

this is my: Hull Screening Centre


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	Good	
Are services safe?	Good	
Are services effective?		
Are services caring?	Good	
Are services responsive?	Good	
Are services well-led?	Good	

Overall summary

this is my: Hull Screening Centre was operated by this is my: limited. The service was an independent private medical provider offering health screening imaging using

ultrasound (use of sound waves to get pictures of the inside of people's bodies), to self-funding or private medical service users but it also saw NHS service users under contract.

this is my: Hull Screening Centre was situated on the ground floor of a modern purpose-built building that was

Summary of findings

wheelchair accessible and had ample on-site parking which was free of charge. The main reception was managed by the building operator but service users were directed down a corridor to the service's office. The service's office opened into a room which had adequate seating and a desk with a radio playing, lockable low-level storage cabinets, and two further rooms, one of which was the treatment room and the other a room with extra seating. Service users could access toilets and a café in the main building.

The service provided a screening and ultrasound scans for service users aged 17 to 65 in relation to pregnancy (from the earliest stages of pregnancy through to 42 weeks, including endometrial thickness measuring (for women going overseas for fertility treatment)), and non-pregnancy related scans, such as pelvic scans. Also, the service provided what it called '4D meet your baby bond scans'.

In addition, it supplied Non-Invasive Pre-Natal Testing (NIPT) (a test used to predict certain conditions in the unborn baby, such as Down's syndrome), with blood samples taken at the centre and then transported to the Leeds site for onward transportation to a third-party laboratory.

We inspected this service using our comprehensive inspection methodology. We carried out the short-announced part of the inspection on 19 December 2018. We had to conduct a short-announced inspection because the service was only open if demand from users of the service required it. We conducted a follow-up inspection on 25 January 2019 because, when we inspected on 19 December 2018, we were unable to view records of service users or speak with staff owing to demand from service users.

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 previously rated this service in June 2013. At that time the service met the fundamental standards inspected against.

At this inspection we rated it as **Good** overall.

We found the following areas of good practice:

- Staff training in mandatory training was up to date.
- The service was visibly clean and un-cluttered and all 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 there was a process to follow.
- The service ran to time, with no cancellations.
- The service users we spoke with were positive about their experience at the service.
- The service had a complaints system in place, with low levels of complaints over the last year, and made changes to the service as needed considering feedback from service users.
- The service had a clinical governance process in place to maintain quality which put safety of users of the service first, and had a system for recording and acting on risks.
- Staff we spoke with and minutes of meetings we reviewed showed an open culture where the leadership team were accessible and approachable.

We found a breach of regulation because staff were not trained in consent and mental capacity.

While not a breach of a regulation, we also found the following issues, that the service provider needs to improve:

- The flooring in the treatment room was carpeted: this posed a challenge for infection prevention and control, say, if, when taking blood for a NIPT, there was a spillage of human blood products onto the floor in the treatment room.
- The service was operated by a lone worker: this posed not only a risk to their personal health and

Summary of findings

safety, if a service user (or their relative) became violent, but also to that of a service user waiting to be seen that deteriorated, while the lone worker was treating another service user.

- The location did not have a written policy for staff to follow to support staff with their obligations in relation to female genital mutilation (FGM) and neither had staff been trained in FGM.
- The location did not have a written policy for staff to follow to support staff in complying with the relevant regulations and associated published guidance around transportation of human blood products from the location to the Leeds location where samples were sent to a laboratory.
- The location did not display any information to inform service users about their right to and how to complain.

- The risk register for the location needed to be reviewed to ensure that it accurately reflected the risks posed at the location.

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

After the initial inspection in December 2018 and prior to the follow-up inspection in January 2019, the service had already actioned or set in progress to complete, all the improvements we had highlighted above.

Ellen Armistead

Deputy Chief Inspector of Hospitals (North)

Summary of findings

Our judgements about each of the main services

Service

Diagnostic imaging

Rating Summary of each main service

At this inspection we rated it as **Good** overall.
We found the following areas of good practice:

- Staff training in mandatory training was up to date.
- The service was visibly clean and uncluttered and all 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 there was a process to follow.
- The service ran to time, with no cancellations.
- The service users we spoke with were positive about their experience at the service.
- The service had a complaints system in place, with low levels of complaints over the last year, and made changes to the service as needed considering feedback from service user users.
- The service had a clinical governance process in place to maintain quality which put service user safety first, and had a system for recording and acting on risks.
- Staff we spoke with and minutes of meetings we reviewed showed an open culture where the leadership team were accessible and approachable.

Good



We found a breach of regulation because staff were not trained in consent and mental capacity. While not a breach of a regulation, we also found the following issues, that the service provider needs to improve:

- The flooring in the treatment room was carpeted: this posed a challenge for infection prevention and control, say, if, when taking blood for a NIPT, there was a spillage of human blood products onto the floor in the treatment room.
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Summary of findings

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Good 

this is my: Hull Screening Centre

Services we looked at

Diagnostic imaging.

Summary of this inspection

Background to this is my: Hull Screening Centre

this is my: Hull Screening Centre was operated by this is my: limited. It was a private ultrasound scanning service which opened in Hull in 2013. The service primarily served Hull and the surrounding area.

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

- Diagnostic and screening procedures

We conducted a short-announced inspection of the ultrasound, (including 4D meet your baby bond scans) and NIPT testing part of the service on 19 December 2018. The service also offered gene screening for inherited disorders. We did not inspect these services.

We conducted a follow-up inspection on 25 January 2019 because, when we inspected on 19 December 2018, we were unable to view service user records or speak with the lone worker owing to service user demand and because electronic service user records were being used.

The previous CQC inspection of this service was in June 2013. At that time the service met the fundamental standards inspected against.

Our inspection team

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

Information about this is my: Hull Screening Centre

The clinic was registered to provide the following regulated activities:

- Diagnostic and screening procedures.

During the inspection, we inspected the ultrasound, (including 4D meet your baby bond scans) and NIPT part of the service. We spoke with two staff who were the radiographer who conducted the ultrasound scan and NIPT blood taking (who was also the managing director who occupied other roles within the company, such as safeguarding lead) plus the corporate business manager (not usually present, who, because the radiographer was busy seeing service users, was asked to attend). We spoke with 12 service users and or their relatives and (during the follow-up inspection), reviewed six service user records. We reviewed staff records in relation to the radiographer.

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 services first inspection since June 2013, which found that the service had met all standards of quality and safety it was inspected against.

Summary of this inspection

Activity - October 2017 to October 2018 (reporting period)

In the reporting period there were:

- 1624 scans and 27 NIPT's.
- Seven complaints, six of which were upheld.
- Zero service users seen who were aged 17.

The service at the location employed a radiographer who scanned service users, took blood for NIPT testing and met and greeted service users. Opening times at the location depended on service user demand.

The service outsourced analysis of the NIPT blood samples to NIPT laboratory services and blood analysis to a local NHS trust.

Track record on safety

- No 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.
- 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).
- 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?

We rated it as **Good** because:

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

However, we did find the following where the service could improve:

- The location did not have a written policy for staff to follow to support staff with their obligations in relation to female genital mutilation (FGM) and neither had staff been trained in FGM.
- The flooring in the treatment room was carpeted: this posed a challenge for infection prevention and control, say, if, when taking blood for a NIPT, there was a spillage of human blood products onto the floor in the treatment room.
- The service was operated by a lone worker: this posed not only a risk to their personal health and safety, if a service user (or their relative) became violent, but also to that of a service user waiting to be seen that deteriorated, while the lone worker was treating another service user.
- The location did not have a written policy for staff to follow to support staff in complying with the relevant regulations and associated published guidance around transportation of human blood products from the location to the Leeds location where samples were sent to a laboratory.

Good



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.
- Service users had access to nutrition and hydration and 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.
- The service provided services from the location on a service user demand basis.

However:

Summary of this inspection

- While the service did not intend to see or treat service users who lacked mental capacity because staff were not trained in consent and mental capacity it was difficult to see how staff were enabled to identify whether a patient had mental capacity. The service told us it was going to organise training for staff on consent and mental capacity.

Are services caring?

We rated it as **Good** because:

- The service provided compassionate care to its service users with all service users we spoke with describing a positive experience.
- The service thought about the emotional needs of service users by offering a chaperone where needed and by staff being trained in delivering news that may be challenging.
- The service understood and involved service users in their care by providing clear information on costs and timings for receipt of reports.

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.
- The service operated a complaints process and had a low level of complaints over the last year and acted where necessary to learn from complaints.

However:

- The location did not display any information to inform service users about their right to and how to complain. Following the inspection and prior to the follow-up inspection this was corrected.

Good



Are services well-led?

We rated it as **Good** because:

- The leadership team 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.

Good



Summary of this inspection

- Staff reported an open and positive culture with good engagement with the staff and service users.
- The service had governance processes in place to measure quality and improve and monitored risk and acted where needed.

However:

- The risk register for the location needed to be reviewed to ensure that it accurately reflected the risks posed at the location.

Detailed findings from this inspection

Overview of ratings





Our ratings for this location are:

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

Notes

We currently do not rate effective.

Diagnostic imaging

Safe	Good 
Effective	
Caring	Good 
Responsive	Good 
Well-led	Good 

Are diagnostic imaging services safe?

Good 

We rated it as **good**.

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 100% of staff achieved the 100% target of having received training in: safeguarding; data security and confidentiality; first aid; taking of blood; and counselling.
- We saw from records supplied that staff took part in regular continuing professional development training.

Safeguarding

- **Staff understood how to protect service users from abuse and the service worked well with other agencies to do so.**
- The service had an up to date care of the vulnerable adult and adult abuse policy which outlined what abuse looked like and what to do if abuse was suspected. We saw that the service had forms for staff to use to report safeguarding and staff we spoke with knew how to do so.
- Staff (both administrative and clinical) had been trained to safeguarding level 1 for adults and children and knew how to report safeguarding. Following the inspection, the service confirmed that relevant staff were being trained to safeguarding level 2 for adults.

- The service had a lead for safeguarding who was not trained to Level 3 safeguarding. Following the inspection, the service told us that Level 3 safeguarding training for senior staff was being organised but no specific date was supplied.
- There was no written policy to support staff in reporting female genital mutilation (FGM). Staff we spoke with could not articulate what they would do if they came across a service user with FGM or confirm that the safeguarding training they had received covered FGM. After the inspection, the service confirmed relevant staff would receive training in FGM after which a revised policy covering FGM would be issued.
- In the last twelve months prior to inspection there were no safeguarding referrals by the service.
- The service made the improvements we had highlighted or set them in progress to complete them, in between the initial inspection and the follow-up inspection.

Cleanliness, infection control and hygiene

- **The service controlled infection risk well.**
- The service had an up to date policy on infection control. The staff member at the location on the day of our inspection was also the infection control lead.
- The premises were visibly clean. In the twelve months prior to inspection there were zero incidences of healthcare acquired infections.
- An infection control audit carried out by the service's infection control lead on 1 October 2018 for the period August to September 2018 checked on staff awareness

Diagnostic imaging

of the company infection control policy and did spot checks of infection control. The result indicated that clinical staff demonstrated a good understanding of the company policy on infection control.

- The flooring in the treatment room was carpeted and because of this presented a challenge with infection control. Staff explained that if there were a biological spillage on the carpet, say human blood, the building owner supplied cleaning aids to which they had access. Following the inspection, the service added the risk of blood spillage to its risk register, obtained a spillage kit, and placed a clean easy mat in the treatment room.
- The couch in the treatment room used by service users was covered with disposable paper which was changed between service users and the couch wiped with an antiseptic wipe before laying out a new disposable paper.
- Any probes were wiped before and after service user use with an antiseptic wipe. If an invasive probe were used this was covered with a single use disposable antiseptic cover.
- Whilst sinks were available in the toilets in the corridor, the treatment room had no handwashing facilities. Instead, between treating service users, staff used alcohol gel to clean their hands. Staff explained that the ultrasound procedures carried out at the location were non-invasive and involved minimal contact with service users. Service users were not required to remove any clothing. Staff were seen to be bare below the elbow when treating service users. For NIPT, when taking blood, staff showed us disposable gloves they wore.
- Sharps and clinical waste were disposed of in a sealed 'burn' bin which was taken to the Leeds site and collected by a local NHS trust for disposal.
- The service made the improvements we had highlighted or set them in progress to complete them, in between the initial inspection and the follow-up inspection.

Environment and equipment

- **The service had suitable premises and equipment and looked after them well.**

- Service users accessed the service on the ground floor of a modern purpose-built building that was wheelchair accessible and had ample on-site parking which was free of charge. The building and main reception was managed by the building owner and service users were directed to the service's office.
- The service's office consisted of a main room containing a desk (on which a radio was playing) with ample seating for service users. Another room with more seating led off the main room. Next to that room was the treatment room. The main room was not staffed by a receptionist. Instead, if staff were treating a service user, service users waiting were told by a notice on the desk in the main room to remain seated while waiting to be seen.
- The treatment room contained seating, the couch the service user used, and the ultrasound machine, together with a computer staff could use to access the electronic service user record.
- All equipment used for taking bloods were pre-packed in sealable bags and single use with disposable gloves.
- The human blood products collected from service users having NIPT had to be transported from Hull to Leeds because it was at Leeds, prior to being sent to the laboratory, where all final labelling of the blood took place. The system staff employed to classify, label, package and transport the human blood products from Hull to Leeds confusingly used different classification labels depending on which courier's packaging was used. As a result, we were not satisfied that the system staff were using complied with relevant regulations and associated published guidance for transporting human blood products. Following the inspection, the service took steps to comply with the relevant regulations and associated published guidance for transporting human blood products.
- Staff told us that they regularly checked stocks at the location, such as, antiseptic wipes, and re-stocked the lockable cupboards that were situated around the various rooms. We saw that stock seen was all in date.
- The service supplied data showing all equipment seen had been safety electrical tested and the ultrasound machine had been serviced in the last year.

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- The service made the improvements we had highlighted or set them in progress to complete them, in between the initial inspection and the follow-up inspection.

Assessing and responding to service user risk

• **Staff completed and updated risk assessments for each service user.**

- 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 medically fit and stable. For instance, they did not see service users with serious life-threatening conditions. Also, they did not see service users below the age of 17. 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 or NIPT.

- 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 whenever it performed such a scan it would always carry out an anomaly scan as well, so in fact its scans were always diagnostic. Nevertheless, after the inspection, the service confirmed that it would put on its website a link to Public Health England's advice about baby souvenir scanning.

- The service listened to our concerns about risks to staff health and safety as noted in the summary above and after the inspection issued staff with attack alarms and introduced a lone worker policy.

- All staff that worked in the service undertook cardio pulmonary respiratory and emergency first response training provided by one of the service's consultants whom staff could access for expert advice as necessary. While the policy stated training was updated, the regularity of this was not specified, but the service told us staff were updated annually and we saw that this was so.

- If a service user waiting to be seen suddenly deteriorated the company policy required staff to call an ambulance using 999 and follow advice to administer basic life support. But because the staff

member was a lone worker, whilst treating another service user in the treatment room, they had no means of observing whether a service user was deteriorating in the waiting room. As such, in this scenario, it was difficult to see how staff could comply with this policy. After the inspection, the service installed an alarm in the waiting room, so that if a service user deteriorated and required help, they could summon the staff from the treatment room.

- 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, an anomaly were detected which required a referral to the NHS for follow-up. With service user consent, if follow-up was required, for example, to address a risk, the service could share the scan result with third party healthcare professionals. We saw the standard letter staff used to make the referral which could be amended where needed.
- The service made the improvements we had highlighted or set them in progress to complete them, in between the initial inspection and the follow-up inspection.

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 qualified and accredited clinical staff member. Reception staff (supplied by the building operator) directed service users to the service's offices. Administrative staff worked out of the head office based in Leeds and in the main they handled, by phone, appointment bookings.
- In the period 1 October 2017 to 1 October 2018 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.

Diagnostic imaging

- For the one clinical staff member employed at the location, we saw they were registered with the Health and Care Professions Council (HCPC) and had an up to date appraisal and we saw they had their professional registration checked annually.
- All 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 a consultant radiologist who provided training for staff in basic life support training, and was a source of expert advice which staff could access as required. The consultant did not see service users but did review scans as required and protocols and attended meetings as part of the service's clinical governance process.

Records

- **Staff kept detailed records of service users' care and treatment.**
- We reviewed six service user records. All service user records seen were detailed, legible and secure.
- Service user records were largely in electronic format and stored on a central database operated by the service which staff accessed using passwords. Any paper elements of the service user record would be scanned onto the service user electronic record.
- All service users received a report after their scan which could be emailed and printed and placed in their electronic 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.

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.
- 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 the clinical governance process and fed back directly to frontline staff concerned and shared at weekly team meetings.

Are diagnostic imaging services effective?

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.
- The service benefited from access to clinical medical supervisors being consultants in the fields of radiology and obstetrics who undertook quarterly reviews of protocols and shared any changes with relevant staff.
- We saw examples of protocols, say for common ultrasound scans, which showed that staff were referred to national guidance as above.

Nutrition and hydration

- **Staff gave service users enough food and drink to meet their needs and improve their health.**
- Service users had access to a café which was operated by the building owner.

Diagnostic imaging

Service user outcomes

- **Managers monitored the effectiveness of care and treatment and used the findings to improve them.**
- Outcomes were monitored against the original report conclusion. Images generated at the service location were randomly reviewed by the clinical specialist responsible for uploading the images to the computer system with any issues raised directly with the specialist who performed the scan. The service kept a log of any issues raised.
- Reports were subject to quarterly audit. Images taken over the preceding three months were reviewed at clinical governance meetings on a random sampling basis. Any learning from these reviews was captured as part of the clinical governance process.
- If there was a need, say because the reporting specialist had any doubts, non-obstetric ultrasound procedures were capable of being reviewed by the service's radiologist.
- Service user outcomes were also monitored through the customer satisfaction surveys and outcome forms sent to service users following their scan and changes to the service made as necessary.

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 clinical staff member working at the location.
- On being employed by the service, staff received an induction focussing on the importance of data security and confidentiality. This was repeated annually and staff signed to say that they had completed annual data security and confidentiality training. Staff also received instruction on items such as: about the company; staff roles; employment; quality management; health and safety; and security. Staff had access to an employee handbook to support them in being competent about company policies.

- We saw that staff were mandated to complete workbooks for training that they undertook. For example, on data security.
- Staff received an annual appraisal and annually had their professional registration checked. At the appraisal staff training needs were checked and training undertaken as necessary.
- We saw evidence that the clinical staff member working at the location had attended national conferences about ultrasound practice.
- Staff had received additional training. For example, in how to take blood, deliver news that could be challenging and on how to perform cardio pulmonary resuscitation.

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 did not train staff on consent and mental capacity.**
- 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 did not have a policy for staff to follow around consent. Instead, in relation to consent, staff followed national guidance relevant to their field, noted above.
- The service did not train its staff on consent and mental capacity. Without this training it was difficult to see how staff were enabled to carry out the duties they were employed to perform, such as ensuring they do not see service users without mental capacity (if that is what they intended) or if they did, what they should do about it to ensure service users were consenting to a given procedure.

Diagnostic imaging

Are diagnostic imaging services caring?

Good 

We rated it as **good**.

Compassionate care

- **Staff cared for service users with compassion.**
- We saw staff interact with service users before and after the ultrasound scan with compassion and care.
- During the inspection we spoke to 12 service users. Service users said: “out of all the scans we have had this was the best”, “the staff have been very professional and reassuring” and “the images were excellent and the clinician gave me time”.

Emotional support

- **Staff provided emotional support to service users to minimise their distress.**
- Counselling for news that could be challenging or for results of NIPT blood samples could be given in person or by phone. Staff had been trained to deliver news that could be challenging. Staff told us that an empty room adjacent to the treatment room would be used to support service users who had received such news. However, as the service operated at the location with a lone worker, and scan appointments were scheduled every 15 minutes, to provide this support service users not yet seen would have to wait.
- If a service user on booking required a chaperone staff told us this could be arranged on a ‘as needed’ basis.
- Staff told us that, where service users sought additional reassurance, they would be happy to share their mobile number and to be contacted when needed.

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.**
- All the service users we spoke with understood when and how they would receive their scan results. Many service users had been emailed their scan reports and

images before leaving the building. Service users also told us that scan information had been shared where appropriate with midwives and general practitioners via email. Service users waiting for blood tests were aware of how long this would take and when they would receive their results.

- Service users told us that they had been clearly informed of the costs relating to the scans and tests during their initial phone call and subsequent emails. We saw that a price list was present in the waiting area. Pricing information was also supplied in the booking confirmation letter.
- One service user we spoke to told us that she was happy to have been permitted to use her mobile phone to video the scan as it was being done and displayed on the monitor. A service user showed us a memory stick that had been provided by the service with the scan images on it so that she could easily share these with friends and family.
- 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

- **The service planned and provided services in a way that met the needs of local people.**
- Appointments were made for service users at a time to suit them. Service users told us that they were provided with a free parking pass before coming for their scan appointment.
- To make viewing images much easier and more comfortable, the ultrasound monitor was placed on the end of the couch.
- The service had links with ultrasound departments in the wider NHS and could directly refer service users to ensure necessary follow-up particularly where there was a need to do so.

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- The service worked with the cleft lip and palate association (CLAPA) to provide free scans to inform parents so they could make informed decisions about future treatment options.

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. Service users were later emailed details about their appointment, the type of scan they were having, plus consent forms and cost information.
- 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

- **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.
- To ensure effective access and flow the service audited appointment times for the service, waiting times and report turnaround times. No issues were identified.
- All the 12 service users we spoke to were positive about the availability of scans and they told us that they had received appointments in a timely fashion that they were happy with.

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.**
- Service users could access the service's complaints system through the public website, by telephone, or by email or letter. Yet none of the service users we spoke with knew how to complain. The service did not display posters or leaflets at the service telling service users about how to complain.
- The service had a complaints policy which had been reviewed in October 2018 with a further review date for October 2019.
- Formal complaints were dealt with ultimately by the managing director and a response issued within seven working days although frontline staff were empowered to try and handle complaints informally.
- In the period October 2017 to October 2018 there were seven complaints, six of which were upheld. The number of complaints was so low it was not possible to identify a theme.
- The service told us that learning from complaints was shared during weekly team meetings and as part of the clinical governance process with changes made to practice as necessary. For example, in response to one complaint, the service ensured all service users had access to the privacy policy relating to the laboratory they used. We reviewed minutes of team meetings and saw that business improvement was always discussed.
- Following the inspection, the service placed information on how to complain in the waiting areas.

Are diagnostic imaging services well-led?

Good 

We rated it as **good**.

Leadership

- **Managers at all levels in the service had the right skills and abilities to run a service providing high-quality sustainable care.**

Diagnostic imaging

- The leadership team was made up of the managing director, corporate director and an executive director, all of whom reported to a chairman.
- The leadership team were supported by a business manager, office manager, the clinical team, and administration team. The clinical team had at least 20 years' experience of providing an ultrasound service.
- 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, service users, and local community groups.**
- The service's aims and objectives were to provide the best possible service in terms of service user care, accuracy and diagnosis and 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 clinical staff member backed up by a central administration team, with access to expert advice from consultants in radiology and feto-maternal medicine, as needed.
- We saw an up to date duty of candour policy.

Governance

- **The service systematically improved service quality and safeguarded high standards of care by creating an environment for excellent clinical care to flourish.**
- The service shared with us a range of minutes of meetings which took place weekly and quarterly at which issues were discussed. This included actions arising from the action log, complaints, issues with blood testing, information governance, radiology audits and any other business.

- While the minutes we reviewed showed the service was committed to improving service quality with a focus on safe service user care, the way in which it organised its discussions made it challenging to clearly identify what was clinical and what was non-clinical. Following the inspection, the service, having listened to feedback we supplied, introduced standardised agendas and separated the meetings so that there was a clear division between clinical and non-clinical matters arising and the associated action logs and feedback mechanisms.
- We saw that the service had policies and procedures in place for, say, information governance and kept a log of staff to ensure that staff had read and understood the policies.
- The service had a senior member of staff to oversee confidentiality of service user healthcare information known as a Caldicott guardian.

Managing risks, issues and performance

- **The service had good systems to identify risks, plan to eliminate or reduce them, and cope with both the expected and unexpected.**
- The service had a risk and incident management policy which described how to report and grade incidents.
- The service's corporate business manager was responsible overall for risk and they would be responsible for addressing any risks arising in between review dates of risk laid down by the local risk registers.
- The service had a local risk register for the location. The risks related to infection control and fire. Controls were noted for each risk and a review date was in place. One of the directors diarised the review date.
- The service had a business continuity plan covering failure of utilities and such like. The service explained to us that if there was an issue affecting delivery of the service at the location then clinics would be re-located or service users re-booked.
- Following the inspection, we saw that the service's revised meeting agendas ensured that risk was a standing item for discussion at the clinical governance

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meeting. Also, while the local risk register did not reflect the risks we found at the location as noted in the summary above, after the inspection the service sent us a revised local risk register which did so.

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 an electronic database to create and share service user information. Where paper was used the completed paper form would be scanned onto the service user electronic record and the paper confidentially destroyed.
- Staff could use the electronic database to audit its service, for example, by examining appointment times, waiting times or report turnaround times.

Engagement

- **The service engaged well with service users, staff, the public and local organisations to plan and manage appropriate services, and collaborated with partner organisations effectively.**

- We saw that the service had weekly staff meetings at which business improvement was discussed as well as staff issues.
- 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 experience survey they were asked to complete or by using any of the routes noted above.

Learning, continuous improvement and innovation

- **The service was committed to improving services by learning from when things went well or wrong, promoting training, research and innovation.**
- The service told us that it had moved to a third-generation technology sequencing for its NIPT service and tried to keep ahead of offerings from third parties regarding new sequencing technologies, for example, for spotting Down's syndrome.

Outstanding practice and areas for improvement

Areas for improvement

Action the provider **MUST** take to improve

- Train all staff on consent and mental capacity.

Action the provider **SHOULD** take to improve

- For staff working with human blood products, conduct a review of staff knowledge of and compliance with relevant regulations and associated published guidance for the classification, labelling, packaging and transportation of human blood products between the Hull and Leeds location and address any non-compliance identified.
- Perform a risk assessment of the infection risk posed by using carpeted flooring in the treatment room and complete all actions arising from the risk assessment.
- Perform a risk assessment of the health and safety risks posed to staff and deteriorating service users by lone working at the Hull location and complete all actions arising from the risk assessment.
- Review the safeguarding training and policies and procedures to ensure that staff know about FGM and what they need to do if they come across it when examining service users.
- Review its risk policy to ensure it is fit for purpose and its risk register for the location to ensure it is up to date and accurately reflects the risks posed at the location and complete all actions arising from the review.
- Review how it informs service users about their right to and how to complain about the service and complete all actions arising from the review.

This section is primarily information for the provider

Requirement notices

Action we have told the provider to take

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

Regulated activity	Regulation
Diagnostic and screening procedures	<p>Regulation 18 HSCA (RA) Regulations 2014 Staffing Reg. 18 (2) (a) Health and Social Care Act 2008 (Regulated Activities) Regulations 2014</p> <p>The above regulation was not being met because staff were not being trained on consent and mental capacity</p> <p>"(2) Persons employed by the service provider in the provision of a regulated activity must-</p> <p>(a) receive such appropriate support, training, professional development, supervision and appraisal as is necessary to enable them to carry out the duties they are employed to perform,"</p> <p>Reg. 18 (2) (a)</p>