19 (1)(a)(b)(2)