Tyneside Pregnancy Advice Centre

Quality Report

14 Portland Terrace
Newcastle upon Tyne
NE2 1QQ
Tel: 0191 239 9933
Website: www.tyneside-pregnancy.org.uk

Date of inspection visit: 14 May 2019
Date of publication: 31/07/2019

This report describes our judgement of the quality of care at this location. It is based on a combination of what we found when we inspected and a review of all information available to CQC including information given to us from patients, the public and other organisations

Ratings

Overall rating for this location	Requires improvement
Are services safe?	Requires improvement
Are services effective?	Not sufficient evidence to rate
Are services caring?	Good
Are services responsive?	Good
Are services well-led?	Requires improvement

Overall summary

Tyneside Pregnancy Advice Centre is operated by Foundation For Life. The service provides an opportunity to have a free ultrasound scan (use of sound waves to get pictures of the inside of a body) to adolescents and women who think they may be pregnant: specifically, the scan is limited to confirming the presence of a heartbeat in the womb. If it is not possible to identify a heartbeat in the womb the service user is referred to a local early pregnancy assessment unit (EPAU) at the local NHS trust to exclude other possible diagnoses, such as, an ectopic pregnancy or miscarriage. It sees adolescents and women who self-refer or who have been referred by their GP (or other healthcare provider).

The service is situated on the ground floor of a terraced house and is located a short walk from local public

Summary of findings

transport networks. The house is owned by a third party and is occupied by other businesses. Service users arriving were met by staff and directed to a reception room and waiting area. Adjacent to this (and moving down towards the back of the premises) was an advising room, a multi-sex toilet, the ultrasound scanning room, a store room, kitchen and staff toilet, ending with the fire exit. On the first floor were staff offices to which service users and the public did not have access.

The service provided an ultrasound scan to service users aged below 16 to 65 in relation to pregnancy (from the earliest stages of pregnancy at six weeks). Although not the primary purpose of an ultrasound scan, service users could take home with them a two dimensional non-colour picture of their ultrasound scan where appropriate.

We inspected this service using our comprehensive inspection methodology. We carried out the short-announced part of the inspection on 14 May 2019. We had to conduct a short-announced inspection because the service was only open at limited times during the week.

To get to the heart of experiences of care and treatment for service users, we ask the same five questions of all services: are they safe, effective, caring, responsive to people's needs, and well-led? Where we have a legal duty to do so we rate services' performance against each key question as outstanding, good, requires improvement or inadequate.

Throughout the inspection, we took account of what people told us and how the provider understood and complied with the Mental Capacity Act 2005.

Services we rate

We had not previously rated this service which was registered on 1 October 2013.

At this inspection we rated it as **Requires improvement** overall.

We found the following issues, that the service provider needs to improve:

- Governance: the service had gaps in its clinical governance process that was in place to maintain quality and put safety of users of the service first. For instance, the service regarded the guidance for staff on discrete risks, such as premises and equipment, fire safety, aggression, and infection control, as its risk policy. However, this did not set out details of the tools and processes staff should use to assess risks, such as a risk management framework, or how staff measured performance on managing risks, plus there was no risk register. Further, lack of a quality assurance system around safeguarding referrals for adolescents engaged in sexual activity under the age of 16 but older than 13 ('under age adolescents'); or no policy for the deteriorating service user.
- Children safeguarding: we found issues with: the policy for referring under age adolescents to safeguarding authorities; benchmarking with published national guidance of in-house training for staff about children safeguarding; having regard to such national guidance, the levels to which staff were trained in children safeguarding; staff undertaking ultrasound scans not being trained in spotting physical signs of female genital mutilation (FGM).
- Complaints: the location did not display any information to inform service users about their right to and how to complain about the service. Further, there was no independent body a service user could progress their complaint with after a final decision under the service's complaints system had been made.
- Infection control: clinical waste was not disposed of in accordance with guidance set out in Health Technical Memorandum 07-01: Safe management of healthcare waste.
- Equipment: items of portable electrical equipment in use, such as electrical heaters or light stands, had not been safety electrical checked.

But we found the following areas of good practice:

- Staff training in mandatory training was up to date.
- The service was visibly clean and mostly un-cluttered and all ultrasound equipment seen had been maintained.
- The service used competent staff to do the scanning who had been appraised.
- If needed service users could be referred to the NHS and staff had a process to follow.
- The service ran to time, with no cancellations.
- The feedback forms we saw were positive about service user experience at the service.

Summary of findings

- Staff we spoke with and minutes of meetings we reviewed showed an open culture where the leadership team were accessible and approachable.

Following this inspection, we asked the provider to provide us with an action plan to address our concerns above about children safeguarding. The provider supplied an action plan to address our concerns. This will be monitored by way of continuing engagement.

We also issued the provider with one requirement notice that affected the service. Details are at the end of the report.

Also, below we have suggested other improvements, even though a regulation had not been breached, to help the service improve.

Ann Ford

Deputy Chief Inspector of Hospitals (North)

Summary of findings

Our judgements about each of the main services

Service	Rating	Summary of each main service
Diagnostic imaging	Requires improvement 	At this inspection we rated the service as **Requires improvement** overall. We found the following issues, that the service provider needs to improve: • Governance: the service had gaps in its clinical governance process that was in place to maintain quality and put safety of users of the service first. For instance, the service regarded the guidance for staff on discrete risks, such as premises and equipment, fire safety, aggression, and infection control, as its risk policy. However, this did not set out details of the tools and processes staff should use to assess risks, such as a risk management framework, or how staff measured performance on managing risks, plus there was no risk register; further, lack of a quality assurance system around safeguarding referrals for under age adolescents; or no policy for the deteriorating service user. • Children safeguarding: we found issues with: the policy for referring under age adolescents to safeguarding authorities; benchmarking with published national guidance of in-house training for staff about children safeguarding; having regard to such national guidance, the levels to which staff were trained in children safeguarding; staff undertaking ultrasound scans not being trained in spotting physical signs of female genital mutilation (FGM). • Complaints: the location did not display any information to inform service users about their right to and how to complain about the service. Further, there was no independent body a service user could progress their complaint with after a final decision under the service's complaints system had been made. • Infection control: clinical waste was not disposed of in accordance with guidance set out in Health Technical Memorandum 07-01: Safe management of healthcare waste.

Summary of findings

- Equipment: items of portable electrical equipment in use, such as electrical heaters or light stands, had not been safety electrical checked.

But we found the following areas of good practice:

- Staff training in mandatory training was up to date.
- The service was visibly clean and mostly un-cluttered and all ultrasound equipment seen had been maintained.
- The service used competent staff to do the scanning who had been appraised.
- If needed service users could be referred to the NHS and staff had a process to follow.
- The service ran to time, with no cancellations.
- The feedback forms we saw were positive about service user experience at the service.
- Staff we spoke with and minutes of meetings we reviewed showed an open culture where the leadership team were accessible and approachable.

Summary of findings

Contents

Requires improvement

Tyneside Pregnancy Advice Centre

Services we looked at
Diagnostic imaging

Summary of this inspection

Background to Tyneside Pregnancy Advice Centre

Tyneside Pregnancy Advice Centre is operated by Foundation For Life. The service provides an opportunity to have a free ultrasound scan (use of sound waves to get pictures of the inside of a body) to adolescents and women who think they may be pregnant: specifically, the scan is limited to confirming the presence of a heartbeat in the womb. If it is not possible to identify a heartbeat in the womb the service user is referred to a local EPAU to exclude other possible diagnoses, such as, an ectopic pregnancy or miscarriage. The service sees adolescents and women who self-refer or who have been referred by their GP (or other healthcare professional). The service primarily served the communities of Newcastle Upon Tyne.

The service has had a registered manager in post since 2013. The service is registered for the following regulated activities:

- Diagnostic and screening procedures

We conducted a short-announced inspection of the ultrasound scan part of the service on 14 May 2019.

The service also offered: a pregnancy advice service and scanned volunteer adolescents and women, not as any part of their care or treatment, but for training purposes. We did not inspect these services.

Our inspection team

The team that inspected the service comprised a CQC inspector. The inspection team was overseen by Sarah Dronsfield, Head of Hospital inspection.

Information about Tyneside Pregnancy Advice Centre

The clinic is registered to provide the following regulated activities:

- Diagnostic and screening procedures.

During the inspection, we inspected the ultrasound scan part of the service. We spoke with three staff, (two part-time sonographers, one of whom was also the service's registered manager) and the service's co-ordinator. We were unable to speak with any service users but reviewed written feedback sheets from ten service users and reviewed ten service user records. We reviewed staff records in relation to the three part-time sonographers and one trainee sonographer and the directors.

There were no special reviews or investigations of the service ongoing by the CQC at any time during the 12 months before this inspection. This was the service's first inspection since registration in October 2013.

Activity – March 2018 to March 2019 (reporting period)

In the reporting period there were:

- 115 ultrasound scans.
- Zero complaints.

The service at the location employed three part-time sonographers and one trainee sonographer who scanned service users. The balance of staff was made up of volunteer receptionists and the directors, totalling 15 staff. Opening times at the location were invariably 10am to 1pm apart from Wednesdays which tended to be 7.30pm to 9pm. Opening times were displayed on the service's website.

Track record on safety

- Zero service user deaths or never events.
- Zero duty of candour notifications.

Summary of this inspection

- Zero safeguarding referrals.
- Zero incidences of healthcare acquired infections.
- Zero unplanned urgent transfer of a service user 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?

Requires improvement

Are services safe?

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

- Children safeguarding: we found issues with: the policy for referring under age adolescents to safeguarding authorities; benchmarking of in-house training for staff about children safeguarding with published national guidance; levels to which staff were trained in children safeguarding, having regard to such national guidance; staff undertaking ultrasound scans not being trained in spotting physical signs of female genital mutilation (FGM).
- Assessing and responding to risk: there was no policy for the deteriorating service user.
- Infection control: clinical waste was not disposed of in accordance with guidance set out in Health Technical Memorandum 07-01: Safe management of healthcare waste.
- Equipment: items of portable electrical equipment in use, such as electrical heaters or light stands, had not been safety electrical checked.

However:

- All staff mandatory training was up to date.
- All areas of the location appeared visibly clean and ultrasound equipment was maintained.
- Infection control audits had recently been implemented and were being conducted to ensure compliance.
- Staffing was safe.
- Service user records were secure, detailed and legible and staff knew how to report incidents.

Are services effective?

Not sufficient evidence to rate

Are services effective?

We do not rate effective at present but found the following:

- Staff followed national guidance such as that published by the British Medical Ultrasound Society.
- The service monitored service user outcomes by reviewing scans and reports and acting on service user feedback.
- The service employed competent staff and checked their competency at an annual appraisal.

Summary of this inspection

- The service provided services from the location on a service user demand basis.

Are services caring?

Good

We rated it as **Good** because:

- The service provided compassionate care to its service users with all service users' feedback forms we reviewed describing a positive experience.
- The service thought about the emotional needs of service users by offering a chaperone where needed.
- The service understood and involved service users in their care by providing clear information on the results of their scan.

Are services responsive?

Good

Are services responsive?

We rated it as **Good** because:

- The service operated around the needs of service users with appointments made to suit the service user.
- Individual needs were addressed on booking with a medical history being taken and any needs, such as an interpreter or chaperone, being addressed.
- The service ran to time and there were no cancellations.

However:

- Complaints: the location did not display any information to inform service users about their right to and how to complain about the service. Further, there was no independent body a service user could progress their complaint with after a final decision under the service's complaints system had been made.

Are services well-led?

Requires improvement

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

- Governance: the service had gaps in its clinical governance process that was in place to maintain quality and put safety of users of the service first. For instance, the service regarded the guidance for staff on discrete risks, such as premises and equipment, fire safety, aggression, and infection control, as its risk policy. However, this did not set out details of the tools and processes staff should use to assess risks, such as a risk management framework, or how staff measured performance

Summary of this inspection

on managing risks, plus there was no risk register; further, lack of a quality assurance system around safeguarding referrals for under age adolescents; or no policy for the deteriorating service user.

However:

- The leadership team, being employed clinicians in the NHS, had the experience and skills to run the service safely and were visible and approachable for staff.
- The service had a vision and strategy which staff knew about that was focussed on the service user experience.
- Staff reported an open and positive culture with good engagement with the staff and service users.

Detailed findings from this inspection

Overview of ratings

Our ratings for this location are:

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

Notes

We do not currently rate the effective domain.

Requires improvement

Diagnostic imaging

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

Are diagnostic imaging services safe?

Requires improvement

We rated it as **requires improvement.**

Mandatory training

- The service provided mandatory training in key skills to all staff and made sure everyone completed it.
- Data supplied by the service showed that, in the period March 2018 to March 2019, 100% of staff achieved the 100% target of having received training in: early pregnancy ultrasound training and receptionist induction training. For fire safety training compliance was at 80% and for regular full team training updates compliance was at 87%. The failure to achieve the 100% target was due to staff absence.
- We saw from records supplied that sonography staff took part in six monthly reviews of their ultrasound practice carried out by an external radiographer. Although not documented, staff told us volunteer receptionists underwent regular assessments of their role carried out by the service co-ordinator.

Safeguarding

- Staff understood how to protect service users from abuse but we were not able to assess whether the service worked well with other agencies to do so as no safeguarding referrals had been made in the period March 2018 to March 2019.
- The service had an up to date policy which outlined what abuse looked like and what to do if abuse was suspected. This covered female genital mutilation (FGM) and radicalisation (PREVENT) and child sexual exploitation (CSE).
- During the period March 2018 to March 2019 the service had not made any safeguarding referrals to the local authority safeguarding team.
- We had concerns about the lack of a quality assurance system around staff reporting of CSE and whether the policy for CSE kept under age adolescents safe. Also, staff confirmed their ultrasound training did not cover the practical skills of spotting FGM. Further, staff did not have access to standard forms for them to use to record and report safeguarding although they did have a relevant list of safeguarding contact numbers.
- In terms of training for safeguarding, staff at the service had access to two directors who were trained by their main employer, respectively, to level three for safeguarding children and level two for adults, and level two for both children and adults. Apart from this, the only other non-volunteer member of staff who held a formal safeguarding qualification was the registered manager (also a sonographer) who was trained to level two for children and adults.
- All other sonographers working with children and adults and volunteer receptionists received 'in-house' training on safeguarding from the directors. Staff told us this occurred at team meetings (with handouts) and through provision of the policies and procedures noted above. But staff we spoke with were not able to confirm that such training had been benchmarked against published national guidance for children safeguarding training, so it was not possible to say at what level this training was to.

Requires improvement

Diagnostic imaging

- The only intimate ultrasound procedure sonographers performed were trans-vaginal scans and then only if necessary following a trans-abdominal scan. Staff confirmed that with such intimate procedures a chaperone was always offered and to promote privacy and dignity steps were taken to cover the area being scanned.
- All staff working at the service had a DBS check that was current and staff files seen showed a full employment history was taken together with references.
- Staff wore photo identification badges so service users could identify them as staff.
- Following our inspection we asked the service to supply us with an action plan to address the concerns we had, noted above, around policies and procedures regarding children safeguarding, training, and training levels. The service supplied us with an action plan to address our concerns. We will continue to monitor this action plan following publication of this report.

Cleanliness, infection control and hygiene

- The service controlled infection risk well but clinical waste was not disposed of in accordance with guidance set out in Health Technical Memorandum 07-01: Safe management of healthcare waste.
- The service had an up to date policy on infection control. The service had appointed one of its part-time sonographers as infection control lead.
- The premises were visibly clean. In the twelve months prior to inspection there were zero incidences of healthcare acquired infections.
- Since April 2019 the infection control lead had started an infection control audit which looked at infection control issues including hand hygiene. But the audit was still in progress and the results had not been written-up. This meant we could not review the results. Staff confirmed that if there were any actions flowing from the audit they would be discussed at one of the regular monthly team meetings.
- The flooring in the ultrasound scanning room was made of an easily wipeable material which promoted safe infection control. But the mop staff showed us, which was used to clean the ultrasound scanning room floor, appeared dirty. Staff could not tell us when they last had the mop head changed.
- Staff who were sonographers cleaned the ultrasound machine using wipes and gels in between service users but the service did not carry out spot checks of the machine to detect any infections.
- The couch in the ultrasound scanning room used by service users was covered with disposable paper. This was changed between service users and the couch wiped with an antiseptic wipe before laying out a new sheet of disposable paper.
- Any probes were wiped before and after use with an antiseptic wipe. If an invasive probe were used this was covered with a single use disposable antiseptic cover.
- A sink was available in the ultrasound scanning room and staff told us that they washed their hands before and after contact with the service user. The April infection control audits confirmed this. We saw posters above the sink to promote good hand washing technique.
- Staff explained that the majority of ultrasound procedures carried out at the location were non-invasive and involved minimal contact with service users. Service users were only required to remove clothing if a trans-vaginal scan was being performed. If this was necessary, staff told us they left the room to allow the service user to undress and redress. For such procedures staff wore disposable gloves and were bare below the elbow.
- Staff did not routinely check whether service users were infected with any communicable virus, such as flu, but indicated that they would clean down the ultrasound scanning room thoroughly if such a service user had been seen in it. Staff told us that in future they will consider asking service users about such matters as part of the booking process to enable such service users to be a last appointment.
- The service generated clinical waste (disposable probe covers used for vaginal scans) but disposed of these in its domestic waste which was not in accord with guidance set out in Health Technical Memorandum 07-01: Safe management of healthcare waste.

Environment and equipment

- The design, maintenance and use of facilities, premises and equipment kept people safe. Staff were trained to use them.
- Service users accessed the service on the ground floor of a terraced house a short walk from public transport networks.

Diagnostic imaging

- While a wheelchair user could access the service's premises, the service was not offered to service users who used a wheelchair because the service did not have any hoists to safely transfer a service user from their wheelchair to the scanning couch.
- Access to the premises was by using a buzzer which was answered by a member of staff who would escort a service user to reception. The reception area had adequate seating.
- A volunteer receptionist was always on duty with a part-time sonographer.
- In the event of a fire, the premises had smoke alarms but no fire alarm. We walked the route that would be used in the event of a fire following the signs in place. Our route was not obstructed. However, the fire exit door led out onto a car park at the rear of the premises. It was just possible to open the fire exit door without it scraping and being obstructed by a parked car. Staff told us they had reported this to their landlord.
- All fire extinguishers seen had been checked in the last year.
- The environment was visibly clean, and mostly free of clutter and ultrasound equipment used had been maintained in the last year. The multi-sex toilet for use by service users was visibly clean although there was no rota to show when it was last cleaned and by who.
- The ultrasound scanning room had a door that was lockable but no means of telling, from the outside, whether the room was in use. No panic alarm system was in the room should a sonographer be in the room on their own with a service user or relative who became violent.
- The ultrasound scanning room contained seating for one, the couch the service user used, and the ultrasound machine, together with the sink, some unlockable cupboards, and the monitor on the wall.
- Staff told us that they regularly checked stocks at the location, such as antiseptic wipes or ultrasound gel, and re-stocked the unlockable cupboards that were situated in the ultrasound scanning room. We saw that stock seen was all in date. However, even though some of the ingredients on some of the stock seen appeared hazardous to health if ingested, staff told us they did not lock these substances away. The service did not have a policy for controlling substances hazardous to health.
- Staff told us that portable electrical equipment, (excluding the ultrasound machine) had not been electrical safety checked.

Assessing and responding to service user risk

- The service regarded the guidance for staff on discrete risks, such as premises and equipment, fire safety, aggression, and infection control, as its risk policy. However, this did not set out details of the tools and processes staff should use to assess risks, such as a risk management framework, or how staff measured performance on managing risks, plus there was no risk register. While the service had no written policies or procedures to support staff in assessing and responding to a deteriorating service user, it did provide care and treatment that addressed some risks.
- Prior to the inspection we asked the service to complete a questionnaire. In response to this questionnaire the service stated that it did not have a policy for the management of a deteriorating service user or a policy for transfer of such a service user. If a service user deteriorated while at the service's location staff would phone 999 and request an urgent ambulance. But no staff, apart from those who happened to have a clinical background, had been trained in basic life support to provide care to the service user pending arrival of the ambulance. In particular, volunteer receptionists had not been so trained. Also, there was no alarm in the scanning room to summon other staff if a service user felt unwell.
- One of the principal ways the service assessed and responded to service user risk was by ensuring that on booking, they only saw service users who were low risk adolescents or women with an unplanned pregnancy. For instance, they did not see service users with a history of bleeding or cramping. Further, on booking, a relevant medical history was obtained from the service user.
- We saw staff identified service users by name and address and date of birth. This ensured the right person was receiving the ultrasound scan.
- Public Health England had issued advice about the risks linked to baby souvenir scanning, where the purpose of the scan is not diagnostic but instead to obtain a picture of the baby. Staff told us the service never performed an ultrasound scan purely to obtain a picture of the baby. Any picture of the baby would be supplied as part of an ultrasound scan designed to establish a heartbeat and its location.

Requires improvement

Diagnostic imaging

- The service reported zero unplanned urgent transfer of a service user to another health care provider and zero cancelled appointments for a non-clinical reason.
- Staff had a process to follow if, following an ultrasound scan, the sonographer was unable to obtain a clear scan of a heartbeat in the womb. In such a situation, the service user would be referred to a local NHS hospital EPAU. The service could supply a copy of the ultrasound scan but not electronically.

Staffing

- The service had enough staff with the right qualifications, skills, training and experience to keep people safe from avoidable harm and to provide the right care and treatment.
- The service staffed the location on a 'as needed' basis in line with service user demand with a sonographer, trained in early pregnancy ultrasound, who was subject to supervision every six months by an external radiographer. Reception staff were volunteers. Staff tended to work in pairs so each time the service was open there would a part-time sonographer and receptionist on duty.
- In the period March 2018 to March 2019 there had been no vacancies for directly employed staff and the service did not use bank or agency staff. Also, there had been no sickness in this period.
- The sonographers were not voluntarily registered with the Health and Care Professions Council (HCPC), but all had an up to date appraisal which was carried out by one of the directors who had a clinical background although not in ultrasound.
- All sonography staff who worked out of the location had received a DBS check which we saw was up to date.

Medical staffing

- The service had access to an external radiographer who, every six months, assessed sonographer competence in early pregnancy ultrasound scans. The report from the radiographer was supplied to the director undertaking a sonographers annual appraisal.

Records

- Staff kept detailed paper records of service users' care and treatment, including an electronic copy of the ultrasound scan.
- We reviewed ten service user records. All service user records seen were signed, dated, and legible.
- Service user records were in paper format and when not in use stored in a lockable filing system. Any electronic elements of the service user record, such as the ultrasound scan, were stored on a computer which was backed up remotely and password protected.
- All service users could receive a report after their scan which could be emailed and printed and any referral letters placed in their notes.
- With prior consent from the service user, records could be shared with third party healthcare professionals such as GPs or NHS maternity/gynaecological services.
- Staff told us they carried out non-documented audits of records. We fed back to staff that a formal system of documented record audits should be implemented.

Incidents

- The service managed service user safety incidents well.
- The service had an incident/near miss reporting policy and staff knew how to report incidents using the form provided by the service. This policy also covered duty of candour.
- In the last twelve months before the inspection the location did not report any service user deaths or never events (never events are serious service user 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 service user harm or death but neither need have happened for an incident to be a never event), or serious incidents.
- In the same period there had been 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 service users (or other relevant persons) of certain 'notifiable safety incidents' and provide reasonable support to that person).
- Staff described any learning arising out of scanning activity would be picked up as part of incident reporting and fed back directly to frontline staff concerned and shared at monthly team meetings.
- However, staff did not maintain an incident log (as distinct from an accident book log). We fed back to staff that they should do so.

Are diagnostic imaging services effective?

Requires improvement

Diagnostic imaging

Not sufficient evidence to rate

The effective domain was not rated.

Evidence-based care and treatment

- The service provided care and treatment based on national guidance and evidence of its effectiveness.
- Staff conducting and reporting on scans followed national guidance such as that issued by the British Medical Ultrasound Society or the Royal College of Radiologists or Royal College of Obstetricians and Gynaecologists.
- We saw examples of protocols, say for the ultrasound scans sonographers did, which showed that staff were referred to national guidance as above.
- Staff told us any changes to the guidelines would be picked up at the monthly staff meetings although we saw no evidence this was discussed in the minutes we saw.

Service user outcomes

- Apart from feedback forms, we saw no evidence that managers monitored the effectiveness of care and treatment and used the findings to improve them.
- Images generated at the service location and reports were not routinely reviewed by anyone in order to check whether the image quality and report was of the required standard and to address any issues raised, for example, with equivocal scans. Staff told us this was something the external radiographer looked at during the six monthly reviews they undertook but it was not apparent that this was something discussed at the monthly team meetings.
- Staff told us service user outcomes were monitored through the service user feedback surveys given to service users following their scan. However, we could not see any formal output from this monitoring and neither was it reported in the staff meeting minutes we saw.

Competent staff

- The service made sure staff were competent for their roles.
- To work at the service, staff had to complete an application, provide a history of employment, undertake a successful interview, supply professional references, and pass an enhanced criminal records bureau check. We saw evidence of all of this for the staff files we reviewed.
- On being employed by the service, staff received an induction appropriate to their role. For sonographers this meant that they were not allowed to scan on their own until they were signed off as being competent, which supervision could take upwards of a year.
- We saw that all sonography staff were mandated to complete and pass an externally approved course in early pregnancy ultrasound scanning before starting work as a sonographer.
- Staff received an annual appraisal and annually had their competence to scan checked. At the appraisal staff training needs were checked and training undertaken as necessary.
- We noted that not all staff had received training in basic life support and no staff had received training in how to deliver challenging news, (other than in-house training).

Seven-day services

- At the location services were supplied depending on service user demand. This meant services at the location were not necessarily open seven days a week.

Consent and Mental Capacity Act

- The service provided in-house training on consent and mental capacity and some of the staff undertaking sonography had received training on this from their main employer.
- We saw that the service obtained written consent from the service user for the procedure and disclosure of their results to third party healthcare professionals involved with their continuing care.
- The service's policy and procedures guided staff about consent and mental capacity.
- The service trained its staff on consent and mental capacity in the manner described above.
- Staff spoken with were knowledgeable about Gillick consent which is relevant to children giving consent. If a service user had a learning disability the service's policy and procedures required discussion with the safeguarding lead and consideration of the appointment of an advocate.

Are diagnostic imaging services caring?

Requires improvement

Diagnostic imaging

Good

We rated it as **good.**

Compassionate care

- During the inspection, there were no service users to speak to. However, we reviewed a sample of recent feedback forms all of which spoke positively about the care and treatment staff had supplied.

Emotional support

- We saw from records reviewed that staff provided emotional support to service users to minimise their distress.
- While staff had not had any externally accredited training in delivering challenging news, staff explained they had received in-house training about such topics from one of their directors who had a relevant clinical background. Based on our review of medical records we saw several examples where staff had provided emotional support which was appreciated by the service user.
- We saw that staff could give service users long and extended appointment times so that the emotional impact on the service user and any support could be fully explored.
- We saw that staff had access to a range of leaflets and could signpost service users to third party agencies in order to arrange further emotional support.
- If a service user on booking required a chaperone staff told us this could be arranged on a 'as needed' basis. All trans-vaginal scans took place with a chaperone.

Understanding and involvement of service users and those close to them

- Staff involved service users and those close to them in decisions about their care and treatment.
- We saw from medical records reviewed that all the service users had been told about their scan result and some of them had been supplied with a picture.
- We saw the service sought feedback from service users about many aspects of the service they had received.

Are diagnostic imaging services responsive?

Good

We rated it as **good.**

Service delivery to meet the needs of local people

- Appointments were made for service users at a time to suit them.
- To make viewing images much easier and more comfortable, the ultrasound monitor was placed on the wall at the end of the couch.
- The service had links with local NHS ultrasound departments and could directly refer service users to ensure necessary follow-up particularly where there was a need to do so.
- The service had analysed its data to ascertain that there was a need for a similar service in a different location and had plans to open a new location as a result.

Meeting people's individual needs

- The service took account of service users' individual needs.
- Service users initially had a phone call with the service during which screening took place to ensure the service could meet the needs of the service user. Any specific needs were noted at this point. For example, the need for a chaperone.
- Staff told us that there was no provision of information in any language other than English.
- If a service user required an interpreter this would be identified during the booking appointment and arrangements made with local agencies to request interpreter support.

Access and flow

- The service sees adolescents and women who self-refer or who have been referred by their GP and are unable to obtain an ultrasound scan through the NHS or privately. People could access the service when they needed it.
- Service users could book an appointment at a time to suit them and appointments took place according to service user demand with staffing organised accordingly.
- The service did not have a waiting list.
- No planned appointments were cancelled or delayed for a non-clinical reason such as breakdown of equipment.

Requires improvement

Diagnostic imaging

- The service did not conduct any audits to ensure effective access and flow to the service but had discussed plans to address any sudden peak in demand.

Learning from complaints and concerns

- The service treated concerns and complaints seriously, investigated them and learned lessons from the results, and shared these with all staff.
- The service had a complaints policy which was in date.
- Service users could access the service's complaints system by telephone or by letter. The service did not display posters or leaflets at the service telling service users about how to complain. Instead, a brief note of how to complain had recently been placed at the foot of the feedback questionnaire. We fed back to staff that they needed to do more to bring to the attention of service users how to complain.
- Formal complaints were dealt with ultimately by the director. However, service users had no route to progress their complaint beyond the service to an independent body. We fed back to staff that they should consider registering the service with an independent complaint review body.
- In the period March 2018 to March 2019 there were no complaints.
- The service told us that learning from complaints was shared during monthly team meetings. As there had been no complaints we saw no evidence of this in the minutes of meetings that we reviewed, but equally the minutes did not have a sub-heading or agenda item specifically to address complaints or compliments.

Are diagnostic imaging services well-led?

Requires improvement

We rated it as **requires improvement.**

Leadership

- While managers at the service had the right skills and abilities to perform ultrasound scans we found gaps in the governance processes.
- The leadership team was made up of the managing directors (who were also trustees of the charity), registered manager, and co-ordinator.
- Staff we spoke with told us the leadership team were highly visible, open and approachable and that they regularly met with them to discuss service related issues.

Vision and strategy

- The service had a vision for what it wanted to achieve and workable plans to turn it into action, which it developed with staff.
- The service's aims and objectives were to provide information, advice and support for adolescents and women facing unplanned pregnancy. Staff we spoke with were aware of this.

Culture

- Managers across the service promoted a positive culture that supported and valued staff, creating a sense of common purpose based on shared values.
- The service at the location consisted of one sonographer, a volunteer receptionist, and a service co-ordinator.
- Staff we spoke with reported a positive culture where everyone was passionate about providing a free ultrasound service to adolescents and women of childbearing age who may be facing an unplanned pregnancy.
  - We saw an up to date duty of candour policy.

Governance

- We were not satisfied that the service systematically used systems to improve service quality and safeguard high standards of care although this was certainly the aim of all staff who worked at the service.
- At various points throughout this report we have mentioned a number of areas which touch on gaps in governance. For instance: the lack of a documented review of receptionist capability; the issues with children safeguarding; the lack of a policy on control of substances hazardous to health; the absence of safety electrical testing; no policy for the deteriorating service user; no training for most staff in basic life support; absence of quality assurance policy for scans and reports of scans; lack of notices about how to complain; lastly, a general absence of an quality assurance audit programme, albeit some audits had started.

Requires improvement

Diagnostic imaging

- The service shared with us a range of minutes of meetings which took place monthly at which a range of issues were discussed. However, as we fed back to staff, these meetings lacked the rigour of a clinical governance meeting minute.
- While the minutes we reviewed showed the service was committed to providing a safe service with a focus on quality, the informality, coupled with the absence of a risk register, or incident log, or central action log, made it challenging to clearly identify what governance looked and felt like in this service.
- Following our inspection we asked the service to supply us with an action plan to address the concerns we had, noted above. The service supplied us with an action plan to address our concerns. We will continue to monitor this action plan following publication of this report.

Managing risks, issues and performance

- The service had no systems to identify risks, plan to eliminate or reduce them, and cope with both the expected and unexpected.
- The service regarded the guidance for staff on discrete risks, such as premises and equipment, fire safety, aggression, and infection control, as its risk policy. However, this did not set out details of the tools and processes staff should use to assess risks, such as a risk management framework, or how staff measured performance on managing risks, plus there was no risk register, or any link into meetings to expressly discuss risk.
- The service did not have a business continuity plan covering failure of utilities and such like. In particular, if there was a fire, no back up copy of paper records (say by scanning a hard copy into electronic format) was in place.

Managing information

- The service had policies and procedures in place to promote the confidential and secure processing of information held about service users.
- The service mainly used paper records to store service user records and an electronic database create electronic scan images and store them.
- Analysis of data was in its infancy and there was limited evidence that data was being systematically turned into reports for directors to consider and take action on.

Engagement

- The service engaged well with service users, staff, and the public to plan and manage appropriate services although we saw no evidence of effective collaboration with partner organisations, such as social services and local safeguarding children boards.
- We saw that the service had monthly staff meetings at which a range of issues were discussed and sometimes in-house training was delivered.
- The service user body was engaged through the service's website which promoted its services, and by providing a means of complimenting or complaining about the service, either by responding to the service user feedback survey they were asked to complete or by using any of the routes noted above.

Learning, continuous improvement and innovation

- It was clear from our discussions with staff that the service was committed to improving its services by learning from when things went well or wrong, promoting competent ultrasound scanning, and keeping service users safe.

Outstanding practice and areas for improvement

Areas for improvement

Action the provider MUST take to improve

- Ensure all children safeguarding training staff receive is benchmarked against published national guidelines and any gaps identified are addressed by compliant training, and that staff training for children safeguarding is of the right level for the role staff perform. (Reg.17)
- Train sonography staff in the identification of FGM and how to escalate and report as required. (Reg.17)
- Ensure that the policy and procedures staff adhere to in order to report to safeguarding agencies abuse of children, including but not limited to CSE, particularly for under age adolescents, is fit for its purpose of protecting such adolescents from such abuse, and that there are systems and processes in place which underpin such policy and procedures to review both decisions not to refer and to refer, correct any errors, and provide re-training to staff where needed. (Reg.17)
- Ensure that staff have access to policy and procedures about control of substances hazardous to health and that systems and processes are in place, including but not limited to lockable cupboards, to underpin such policy and procedures to ensure staff compliance. (Reg. 17)
- Ensure that all portable electrical equipment is electrical safety checked and any such equipment that does not pass the test is not used. (Reg.17)
- Ensure that staff have access to policy and procedures about care of the deteriorating service user and that systems and processes are in place to underpin such policy and procedures to ensure staff compliance, including but not limited to, ensuring staff are trained in basic life support. (Reg.17)
- Ensure that there is a system and process to continually review, document such reviews and change as necessary all clinical policies and procedures including but not limited to protocols for diagnostic ultrasound imaging. (Reg.17)
- Ensure that information about how to complain about the service is clearly displayed for service users to see. (Reg.17)
- Ensure that staff have access to a policy and procedures about risk and that systems and processes are in place to underpin such policy and procedures to ensure staff compliance, including but not limited to, a risk register, incident log, and centralised action log. (Reg.17)
- Ensure that there is a system and process in place to continually assess and audit the quality of the services provided including but not limited to, clinical governance meetings addressing issues around infection control, medical records, quality of scans and reports of scans, and access and flow. (Reg.17)

Action the provider SHOULD take to improve

- To promote quality and improvement, consider documenting all receptionist capability assessments.
- To promote access of the service to wheelchair users, consider alternative options so that the service can be offered to wheelchair users.
- To promote fire safety for service users, consider placing a sign on the fire exit door so users of the car park know not to park too close to the door to avoid obstructing it.
- To promote privacy and dignity of service users, consider placing a sign on the ultrasound scanning room door so that third parties know that an ultrasound scan is in progress.
- To promote staff safety if working alone in the ultrasound scanning room, consider installing a panic alarm system.
- To promote independent scrutiny of the complaints process, consider voluntary registration with an independent complaints body.
- To promote infection control, consider guidance set out in Health Technical Memorandum 07-01: Safe management of healthcare waste and comply with it regarding any clinical waste generated.

This section is primarily information for the provider

Requirement notices

Action we have told the provider to take

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

Regulated activity	Regulation
Diagnostic and screening procedures	Regulation 17 HSCA (RA) Regulations 2014 Good governance Reg. 17 Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 The above regulation was not being met because of the matters addressed above. 17 Good governance (1) Systems or processes must be established and operated effectively to ensure compliance with the requirements in this Part. (2) Without limiting paragraph (1), such systems or processes must enable the registered person, in particular, to (a) assess, monitor and improve the quality and safety of the services provided in the carrying on of the regulated activity (including the quality of the experience of service users in receiving those services); (b) assess, monitor and mitigate the risks relating to the health, safety and welfare of service users and others who may be at risk which arise from the carrying on of the regulated activity; (c) maintain securely an accurate, complete and contemporaneous record in respect of each service user, including a record of the care and treatment provided to the service user and of decisions taken in relation to the care and treatment provided; (d) maintain securely such other records as are necessary to be kept in relation to (i) persons employed in the carrying on of the regulated activity, and (ii) the management of the regulated activity;

This section is primarily information for the provider

Requirement notices

(e) seek and act on feedback from relevant persons and other persons on the services provided in the carrying on of the regulated activity, for the purposes of continually evaluating and improving such services;

(f) evaluate and improve their practice in respect of the processing of the information referred to in sub-paragraphs (a) to (e).

Reg. 17