

# Precious Glimpse

## 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

Inadequate



Are services safe?

Inadequate



Are services effective?

Are services caring?

Good



Are services responsive?

Requires improvement



Are services well-led?

Inadequate



### Overall summary

Precious Glimpse is operated by Precious Glimpse Limited.

Precious Glimpse provides pregnancy reassurance and keepsake scans to self-paying members of the public. The service carries out trans abdominal ultrasound scans, including 2D, 3D and 4D baby keepsake scans and gender scans. The clinic does not provide diagnostic scans.

The service is based in Burnley and in addition to the manager employs two ultrasound assistants; and one part time receptionist.

The clinic is situated in Burnley Town Centre, close to public transport and nearby parking. The premises have a waiting room reception area; a scanning room; a storage room, office and toilet facilities.

We inspected this service using our comprehensive inspection methodology. We carried out an unannounced inspection on 15 August 2019.

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

# Summary of findings

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 Precious Glimpse was baby keepsake scanning.

## Services we rate

We rated this service as **Inadequate** overall because.

- The service did not provide mandatory training in key skills for all staff and did not ensure everyone completed it
- Staff did not always understand how to protect patients from abuse and had not completed safeguarding training in line with national safeguarding guidance.
- Staff did not identify risks for service users or follow systems to minimise risk.
- The service did not have any policies or procedures for escalating abnormal findings and did not provide evidence for how staff had been trained to identify these.
- The service did not use appropriate control measures to manage the risk of infection.

- The service did not provide care and treatment based on national guidance and evidence-based practice. Managers did not check to make sure staff followed guidance.
- The service did not ensure staff were competent for their roles.
- The service did not have a formal induction process for staff and records for disclosure and barring service enhanced checks were not completed for staff.
- Leaders did not operate effective governance processes throughout the service and there was a lack of systematic performance management which included the failure to identify and manage risk.

Following this inspection, we undertook due process regarding the significant safety concerns and told the provider to suspend the regulated activities at the location. The provider gave us assurances of immediate improvement actions taken and the suspension was removed at the end of the four week period.

We will continue to monitor the location and carry out a future inspection to ensure the provider has continued to make sustained improvements and that these are embedded.

We also issued the provider with two requirement notices with actions they must complete that affected Precious Glimpse Limited.

Ann Ford

Deputy Chief Inspector of Hospitals (North Region)

# Summary of findings

## Our judgements about each of the main services

### Service

#### Diagnostic imaging

### Rating

Inadequate



### Summary of each main service

The service provided at this location was diagnostic and screening procedures. We rated this core service as inadequate overall.

We saw no evidence to confirm staff were sufficiently skilled or qualified to deliver effective care and treatment to individuals using the service.

There were insufficient systems to safeguard adults and children who may be using the service.

Appropriate, policies and guidelines referencing national evidence-based practice were not developed by the provider.

Risk, governance and operational performance arrangements were not robust and there was ineffective monitoring of quality improvements.

# Summary of findings

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Inadequate 

# Precious Glimpse

## Services we looked at

Diagnostic imaging;

# Summary of this inspection

## Background to Precious Glimpse

Precious Glimpse is operated by Precious Glimpse Limited. The service has been registered at a previous location in Burnley from 2016 and has been registered at the current location since December 2018. The service offers pregnancy reassurance scans, 2D, 3D and 4D scans

to fee paying members of the public. It is a private clinic in Burnley England, primarily serving the communities of Burnley and the surrounding area. It also accepts service users on a self-referral basis from outside this area.

The service has had a registered manager in post since May 2016.

## Our inspection team

The team that inspected the service comprised a CQC lead inspector, and a CQC assistant inspector. The inspection team was overseen by Judith Connor, Head of Hospital Inspection.

## Information about Precious Glimpse

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

- Diagnostic and Screening services.

During the inspection, we inspected all areas at the clinic and observed three ultrasound scans. We spoke with three staff, the manager, a director and receptionist. We spoke with patients and reviewed service user feedback.

There were no special reviews or investigations of the clinic ongoing by the CQC at any time during the 12 months before this inspection. This was the clinic's first inspection since registration with CQC.

Activity (July 2018 to July 2019)

In the reporting period 30 July 2018 to 30 July 2019 there were 2,914 scans performed.

Track record on safety

- Zero never events (never events are serious patient safety incidents that should not happen if healthcare

providers follow national guidance on how to prevent them. Each never event type has the potential to cause serious patient harm or death but neither need have happened for an incident to be a never event), or serious incidents.

- Zero duty of candour notifications (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 people who use the services (or other relevant persons) of certain 'notifiable safety incidents' and provide reasonable support to that person).
- Zero safeguarding referrals.
- Zero incidences of healthcare acquired infections.
- Zero unplanned urgent transfers of a patient to another health care provider.
- Zero number of cancelled appointments for a non-clinical reason.

# 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 this service as **Inadequate** because:

- The provider did not identify or provide mandatory training in key skills to staff.
- Staff did not have the right qualifications, skills, training and experience to keep patients safe from avoidable harm and to provide the right care.  
Staff did not always understand how to protect service users from abuse, but staff knew how to contact other agencies in case of any safeguarding concern.
- Staff had only completed safeguarding vulnerable adults' level one training in the month before the inspection and had not completed safeguarding children training, although the service was offered to under 18-year olds.
- The service did not always control infection risk well and did not always use control measures to prevent the spread of infection.
- There was not always a member of staff trained in first aid on the premises.
- Staff did not assess risks to service users.
- The service did not have any policies or procedures for escalating abnormal findings and did not provide evidence for how staff had been trained to identify these.
- The provider did not ensure staff had completed necessary employment checks for new staff, including Disclosure and Barring Service checks.

**Inadequate**



### Are services effective?

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

- The provider did not develop policies or procedures to ensure care and treatment was delivered in line with national guidance and best practice.
- The provider did not monitor the effectiveness of care and treatment delivered or use audit to monitor outcomes and drive improvement.
- 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.

### Are services caring?

We rated this service as **Good** because:

**Good**



# Summary of this inspection

- Staff cared for service users with compassion and respect.
- Staff ensured women were comfortable during their appointments and protected their privacy and dignity.
- 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 this service as **Requires improvement** because:

- The service did not always identify people's individual needs prior to their appointment.
- Information was in English and translation facilities were not routinely provided for.
- Accessible toilet facilities were not available, but the service directed service users to appropriate local retail facilities if this was needed.
- Staff had not completed any training in Equality and Diversity.

However

- Women could access the service when they needed to.
- Appointments were planned to allow sufficient time for any discussion.

**Requires improvement**



## Are services well-led?

We rated this service as **Inadequate** because:

- Although there was an overall aim to develop the service, there was no strategy or plan documented to progress this.
- There was not an effective governance process in place. The service did not review its practice in line with national guidelines or review staff training or competencies.
- The service had few policies and procedures and those it had were very limited.
- The service did not have arrangements in place for identifying, recording and managing risks. Leaders were not always aware of key risks, issues and challenges in the service.
- The service did not have effective recruitment processes and records of Disclosure and Barring Service checks for staff had not been completed.

**Inadequate**







# Detailed findings from this inspection

## Overview of ratings

Our ratings for this location are:

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

# Diagnostic imaging

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

## Are diagnostic imaging services safe?

Inadequate 

We rated this service as **inadequate**.

### 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 completed safeguarding adults training in the month prior to the inspection, otherwise no other formal mandatory training was identified for staff to complete.**

- The service did not have a clear mandatory training policy and staff had not received any training in core subjects such as health and safety, infection prevention and control, and information governance. Prior to inspection, information provided by the service stated, 'all of our staff have the relevant training to carry out their roles to a high standard'. During inspection we did not see any records which confirmed this, and we found a lack of evidence to support this.
- Information provided by the service stated staff would complete training at the start of their employment. However, we did not see any records that were kept by the manager to confirm this and staff did not tell us of any mandatory training apart from safeguarding training.
- The manager had recently introduced a training matrix which documented staff knowledge of different procedures relating to the service. Included in the training matrix were various topics such as: confidence

in use of booking and payment systems; stock control; awareness of gestation for different types of scan offered; awareness of escalation process. A score was recorded for each member of staff to indicate the standard of attainment; these were high standard, requiring improvement, or not trained.

- Information recorded on the training matrix indicated the two ultrasound assistants in the service were deemed to be at a high standard for their ability to carry out abdominal reassurance scans, accurate gender scans, and accurate 3D/4D scans safely. However, there was no other supporting documentation to indicate the criteria and standards that had been applied, in order to assess that staff were competent in their use of ultrasound equipment.
- The manager described how they used their own judgement and observation to supervise staff whilst training, until they had reached a level where they were deemed to be competent. The manager said that on occasion scans were offered free of charge to service users, when these were undertaken by trainee staff.
- During inspection we saw certificates of completed safeguarding vulnerable adults' level one training and fire safety training that were held in staff files. All staff at Precious Glimpse Burnley had been completed these training courses in July 2019.

### Safeguarding

**Staff did not always understand how to protect service users from abuse, but they knew how to contact other agencies to share concerns. Staff had limited understanding of potential safeguarding issues which may arise in the service.**

# Diagnostic imaging

- All staff in the service had completed safeguarding vulnerable adults' level one training. Staff in the service had not completed any safeguarding children training. The service did not have a clear safeguarding policy for adults of children which referenced current national safeguarding guidance.
- Information provided by the service prior to the inspection indicated ultrasound scans, including 3D/4D keepsake and diagnostic screening services were provided to 16-17-year olds and over 17-year olds. The service did not ask for service users' date of birth on appointment booking or client waiver form and therefore were not able to identify if an under 18-year-old woman attended for a scan or if someone under the age of 16 years old had attended for a scan.
- Staff told us they would share any safeguarding concerns initially with the manager for escalation. We did not hear of any examples of safeguarding concerns identified in the service and the manager had not made any safeguarding referrals.
- A safeguarding book was kept in a locked drawer at reception for staff to record any safeguarding concerns where these had been identified. This also contained contact details for the local safeguarding team, adult social care services and Lancashire police service. We saw there had been no details of safeguarding concerns recorded in this book and the service had not made any safeguarding referrals in the last twelve months prior to inspection.
- The manager informed us they had a current Disclosure and Barring Service certificate and evidence of this was provided following inspection. A midwife who worked in the service had a Disclosure and Barring Service certificate relating to their NHS occupation, but the service did not have evidence of this at the time of inspection. The two other staff and one of the directors in the service did not have a completed Disclosure and Barring Service certificate. The service did not have ID of any of the staff or character or professional references.
- The premises appeared visibly clean and were free from clutter. A checklist of cleaning duties identified different cleaning tasks for all areas. Staff managed cleaning duties on a daily basis, following the checklist and cleaning rota. We reviewed latest records of daily checklists and saw these were all completed between 20 May 2019 and 5 August 2019. We were informed a weekly deep clean was carried out of the premises, however we did not see any additional record to confirm this.
- Staff wore uniforms with the company logo and were arms bare below the elbows. Staff did not have access to hand washing facilities in the scanning room but used hand gel prior to scans. Aprons were not provided but gloves were available for ultrasound assistants to wear during scan procedures. However, we observed that staff did not always use these.
- The service did not have an infection prevention and control policy, and staff had not completed any training for this.
- A paper towel covered the treatment couch during client scans and was replaced after each client's use. During the scan, women were given a paper towel to help maintain their dignity. Following the scan, paper towels were used to wipe the gel from the ultrasound transducer head. We observed during one scan the paper roll had fallen on the floor and was picked up and used again during the scan.
- Staff wiped down the treatment couch after each appointment, using domestic cleaning wipes. Although this followed guidance in the cleaning tasks schedule, this was not in line with infection prevention and control guidance, which recommends use of an antibacterial cleaning product. Ultrasound assistants maintained the daily cleanliness of the ultrasound machine.
- Handwashing signs were not displayed in the toilet facilities to prompt service users and staff.
- There had been no incidences of healthcare acquired infections at the service since it opened.

## Cleanliness, infection control and hygiene

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

## Environment and equipment

# Diagnostic imaging

## **The design, maintenance and use of facilities and premises kept people safe although the service was unable to provide records to show staff had completed training for use of the equipment.**

- The service had ground floor premises nearby to parking facilities, with main entrance at street level; this entrance was also the fire exit. External signage was clear for people accessing the service.
- The clinic had a large waiting area with reception, a scan room, toilet facility, a store room and a separate office facility located to the rear of the unit. The reception waiting area was light and spacious, with three sofas providing comfortable seating for people using the service. A large screen displayed family friendly images, in context of the service.
- 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. There were no reports of this having occurred.
- Records we reviewed showed the service arrangements for electrical safety testing with an external contractor. All electrical equipment we saw displayed a current electrical safety testing sticker.
- The scan room contained seating, the treatment couch and ultrasound system, together with a large screen for service users to view the scan. The furniture and equipment appeared in good condition.
- The storage room contained a locked cupboard for storage of substances hazardous to health, such as cleaning products. Various stock and items for sale were stored on shelves in an orderly manner.
- The storage room had two helium cylinders for inflating balloons, we saw these were freestanding and not secured. The storage room did not have a lock on the door but was visible from the reception desk and not immediately accessible from the waiting area.

## **Assessing and responding to patient risk**

## **The service did not have systems in place to assess and manage risks to women and their babies. There was no policy or procedure for escalating abnormal findings to keep women and their babies safe.**

- The service did not offer medical diagnostic imaging scans. Website information stated scans were non-medical, for baby bonding and souvenir purposes, not intended to replace routine NHS maternity scans and services.
- The service did not have a risk policy or guidance for risk assessing women using the service. The service did not have any criteria for excluding women from having a scan. Service users booking in were asked to complete their initials on a client waiver form prior to having a scan. The client waiver form asked women to confirm they were currently in good health and had no new or ongoing health concerns they needed to make Precious Glimpse aware of. Between January and August 2019, the service had scanned four women who were bleeding and therefore may possibly have been having a miscarriage at the time of their scan.
- The service did not have any policies or procedures for escalating abnormal findings and did not provide evidence for how staff had been trained to identify these. However, the service kept records of referral for cases where they had detected a possible anomaly following a scan, or advised the woman to seek further advice. We reviewed 25 referral records completed during January – August 2019. In each case, staff documented whether they had contacted NHS services on behalf at the woman's request, or whether the woman had been directed to seek further advice. Six records indicated staff had followed up the contact with NHS services; 13 records noted no further contact had been received. While the service stated that it was a non-medical service it had identified anomalies in 25 cases, However, staff did not have guidance to follow and staff, including the registered manager, had only received training on how to operate the equipment. This also meant the service was carrying out regulated activities beyond the scope of their registration.
- The client waiver form also stated, "Precious Glimpse Limited follows NICE guidance for frequency (sound waves) and length of scan which has found no detrimental effects in 40 years of case studies, but the British Medical Ultrasound Society do not recommend ultrasound for non-medical purposes." The provider did not have any record to demonstrate how they followed the NICE guidance referenced.

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- Women were not routinely asked to bring their maternity notes and for early pregnancy reassurance scans medical records would not generally be available. We observed pregnancy reassurance scans where ultrasound assistant advised service users on the possible gestation term of the pregnancy. This meant the service was providing a diagnostic scan which was acting beyond the scope of registration.
- The service had a safety policy which stated, 'the registered manager is first aid trained & all employees will complete a health and safety at work course at the start of their employment'. We did not see any records to confirm this and staff informed us they had not completed this.
- The manager stated they had completed first aid training and that a member of staff trained in first aid would always be present on site; however, the manager worked across different locations and was not always present. There were no records to confirm any other staff had completed first aid training and we were not assured there was always a member of staff trained in first aid on site at all times.
- The service did not undertake non-invasive prenatal blood tests for service users.

## Staffing

**There were sufficient staff to meet the needs of the service, however we were not assured all staff had the right skills and experience to keep people safe from avoidable harm and to provide the right care and treatment.**

- There were two part time ultrasound assistants and one part time receptionist working in the service. The registered manager also carried out scans when this was needed; staff worked together in shifts to provide reception cover. On occasion staff worked between other locations of Precious Glimpse limited if there was a need.
- There were no vacancies in the service at the time of inspection. Any sickness was covered between staff, as and when it occurred. The service did not employ bank or agency staff.

## Records

**Staff kept appropriate records of service users' care and treatment, using electronic systems and paper records. Records were clear, up-to-date and available to all staff providing care.**

- Women accessing the service completed a client waiver form at the time of their appointment. This stated the basic terms and conditions and identified the service user's consent for the scan procedure.
- 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.

## Incidents

**The service did not always manage patient safety incidents. Staff did not recognise or reported incidents and near misses. Managers did not investigate incidents or share lessons learned with the whole team and the wider service.**

- The provider had an incident policy dated 1 March 2019, which said 'All Incidents that happen while inside any Precious Glimpse studio must be reported using the accident and incident book which is located at reception. All incidents will also be reported immediately to the Registered manager'.
- The incident policy did not define what may constitute an incident and we saw no incidents had been recorded in the incident book held at the reception desk. The service had created an accident / incident form for staff to use, however we did not see any records of incident investigations or discussion about incidents.
- Staff were not provided with training regarding incidents but had a general awareness of their roles and responsibilities to raise any concerns and would discuss these with the manager in the first instance.
- 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

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provide reasonable support to that person. We were told of occasions where staff had communicated openly to share information with service users, after identifying a possible abnormality on their scan.

## Are diagnostic imaging services effective?

**The domain for effective was inspected but not rated**

### Evidence-based care and treatment

**The service did not provide care and treatment based on national guidance and evidence-based practice.**

- Protocols and pathways to support safe care and treatment of people who use the services were not established and there were no documented standard operating procedures for staff to follow for scan procedures.
- The manager had completed a two-day private training course in ultrasound awareness in May 2016. Following inspection, the manager provided a letter confirming this training had been completed. The letter stated the training included 'hands on training on the ultrasound equipment that you intend to use, including product training of the GE Voluson E8 Expert (ultrasound machine); how to start the machine, select functions appropriate to the scanning in pregnancy and how to select the correct settings to obtain an image in 2D, 3 / 4D and HD live to obtain images for reassurance and bonding.' The registered manager did not have any evidence of continued professional development or updated training on how to use the equipment.
- Staff were trained in use of the ultrasound equipment by the registered manager. There were no records to confirm the dates when staff had completed this training and records did not indicate the content of this training. Staff had not completed any other training in ultrasound practice outside of the service. The registered manager had not received any training or provide any evidence of competency to provide training on the equipment to others.
- The service had not participated in any audits or used audit information to plan where improvements could be

made. Audits, such as for infection control, booking forms, image quality, principles and safety problems of diagnostic ultrasound guidelines (ALARA), were not identified.

- 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.

### Patient outcomes

**Staff monitored feedback from service users but did not monitor the effectiveness of care and treatment or use the findings to improve them.**

- Staff recorded information about the number and type of scan appointments each month.
- The service maintained a secure file containing details of referrals where any concerns or anomalies had been identified following a scan. This included details of whether the provider had been requested to contact NHS services or not.

### Competent staff

**The service did not always ensure staff were competent for their role.**

- The provider did not maintain records of appropriate staff recruitment. In staff files we did not see completed application forms to work at the service, a history of employment, successful interview records, supply of professional references, or completion of enhanced Disclosure and Barring Service checks, which were appropriate to the current staff job role.
- There were no completed peer reviews for ultrasound assistants although the manager informed us of they would carry out a process of informal supervision.
- Staff had not had an annual appraisal, although the service had recently introduced documentation for conducting performance appraisals and the manager informed us this was a new system in practice and intended for future development. Staff we spoke with said they had met with the manager to identify their development needs.
- The service had recently introduced documentation for an induction checklist, but this had not been implemented to date. There had been no formal induction process for any new staff and no records

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kept for this, although new staff confirmed they would be shown the different tasks required for their role as needed. The manager confirmed they would be present during the first week of a new member of staff's employment to provide this direction.

## 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.
- The service linked with local NHS maternity services with consent of women, where there was an identified need. Staff reported there could be difficulty on occasions in making this communication.

## Seven-day services

- The service was open on Thursday, Friday, Saturday and Sunday between 8.30am and 4.30pm at the location. Should women wish to have an appointment outside of the clinic opening hours, appointments could be offered at other locations operated by Precious Glimpse Limited.

## Consent and Mental Capacity Act

### Staff did not always support service users to make informed decisions about their care and treatment. They did not follow national guidance to gain patients' consent. They did not know how to support patients who lacked capacity to make their own decisions or were experiencing mental ill health.

- The provider told us that people self-referred to the service and consent was captured within the client waiver form, which service users were asked to complete by signing with their initials.
- The service had a consent policy which contained limited information about needing to complete a consent form.
- The client waiver form detailed consent for the ultrasound scan procedure. The manager stated the service saw only medically fit individuals and did not perceive there had been any service users who lacked

mental capacity or who had a need relating to their mental health. We reviewed records which indicated women may have been having a miscarriage at the time of their scan, therefore the provider was not following this guidance in practice.

- At the time of our inspection staff had not completed any training in consent or the Mental Capacity Act (2005) and the consent policy did not reference the Mental Capacity Act (2005).

## Are diagnostic imaging services caring?

Good 

We rated this service as **good**.

## Compassionate care

### Staff treated patients with compassion and kindness, respected their privacy and dignity, and took account of their individual needs.

- Staff were welcoming and informative to people using the service. 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 ultrasound assistant spoke calmly to explain what was happening during the scan and what was being observed on the scan images.
- The ultrasound assistant checked women were comfortable during the scan and where needed, gave clear guidance if women needed to change their position.
- During the inspection we reviewed feedback from people who had used the service. Comments included, "staff were really great" and "the images were really good". One said their favourite part of the experience was, "seeing our little girl and not feeling rushed".

## Emotional support

### Staff provided emotional support for service users to minimise their distress.

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- 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.
- Staff described how they supported women if they needed to communicate any concerns and appointment times allowed for flexibility if this arose. Staff described how they would support women when sharing information regarding possible anomalies, using calmness and clear language. We observed how staff were sensitive and supported a woman who had experienced a positive scan result after having lost a pregnancy in the past.

## Understanding and involvement of patients and those close to them

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

- During our inspection we observed staff supporting and involving women, their partners and families to understand their condition and make decisions about their care
- The ultrasound assistant made sure that women and those close to them, felt able to ask questions about their care and treatment. They gave people who use the services time to ask questions.
- Information regarding the different types of scans and packages available for people to purchase was clearly presented on the provider's website. Feedback from service users indicated they were happy with the service they had received and felt supported throughout.

## Are diagnostic imaging services responsive?

Requires improvement 

We rated this service as **requires improvement**.

## Service delivery to meet the needs of local people

### The service planned and provided care in a way that met the needs of local people.

- The premises were located in the town centre on the ground floor, with a reception area, a scanning room, a storage room, office and toilet facilities.
- In the scan room there was an ultrasound machine, 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.

## Meeting people's individual needs

### The service did not always take account of patients' individual needs and preferences. Staff did not always identify reasonable adjustments to help patients access services.

- The premises were accessible for wheelchair users although toilet facilities were not accessible. Staff would direct any service users to nearby retail facilities for this need. The treatment couch was height adjustable and accessible for service users.
- Staff described how they would respond to different individual needs on a case by case basis, although these were not identified at the time of booking.
- The website and other clinic information was only provided in English language format. The manager stated the service had used internet translation services on previous occasions where there had been a need for language translation.
- Staff had not completed any Equality and Diversity training, but had some awareness of different individual needs.

## Access and flow

### Women could access the service when they needed it and received the right care in a timely way.

- Appointments were booked at a time to suit individuals' preference; appointments and staffing were planned according to demand.
- The service allocated a fifteen-minute gap between appointments to ensure sufficient time for any

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questions and for service users to not feel rushed. This also allowed extra time in cases where staff needed to share any negative findings, such as if there was an absent foetal heartbeat.

- The service had a system in place for service users who required a rescan. Rescans were provided where it had not been possible for the ultrasound assistant to obtain a clear image due to the baby's stage of gestation.
- No planned appointments were cancelled or delayed for a non-clinical reason such as breakdown of equipment.
- The service did not have a waiting list.

## Learning from complaints and concerns

**The service had a limited complaints policy and did not have a process to investigate complaints or share any learning from complaints.**

- The service had a complaints policy containing limited information to say complaints would be responded to by the manager.
- The service recorded no complaints in the reporting period July 2018 to July 2019. The manager stated they were aware of a potential complaint currently but did not know any further details regarding this issue.
- Staff in the service informed us any concerns would be responded to if they arose and raised to the manager if these could not be resolved in the first instance.
- The service reviewed comments from feedback forms to identify any changes or improvements needed.

## Are diagnostic imaging services well-led?

Inadequate 

We rated this service as **inadequate**.

### Leadership

**Leaders had the abilities to run the service and understood the issues the service faced but did not identify priorities. They were visible and approachable for service users and staff.**

- The leadership team was made up of two directors, one of whom was the registered manager and ultrasound technician. The registered manager did not inform us of any specific leadership training they had completed for their role but had an understanding of their service.
- The manager was visible and approachable; staff in the service said they were well supported.

### Vision and strategy

**The service did not have a vision or current strategy.**

The service did not have a vision for what it wanted to achieve or a strategy to turn this into action.

- We were told the previous business plan had reached a stage where it had achieved its current objectives, with the proposed opening of a fourth location
- Staff we spoke with expressed a general aspiration to develop the service, and to complete ultrasound training, but were unaware of any further detailed plans.

### Culture

**Staff felt respected, supported and valued. The service had an open culture where service users, their families and staff could raise concerns without fear.**

- The manager promoted a positive culture across the service that supported and valued staff.
- There was an open and transparent culture within the service; staff we spoke with were enthusiastic about the service and proud of their work.
- 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

**Leaders did not operate effective governance processes and were unclear about their accountabilities. There was no process to oversee key items and a lack of systematic performance management.**

- The service did not have systems or procedures in place to ensure that policies and practice were appropriate, regularly reviewed or referenced current best practice guidelines.
- Whilst we saw for some areas of service activity, the provider had created a policy, these comprised a statement of intention only, without any detail for how the policy would be implemented or monitored.
- There was no governance framework to support the delivery of good quality care. Although the stated aspiration for the service was to 'deliver the highest quality treatment and care possible', the service did not complete quality audits or use this information to drive improvement.
- The service did not have recruitment processes for employees and staff files did not contain certificates of Disclosure and Barring Service (DBS) checks; this also included DBS checks for one of the company directors. We did not see any evidence of references requested or received in staff files, or photographic ID for employees. Following inspection, the registered manager confirmed they had current DBS certification associated with their CQC registration, also another member of staff had current DBS certification in association with their NHS employment.

## Managing risks, issues and performance

**The service did not have systems to identify risks, plan to eliminate or reduce them. There was little understanding or management of risks and issues, and there were significant failures in performance management and audit systems and processes.**

- The service had a business continuity plan which identified actions to take in case of power failure, IT systems failure or phone systems failure. There were no risks identified in relation to clinical aspects of care for women using the service.
- There were no arrangements in place for identifying, recording and managing day to day risks for service

users and staff in the service. During the inspection we identified key areas of risk in mandatory training, safeguarding and recruitment procedures, which leaders had not been aware of.

## 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.
- The ultrasound scan machine was password protected and we were told digital images were manually deleted from here after three months. Scan images were transferred via a data stick to a reception computer for service users to choose their images. The data stick was kept in a locked drawer when not in use.
- The service kept paper records of past client waiver forms from 2018 and 2019, which were stored in a locked office.
- Information on the website was clear about services provided and the various costs of these. The client waiver form confirmed terms and conditions of the service.
- The service did not have a confidentiality and General Data Protection Regulation (GDPR) policy in place and were unable to demonstrate how they fulfilled the requirements of GDPR and related legislation. Staff had not received any training in information governance.

## Engagement

**Leaders and staff openly engaged with service users and staff, to help improve services.**

- The provider engaged with service users through the service's website and social media accounts, to promote its services. The provider monitored feedback from service users via follow up surveys and social media comments.

## Learning, continuous improvement and innovation

## Diagnostic imaging

- Although we did not hear of any specific development plans, staff in the service were keen to improve services where they could and were open to opportunities to do this.

# Outstanding practice and areas for improvement

## Areas for improvement

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

- The provider must review and develop specific policy guidance in relation to mental capacity and consent and ensure staff have the necessary training and understanding in order to support service users to make an informed decision regarding their care and treatment. Regulations 12 (1) (2) (c), 13 (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 staff are trained in and follow infection prevention and control guidance, and use personal protective equipment appropriately at all times. Regulation 12 (1) (2)(c)
- The provider must review and identify training and policies as appropriate for the service, including safeguarding training, to ensure this meets with Safeguarding Intercollegiate document guidance (2018) Regulation 12 (1)(2)(c)
- The provider must review and implement robust systems to identify, assess and mitigate any risks relating to the safety, health and welfare of people who use the service. Regulation 12(1)(2)(a), (b)
- The provider must assess, monitor and improve the quality and safety of the services provided, and implement systems to evaluate and improve their practice. Regulation 17(1)(2)(a)

- The provider must establish effective systems to assess, monitor and mitigate the risks relating to the health, safety and welfare of service users and others who may be at risk from the carrying on of the regulated activity. Regulation 17(1)(2)(b)
- The provider must establish effective systems to ensure records are maintained in accordance with the requirements of the General Data Protection Regulation Regulation 17 (1) (2) (c)
- The provider must ensure an appropriate induction programme is provided for new staff in the service. Regulation 18 (2) (a)
- The provider must ensure there are robust systems in place for the recruitment and employment of persons employed in the service. Regulation 19 (1) (a) (b) (2)

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

- The provider should consider displaying hand washing signs in the toilet facilities.
- The provider should continue to implement appraisal and supervision systems for staff.
- The provider should continue to develop incident investigation procedures to ensure there are systems for sharing learning with staff.
- The provider should review arrangements for safe storage of helium canisters in the stock room and consider a security lock.

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

Diagnostic and screening procedures

#### Regulation

Regulation 5 HSCA (RA) Regulations 2014 Fit and proper persons: directors

The provider did not have robust recruitment and employment procedures and one of the directors did not have a completed DBS check, employment references, or photographic ID.

Regulation 5 (1) (2)(a) (3)(a)(e)

#### Regulated activity

Diagnostic and screening procedures

#### Regulation

Regulation 17 HSCA (RA) Regulations 2014 Good governance

The provider did not have effective systems in place to assess, monitor and improve the quality and safety of the services provided.

The provider did not have effective systems in place to assess, monitor and mitigate the risks relating to the health, safety and welfare of service users and others who may be at risk from the carrying on of the regulated activity.

The provider did not have effective systems for maintaining records to meet the requirements of the General Data Protection Regulation

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

#### Regulated activity

#### Regulation

This section is primarily information for the provider

## Requirement notices

Diagnostic and screening procedures

Regulation 18 HSCA (RA) Regulations 2014 Staffing

The provider did not have an appropriate induction programme for new staff in the service.

The provider did not identify mandatory training appropriate for the service.

Regulation 18 (1) (2) (a)

This section is primarily information for the provider

## Enforcement actions

### 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

Diagnostic and screening procedures

#### Regulation

Regulation 12 HSCA (RA) Regulations 2014 Safe care and treatment

The service did not have systems in place to

Identify and mitigate any risks relating to the safety, health and welfare of people who use the service

Staff had not completed training in consent and were not aware of the requirements of the Mental Capacity Act 2005 with regard to consent.

Staff had not completed training in infection prevention and control.

Regulation 12 (1) (2) (a) (b) (c)

#### Regulated activity

Diagnostic and screening procedures

#### Regulation

Regulation 13 HSCA (RA) Regulations 2014 Safeguarding service users from abuse and improper treatment

Staff had not completed the appropriate level of safeguarding children and adults training and safeguarding systems were not embedded.

Regulation 13 (1)(2).

#### Regulated activity

Diagnostic and screening procedures

#### Regulation

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

This section is primarily information for the provider

## Enforcement actions

The provider did not have robust recruitment and employment procedures and staff did not have completed DBS checks, employment references , or photographic ID.

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