HELLO BABY

Quality Report

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

Ratings

Overall rating for this location	Requires improvement
Are services safe?	Requires improvement
Are services effective?	
Are services caring?	Good
Are services responsive?	Requires improvement
Are services well-led?	Requires improvement

Summary of findings

Letter from the Chief Inspector of Hospitals

Hello Baby is operated by Katie Ellison Limited. It is an independent provider established in 2017 to provide parents with a memorable keepsake of their pregnancy through images of their unborn baby using ultrasound equipment. The service employed four receptionists, the registered manager (who performed the scans) and a locum sonographer who covered for annual leave/sickness.

The service is in St. Helens, with good transport links and off-street parking nearby. The service is located on the ground floor of a privately leased property. The premises consist of a waiting area, a scan room, a wash room, a viewing area, a reception desk and a staff room. The service offered early pregnancy scans for those aged 16 years and above (from six to 12 weeks pregnancy), sexing/gender scans (from 14 weeks pregnancy), 3D and 4D scans undertaken in HD Live (Hello Baby state that 4D scans can be done anytime from 14 weeks but advise the best time for the 4D bonding scans would be 26-31 weeks).

We inspected this service using our comprehensive inspection methodology. We carried out an unannounced visit to the service on 21 June 2019.

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

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

The main service provided by this service was diagnostic imaging for baby keepsake scan pictures.

Services we rate

We had not inspected this service before. We rated it as **Requires improvement** overall.

We found some issues with practice in relation to the service:

- We saw evidence of the manager practising out of their scope of practice.
- There was not a clear process for staff to follow in the event there were concerns about a pregnancy. This was important because we saw evidence that the service had completed a scan for a patient who was bleeding.
- There was no evidence of any multidisciplinary working, as the service did not link in with any local hospitals.
- We saw evidence of a lack of timely and appropriate referral of clients to other medical services.
- Patients were not offered sufficient time to discuss decisions about their care.
- Staff used some equipment and control measures to protect patients, themselves and others from infection. However, there were some areas which looked like they had not been cleaned thoroughly.
- Although the provider had a complaints process, some complaint responses were poor and we saw no evidence of any shared learning from the complaints.
- The provider did not have processes to effectively identify, manage and mitigate risks such as a risk register. During inspection, we did not see any evidence of a risk register or other system and processes for the identification, regular review, or management of risks.

However, we also found the following:

- Staff understood how to protect patients from abuse and the service worked well with other agencies to do so.

Summary of findings

- The service made sure employed staff were competent for their roles. The registered manager appraised staff's work performance and held supervision meetings with them to provide support and development.
- The service operated six days a week, with a Sunday opening on the last Sunday of every month.
- Staff treated clients with compassion and kindness, respected their privacy and dignity, took account of their individual needs, and helped them understand their conditions.

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, to help the service improve. We also issued the provider with four requirement notices. Details are at the end of the report.

Ann Ford

Deputy Chief Inspector of Hospitals

Overall summary

Hello Baby is an independent provider established in 2017 to provide parents with a memorable keepsake of their pregnancy through images of their unborn baby.

We rated this service as requires improvement because we found breaches of regulation in safe, responsive and well-led.

Summary of findings

Our judgements about each of the main services

Service	Rating	Summary of each main service
Diagnostic imaging	**Requires improvement** 	We rated this service as requires improvement because we found breaches of regulation in safe, responsive and well-led.

Summary of findings

Contents

Requires improvement

Hello Baby

Services we looked at
Diagnostic imaging

Summary of this inspection

Background to HELLO BABY

Hello Baby is operated by Katie Ellison Limited. It is a baby keepsake scanning service opened in 2017. It is based in St Helens. The service primarily serves the communities of the local area, but it also accepts clients from outside this area.

The service has had a registered manager in post since opening in 2017.

The service offers early pregnancy scans (from six to 12 weeks pregnancy), sexing/gender scans (from 14 weeks pregnancy), 3D and 4D scans undertaken in HD Live (Hello Baby state that 4D scans can be done anytime from 14 weeks but advise the best time for the 4D bonding scans to be 26-31 weeks). Patients aged sixteen and above could attend for scans.

The inspection took place on the 21 June 2019.

Our inspection team

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

Why we carried out this inspection

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

During the reporting period of 11 March 2018 to 11 March 2019, the service reported: -

Track record on safety

- No never events.
- No clinical incidents.
- No serious injuries.
- No IRMER/IRR reportable incidents
- The information on the number of complaints received between during the reported period was not offered prior to inspection, although we did review several complaints whilst on site.

How we carried out this inspection

During the inspection, we visited the service. During our inspection, we reviewed seven client consent forms.

Information about HELLO BABY

The service has one location and is registered to provide the following regulated activities:

- Diagnostic and screening procedures.

Summary of this inspection

What people who use the service say

We spoke with three staff including the registered manager. We spoke with seven clients.

Summary of this inspection

The five questions we ask about services and what we found

We always ask the following five questions of services.

Are services safe?

Requires improvement 

We had not previously rated this service. We rated it as **Requires improvement** because:

- There were no clear pathways or procedures for the management of complications detected in early pregnancy scans.
- We saw evidence of a lack of timely and appropriate referral of clients to other medical services.
- We saw evidence of the manager practising out of their scope of practice.
- Patients were not offered sufficient time to discuss decisions about their care.
- The service did not always control the risk of infection. Staff used some equipment and control measures to protect patients, themselves and others from infection. However, there were some areas which looked like they had not been cleaned thoroughly.
- All staff had not completed PREVENT training. Reception staff had not completed safeguarding training.

However:

- The service did arrange for some formal mandatory training, but staff were also expected to read relevant policies yearly to keep them updated.
- Staff understood how to protect patients from abuse and the service worked well with other agencies to do so.
- The service had enough staff. Managers offered staff a full induction on starting with the service.

Are services effective?

We do not currently rate the effective domain for diagnostic imaging

Services, but this is what we did find:

- Patients were not offered enough time to discuss decisions about their scans.
- The service used policies. However, some of the policies we looked at did not have a clearly defined review date, but we were told these would be re-written if guidance changed.

However:

Summary of this inspection

- The service made sure employed staff were competent for their roles. Managers appraised staff's work performance and held supervision meetings with them to provide support and development.
- The service operated six days a week, with a Sunday opening on the last Sunday of every month.
- There were snacks and drinks available for clients.

Are services caring?

Good

We had not previously rated this service. We rated it as **Good** because:

- Staff treated patients with compassion and kindness, respected their privacy and dignity, took account of their individual needs, and helped them understand their conditions. They provided emotional support to patients, families and carers.

Are services responsive?

Requires improvement

We had not previously rated this service. We rated it as **Requires improvement** because:

- Although the provider had a complaints process, some complaint responses were poor.
- We saw no evidence of any shared learning from the complaints.
- Staff told us that there was no written provision of information in any language other than English but told us they would be happy for clients' friends or family members to attend appointments to translate.

However:

- The service was inclusive and took account of patients' individual needs and preferences.
- People could access the service when they needed it.

Are services well-led?

Requires improvement

We had not previously rated this service. We rated it as **Requires improvement** because:

- The service was not able to provide any evidence of any learning or shared learning from client feedback.
- During inspection, we did not see any evidence of a risk register or other system and process for the identification, regular review, or management of risks.
- There were concerns regarding the risks when undertaking scans in early pregnancy as there were no clear processes for the management of this.

Summary of this inspection

However:

- Staff felt respected, supported and valued. They were focused on the needs of clients receiving care. The service had an open culture where clients, their families and staff could raise concerns.
- The leader operated some governance processes. Staff at all levels were clear about their roles and accountabilities and had regular opportunities to meet and discuss the performance of the service with the registered manager. The service had substantial systems and processes to meet the fit and proper persons regulations.

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	N/A	Good	Requires improvement	Requires improvement	Requires improvement
Overall	Requires improvement	N/A	Good	Requires improvement	Requires improvement	Requires improvement

Notes

Requires improvement

Diagnostic imaging

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

Are diagnostic imaging services safe?

Requires improvement

We had not previously rated this service. We rated it as **requires improvement.**

Mandatory training

The service offered some formal mandatory training and staff were also expected to read relevant policies on an annual basis to keep them updated.

All the staff had completed a three-hour first aid course, as well as delivering customer service excellence. They were also scheduled to complete mental health awareness and conflict resolution training in July 2019 . One member of staff had also completed a course on stress and conflict in the workplace.

We saw that staff reviewed the various policies on a yearly basis as refresher training, which included topics such as; complaints, data protection and confidentiality, privacy, duty of candour, consent and safeguarding. We could see that all staff members had signed to say they had refreshed themselves on the information in the policy.

Staff told us that the registered manager would also deliver any updates on training topics at team meetings as needed and that these occurred every six months. If an update was urgent, this would be delivered once the registered manager was aware of it.

We were told that new reception staff would shadow a more experienced member of staff for a minimum of ten hours dependent on their experience. They would also spend four hours with the registered manager to review policies and following this they would review policies and updates on a yearly basis, along with the other staff members.

During inspection we saw evidence that staff members was booked onto to a course for mental health awareness and a few of them had also completed a first aid course.

Safeguarding

Clinical staff understood how to protect patients from abuse and the service worked well with other agencies to do so. However, administration staff did not have any safeguarding training.

We saw evidence of the registered manager having completed a safeguarding course in 2016, which was valid until 2019. At the time of inspection, the registered manager was booked onto safeguarding level two for adults a couple of weeks after inspection, after this had been cancelled earlier in the year. They were also booked on to attend the safeguarding children level two training over a two-day period later in the year. Following the completion of this training, the manager was planning to cascade this information to the rest of the staff for their learning. This is not in line with national guidance.

We saw evidence of the service having a safeguarding policy. Within the policy were the contact details for social care services, with a contact number available for use 24-hours a day. The policy listed legal frameworks inclusive of 'Working together to safeguard children, young people, parents and carers' (2015). The policy detailed varying signs and forms of abuse and a flow chart for raising concerns, along with referral forms that could be used for the local safeguarding team.

Diagnostic imaging

One staff member we spoke with had also been keen to include some form of information for those who might be subject to domestic abuse and had ordered information to offer potential victims, current and relevant support numbers. The provider did not give us any evidence that staff within the service were given PREVENT training. This is not in accordance with national guidance.

Cleanliness, infection control and hygiene

The service did not always control the risk of infection . Staff used some control measures to protect patients, themselves and others from infection, although there were some areas which looked like they had not been cleaned thoroughly.

We saw that there was a daily housekeeping schedule for both the scanning room and all other areas of the service. We saw that these had been completed daily. All the cleaning was completed by the staff who worked at the service and we saw evidence that the manager would complete spot-checks monthly.

We saw the cleaning products used by the service, which were kept in a small office within the premises.

Soap and hot water were available in the toilet area. There was a towel in this area, which we were told was changed each day and during days of longer scanning times, it would be changed before the evening scans. There was a poster displaying good hand washing technique next to the sink.

There were areas in the service which did have cobwebs present, so appeared to have been missed from being thoroughly cleaned. This included the room in which the scans were completed.

Environment and equipment

The design, maintenance and use of facilities, premises and equipment kept people safe. Staff were trained to use them.

The building was privately leased. On entering the service, there was a reception area and comfortable seating within the waiting area. There was also a chair and table for clients to view and choose scan pictures, as well as the opportunity to buy gender reveal items. The helium balloon gas cylinder for the gender reveal balloons was kept within the small office. It was freestanding, identified the cylinder as helium and outlined storage requirements. The room could not be accessed by clients. The service had a fire inspection safety certificate and report dated 28 January 2019. There were no areas of concern identified in the report.

The scanning room contained a treatment couch and a large television monitor which was mounted to the wall, on which the images were displayed. There was an ultrasound system which was maintained under a manufacturer's service contract with an ultrasound company. This was regularly serviced to ensure that it was safe to use and we saw evidence that this was current and in date. The room had the door closed during scanning which preserved the privacy of those attending for the scan.

The service had maintenance completed by approved contractors, which included the review of fire extinguishers, which had a yearly service. We saw evidence of the fire assessment and extinguisher check which was current at the time of inspection.

Assessing and responding to patient risk

There was not a clear process for staff to follow in the event there were concerns about a pregnancy. This was important because we saw evidence that the service had completed a scan for a patient who was bleeding.

On arriving at the clinic for a scan, clients were given a consent form to review and sign. Although the form stated that the scan was not to replace NHS scans, it did not clearly state that the person conducting the scan was not a qualified sonographer.

The service offered early pregnancy scans as part of their service. On discussion with the manager undertaking the scans, we were told that if they were unable to see the sac or find a heartbeat, they would offer a free scan a week later. If the registered manager was still unable to see the sac or heartbeat, the client would be advised to attend an early pregnancy unit for further review. We were concerned that the registered manager needed prompting to consider that if they could not identify a pregnancy there may be an underlying complication of early pregnancy such as an ectopic, extra-uterine

pregnancy or molar pregnancy. The registered manager stated that if the woman had any pain or bleeding they were signposted to the local NHS provider or their midwife.

During the course of our inspection it became apparent that the manager had completed a scan on a woman out-of-hours, at request of the woman, as she had concerns over the pregnancy. This lady had been actively bleeding. The registered manager stated that this person had already been in contact with an NHS health provider and subsequently contacted Hello Baby to request the scan.

We saw no evidence of any clear processes to escalate unexpected, or significant findings during scans, particularly those done in early pregnancy. There was no clear process to follow if concerns were detected. There were no clear processes place for any abnormalities picked up during the scan, referral pathways or screening processes.

There was no resuscitation equipment on the site, but staff told us that in an emergency, they would immediately phone '999' for urgent medical assistance.

Staffing

The service had enough staff. Managers ensured staff completed a full induction on starting with the service.

The service was comprised of the registered manager and four reception staff.

We were told about a locum qualified sonographer who would sometimes cover the service if the registered manager was away.

The service did not use agency or bank staff.

The registered manager was not a qualified sonographer, so did not have the skills and knowledge to identify when there might be an issue with the pregnancy. All documentation was clear that the purpose of the scans were for keepsakes only. At the time of the inspection we discussed the scenario where a woman who was bleeding was scanned. The service did not have exclusion criteria, other than for clients under 16 years old. This is not in accordance with best practice and was discussed with the provider at the time of the inspection.

Records

Staff stored consent forms completed by clients attending the service securely.

Written consent was obtained from clients on arrival to the service. All images were reviewed on a computer in the viewing room, after being sent from the main computer. The registered manager would log what had been advised during the consultation. Access to the computer system was password protected.

We observed seven scan appointments including early gestation, gender scans and 3D imaging. Each woman was asked to sign a consent form prior to the scan however the details of the consent form were not discussed with a member of staff to ensure they were understood by the woman and her relatives. The person carrying out the scan did not confirm or gain verbal consent prior to performing the scan.

We saw evidence of a privacy policy, which detailed that the service, with consent, would hold a limited amount of personal data. This also referred to the General Data Protection Regulation (GDPR) which is the regulation which dictates the way in which organisations should manage data.

Consent forms and scans were kept in a locked filing system in another part of the premises and were kept for one year. After the period of one year, the information was shredded and disposed of.

Incidents

The service had a policy for managing incidents.

In the 12 months prior to inspection, there had been no 'never events' or serious incidents.

In the event of an incident occurring, staff said they would be open and honest with clients.

The service reported that there had been no incidents requiring duty of candour to be used. Duty of Candour is used when things go wrong with care and treatment, including informing people about the incident, providing reasonable support, providing truthful information and an apology when things go wrong.

The service had a log for any incidents that occurred. There was only one incident on the log, which related to an abusive person visiting the service.

Requires improvement

Diagnostic imaging

Are diagnostic imaging services effective?

The effective domain was not rated.

Evidence-based care and treatment

The service provided scans based on National guidance, although some of the policies we looked at did not have a clearly defined review date.

The service provided some information referenced to relevant government websites, such as the British Medical Ultrasound Society (BMUS) guidelines from Public Health England (previously the Health Protection Agency) on their website and on the consent form. However, this information was limited and only stated that they scanned within the guidelines set out by the British Medical Ultrasound Society (BMUS) and advised on the consent form, that people should refer to the BMUS website for further information. The service did not refer to more specific Public Health England information, in relation to potential risks with ultrasound scans.

The service used policies. However, some of the policies we looked at did not have a clearly defined review date. Staff told us that all policies were reviewed on an annual basis and they would be updated as required.

Nutrition and hydration

There were snacks and drinks available for clients.

The service had a water cooler and the availability of purchasing snacks, such as crisps and chocolate. The service also had a store of fizzy drinks, which could be offered to women free of charge to help wake babies up, so they would be more awake during their scan. We were unclear what the evidence base was for this recommendation.Clients also had access to nearby cafes and shops, should they wish to use them.

Patient outcomes

Staff did not monitor the effectiveness of care and treatment.

The service did not monitor the quality of scans and patient outcomes. Client experience was monitored through complaints and client feedback forms which were available in the reception area for clients to complete. We reviewed twenty-one customer service and experience questionnaires and noted all were positive about the service they received.

Competent staff

The service made sure employed staff were competent for their roles. Managers appraised staff's work performance and held supervision meetings with them to provide support and development.

The registered manager, who undertook the scans, was not a qualified sonographer but had undertaken training to complete the scans. There was a qualified sonographer who would review the registered manager's practice monthly, although they were not employed by the service. The sonographer practiced within an NHS trust and was Health Care Professional Council (HCPC) registered. We were told that the feedback had always been given verbally. At the time of the inspection they had just started to document this review.

We saw no evidence of links with local hospitals for referral if women needed further review by medical staff.

As the service had a small team, we were told that regular communication ensured that any changes to the service were disseminated.

The registered manager held appraisal meetings every six months and we saw evidence that all the staff had received an appraisal every six months dating back to 2017.

The service held staff meetings every six months, to discuss any issues, or for the registered manager to update on any training, or changes to policy. We were told that everything was diarised into the main reception computer as a reminder for staff.

Multidisciplinary working

There was no evidence of any multidisciplinary working.

The service did not liaise with local GPs, or other healthcare providers. However, it told us that it would refer women to the local early pregnancy unit, midwife or hospital if there were concerns.

Seven-day services

Requires improvement

Diagnostic imaging

The service operated six days a week, with a Sunday opening on the last Sunday of every month.

There was a late-night opening until 8pm and 9pm on two nights (Tuesday and Thursday respectively). This meant those who had commitments in the day had flexibility to attend an appointment.

Health promotion

Staff did not offer patients practical support and advice to lead healthier lives.

We saw no evidence of any health promotion information within the service.

Consent and Mental Capacity Act

Patients were not offered enough time to discuss decisions about their care and treatment.

The service had a consent form for women to read and sign and this included some limited information referring to the British Medical Ultrasound Society (BMUS) advising that further information could be sought on the Health Protection Agency website. However, Public Health England replaced the Health Protection Agency in 2013 and the consent form did not refer to any specific Public Health England advice information.

Consent forms were offered to clients on their arrival and this was taken by whoever was working on the front desk. Each client was provided with a consent form on arrival and they were given some time to read and sign it.

When clients came in for their scan, we saw no evidence of the registered manager, who was undertaking the scans, offering any time to the ladies to discuss the consent form. The registered manager confirmed the client's name, the type of scan they had come for and their estimated date of delivery. This meant that clients were not offered enough opportunity to discuss what it was they had consented for, or inviting them to ask questions about the procedure, or any risks that may pose. We saw no evidence of verbal consent being obtained immediately prior to the scan being completed and compliance was taken as the consent.

The registered manager did not make it clear prior, or during the scans, that they would not be able to rule out any potential medical complications with the pregnancy, or scan. However, the consent form did clearly outline this information.

The consent forms did detail that the scans were not diagnostic and they did not provide obstetric care or replace any scans with the NHS.

We were told that those attending under the age of 18 would be asked to provide identification to confirm their date of birth. However, we were told there were few people under the age of 18 who attended, so we were unable to review evidence of this.

We found no evidence that the provider offered training for staff on the Mental Capacity Act. There was not a policy for this. We were not assured that the provider had an effective system for identifying patients who did not have capacity.

Are diagnostic imaging services caring?

Good

We had not previously rated this service. We rated it as **good.**

Compassionate care

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

Clients were respected and their privacy and dignity were maintained.

We saw clients treated with warmth and compassion from arriving at the service, but particularly whilst having their scans. The sonographer explained each part of the baby on the scan and tried to show the baby's face as much as possible. Many of the clients we saw on inspection were choosing to have gender reveal celebrations with their wider family and friends so had chosen not to find out at the time of the scan. The staff member undertaking the scans would ask them to look away when she was going to check for the gender of the baby, to ensure their surprise could be enjoyed at the time of their choosing.

Requires improvement

Diagnostic imaging

We saw seven scans during inspection and at each one, people were welcomed and treated with care.

Emotional support

Staff provided emotional support to clients, families and carers to minimise their distress.

We saw staff welcoming the clients through the front door and they responded to different emotions appropriately, in that if someone was excited for their scan, they would join in and share the excitement, but they were equally receptive to those attending who might have been nervous and would offer reassurance.

The scans were done in a private scanning room with the door closed, so that further emotional support could be given to those needing it and for as long as necessary.

Understanding and involvement of clients and those close to them

Staff involved clients and their friends and family.

The service encouraged women to bring along friends and family members (including children) to their ultrasound scan, if they so wished. During our inspection, we saw women accompanied by various companions such as, their partner, other family members and friends. We saw that everyone was made to feel welcome and included in the experience.

During our inspection we observed the sonographer explaining the images whilst they were on the screen to the mother and whoever was in attendance with them. This was done in a way that made it easy to understand, with full explanations of detail given. We saw different family members and, as well as partners attend with the women and we saw that relatives and friends were also welcomed to the service and involved in the excitement of the scans.

Following the scan, the women and their families had many images to choose from and during our inspection we observed they were not rushed in picking the ones they wanted.

Information regarding the different types of scans and packages available for people to purchase was clearly presented on the provider's website.

We saw the service sought feedback from clients about the quality of service they had received.

Are diagnostic imaging services responsive?

Requires improvement

We had not previously rated this service. We rated it as **requires improvement.**

Service delivery to meet the needs of local people

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

The service was located near to the centre of a town with access via public transport. There was lots of free parking on the roads and there was also a free car park nearby to the service.

The clinic was located on the ground floor and consisted of a reception area, the scanning room, a small staff office and another area which offered women the opportunity to review their keepsake scan pictures. There was also a toilet with hand washing facilities. Everything within the service was easily accessible for wheelchair users and those with prams and push chairs.

In the scanning room there was an ultrasound machine, a bed for the women to lie on whilst having their scan and several chairs for partners and other relatives and friends to sit on. There was a large raised screen on the wall directly in front of where the women would lie for their scan, so they had clear sight of their baby.

The service was flexible in meeting womens' needs, offering appointments after working hours during the week and at weekends.

Meeting people's individual needs

The service was inclusive and took account of patients' individual needs and preferences.

Staff told us that there was no written provision of information in any language other than English. Staff said they would be happy for clients' friends or family members to attend appointments to translate, if required

and that if need be, they would use an internet translation application. Staff told us that they had never had anyone attend the service who was not English-speaking.

The service had no limit of how many people could attend client scans to share the experience with them, but we were told that people would be informed regarding limitations of the seating area and scan room seating beforehand to create awareness.

The toilets had baby change facilities.

Access and flow

People could access the service when they needed it.

Women could arrange an appointment over the phone seven days a week for one week in every month and for six days on other weeks.

Learning from complaints and concerns

Although the provider had a complaints process, some complaint responses were poor and we saw no evidence of any shared learning from the complaints.

The service had a complaints policy which we reviewed. The policy detailed what to do if someone raised a complaint and this detailed that the service acknowledged receipt of the complaint within a maximum of two days. The policy stated that the complaint would be reviewed by the director of Hello Baby and a formal response sent within seven to ten days of the original receipt. Anyone wanting to make a verbal complaint, was asked to put the complaint in writing. Written complaints were then printed and filed, along with the reply from the service. It also referred to CQC being notified for more serious complaints. We saw no evidence of a review date on the policy, but we were told every policy was reviewed each year.

We saw a log of all emailed complaints and between May 2018 up to the date of inspection, there were six complaints received. Although the name, date received and the actual complaint were logged, there was no recorded outcome. We reviewed one complaint, in which the response given to the complainant were defensive and lacked complete compassion. There was also a log of complaints made through a social media application. We found there to be 25 complaints between March 2018 to the date of inspection, with a theme of feeling rushed during the scanning process and two incorrect gender predictions.

We found that although there was a process in place to manage complaints, responses were varied and we saw no evidence of any robust systems, or processes in place that demonstrated any learning was taken from the complaints, or any sharing of issues with other staff members.

Prior to inspection, we were not told how many complaints had been received for the reporting period, but we did review some complaints whilst on site.

We saw 21 completed 'Hello Baby customer service and experience questionnaires', which were all positive.

Are diagnostic imaging services well-led?

Requires improvement

We had not previously rated this service. We rated it as **requires improvement.**

Leadership

Leaders were visible and approachable in the service for patients and staff.

The company had the registered manager who undertook the scans, as well as four reception staff and a locum sonographer who would cover the service if the registered manager was away. The registered manager had been in post for over three years.

The staff all worked closely as a team and ensured there was effective communication amongst all the staff members.

Vision and strategy

The service had a vision for what it wanted to achieve.

The service provided parents with a memorable keepsake of their pregnancy with images of their unborn baby.

We saw the service regularly sought feedback from clients and acted on suggestions made by them.

Culture

Requires improvement

Diagnostic imaging

Staff felt respected, supported and valued. They were focused on the needs of clients receiving care. The service had an open culture where clients, their families and staff could raise concerns.

The service worked closely as a team and tried to promote an effective and supportive culture. Members of the team had been there for varying amounts of time.

Staff we spoke to reported to be able to discuss any issues with the registered manager as required. We were told that staff would also have the opportunity to raise any issues during team meetings.

Staff were passionate about the service they delivered, but also ensured women were also aware of the importance of attending for all their routine hospital appointments.

Governance

The service operated some governance processes. Staff at all levels were clear about their roles and accountabilities and had regular opportunities to meet and discuss the performance of the service with the registered manager. The service had robust systems and processes to meet the fit and proper persons regulations.

The registered manager had a staff member who took the lead for governance of the service. Staff were clear about their roles and understood their responsibilities. Staff files contained detailed information, including references, DBS checks (for staff delivering care), the application form/CV, photographic identification and evidence of eligibility to work in the UK.

The service had a recruitment policy which detailed that as part of the recruitment process, potential employees should send a copy of their CV and detail reasons as to why they might be suitable for the role. The policy also details that photographic identification, proof of address and proof of any qualifications would also be needed. The policy also stated that a copy of a recent disclosure and barring service check would be required.

Team meetings were held every six months and we saw evidence of the detail of these meetings having occurred twice-a-year for the three-year period leading up to inspection. The content of these meetings would often include updates regarding training or procedures.

We were told that policies were reviewed regularly, however the policies did not have review dates on them to evidence this.

Managing risks, issues and performance

We saw no evidence of a robust risk register for the service.

During inspection, we did not see any evidence of a risk register or other system and process for the identification, regular review, or management of risks.

There were concerns regarding the risks when undertaking scans in early pregnancy as there were no clear processes for the management of this.

There were up to date risk assessment, and health, safety and environment policies and procedures in place and we saw evidence of safety checks such as electrical reviews and fire safety risks having been regularly assessed and evidenced.

Managing information

Client information was managed in a secure way.

Consent forms were stored securely in a locked cabinet in a separate area of the service. If evidence of age had also been obtained for the purpose of the scan, this would also be stored with the consent form. One of the staff members told us that each month, she would be responsible for removing the forms for the month in the year previous and ensuring they were shredded appropriately. This was a process carried out each month, so there were always the consent forms for the exact month a year earlier, in case required.

Engagement

The service engaged with clients and staff to plan and manage services.

There was a social media page for the service, which enabled clients who attended for scans to share posts of their gender reveal celebrations, as well as offering feedback on the service they had received.

The service had feedback forms which were available for clients to complete.

Learning, continuous improvement and innovation

Requires improvement

Diagnostic imaging

The service engaged with clients and staff to plan and manage services, but there was no evidence of any shared learning.

The service was not able to provide any evidence of any learning or shared learning from client feedback.

Outstanding practice and areas for improvement

Areas for improvement

Action the provider MUST take to improve

- The provider must ensure that all staff have appropriate training to ensure that they understand the principles of the Mental Capacity Act in relation to obtaining valid consent.
- The provider must ensure that those using the service are given the opportunity to discuss the consent in detail prior to the scan being completed and therefore enable conversations about risks relating to the procedure.
- The provider must ensure that actions are taken to prevent similar complaints happening. The provider must also review how they respond to complaints made.
- The provider must ensure that all reception staff receive sufficient safeguarding training.
- The provider must ensure that all eligible staff receive PREVENT training.

Action the provider SHOULD take to improve

- The provider should consider adding review dates to their policies and procedures.
- The provider should consider reviewing its cleaning procedures.
- The service should consider the implementation of a risk register for risks within the service.

This section is primarily information for the provider

Requirement notices

Action we have told the provider to take

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

Regulated activity	Regulation
Diagnostic and screening procedures	Regulation 11 HSCA (RA) Regulations 2014 Need for consent The provider did not ensure that those using the service were given the opportunity to discuss the consent in detail prior to the scan being completed and therefore not enabling conversations about risks relating to the procedure. The provider did not ensure that all staff had appropriate training to ensure that they understood the principles of the Mental Capacity Act in relation to obtaining valid consent.

Regulated activity	Regulation
Diagnostic and screening procedures	Regulation 12 HSCA (RA) Regulations 2014 Safe care and treatment The provider did not ensure that it did everything reasonably practicable to mitigate any risks to those using the service.

Regulated activity	Regulation
Diagnostic and screening procedures	Regulation 13 HSCA (RA) Regulations 2014 Safeguarding service users from abuse and improper treatment The provider did not ensure that all members of staff had received safeguarding training.

This section is primarily information for the provider

Requirement notices

Regulated activity	Regulation
Diagnostic and screening procedures	Regulation 16 HSCA (RA) Regulations 2014 Receiving and acting on complaints The provider did not ensure there that actions were taken to prevent similar complaints happening, nor was there a standardised approach in responses to complaints made.

This section is primarily information for the provider

Enforcement actions

Action we have told the provider to take

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