Hello Baby (UK) Limited

Hello Baby

Inspection report

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Overall summary

We carried out an announced comprehensive inspection on 31 March 2016 to ask the service the following key questions; Are services safe, effective, caring, responsive and well-led?

Our findings were:

Are services safe?

We found that this service was not providing safe care in accordance with the relevant regulations.

Are services effective?

We found that this service was not providing effective care in accordance with the relevant regulations.

Are services caring?

We found that this service was providing caring services in accordance with the relevant regulations.

Are services responsive?

We found that this service was providing responsive care in accordance with the relevant regulations.

Are services well-led?

We found that this service was not providing well-led care in accordance with the relevant regulations.

Background

This comprehensive inspection was undertaken as a result of a number of concerns about the service being highlighted to CQC.

CQC last inspected the service on 5 December 2014 and asked the provider to make improvements regarding infection control and supporting workers. We checked these areas as part of this comprehensive inspection and found these had been resolved.

Hello Baby is an ultrasound scanning business which provides non-clinical baby scans in 2D and 3D/4D. Non-clinical scans are also referred to as souvenir or entertainment scans.

Hello Baby is located on a busy high street in an area of St Helens. The service is open on a Monday, Wednesday, Friday, Saturday and Sunday mornings for scanning but there are also receptionists working each day. People can either book an appointment direct with the service or via the on-line booking system.

At the time of the inspection there were no qualified sonographers employed by the service.

The provider is the registered manager. A registered manager is a person who is registered with the Care Quality Commission to manage the service. Like registered providers, they are 'registered persons'. Registered persons have legal responsibility for meeting the requirements in the Health and Social Care Act 2008 and associated Regulations about how the service is run.

Summary of findings

Our key findings were:

- People reported they were treated with compassion, dignity and respect and they were involved in their care and decisions about their treatment.
- Information about services and how to complain was available and easy to understand.
- The scanning room were well organised and equipped.
- There were systems in place to check all equipment had been serviced regularly.
- Staff maintained the necessary skills and competence to support the needs of people
- Staff were not working within current guidelines.
- Staff were kind, caring, competent and put people at their ease.
- The provider was aware of, and complied with, the requirements of the Duty of Candour.

We identified regulations that were not being met and the provider must**:**

- Review and implement current guidelines regarding the frequency of scans and ensure those guidelines are adhered too.
- Review the content of the consent form to ensure it contains British Medical Ultrasound Society advice and guidance on entertainment scans.
- Implement appropriate risk assessments to ensure service users were not put at risk.
- Ensure that staff receive training in safeguarding and whistleblowing and develop local procedures to inform staff how to follow local reporting processes.

You can see full details of the regulations not being met at the end of this report.

There were areas where the provider could make improvements and should:

- Review the advertising of the service to ensure that they are not in breach of advertising standards and guidelines.
- Implement a system of audit for identifying where quality and/or safety may have been compromised.
- Review all policies and procedures to ensure they reflect the business of the service and comply with regulations.
- Use password protection on the scanning machine

Summary of findings

The five questions we ask about services and what we found

We always ask the following five questions of services.

Are services safe?

We found that this service was not providing safe care in accordance with the relevant regulations.

There were no systems in place for identifying, investigating and learning from incidents relating to the safety of service users and staff.

The staffing levels were appropriate for the provision of the service provided.

Risk management processes were not in place to manage and prevent harm.

Staff had not received training in safeguarding and whistleblowing but did know the signs of abuse. Local procedures were not available to enable staff to report safeguarding concerns.

We found the equipment and premises were well maintained with a planned programme of maintenance.

Are services effective?

We found that this service was not providing effective care in accordance with the relevant regulations.

Each person was assessed to establish needs and preferences. Equality and diversity was recognised within the practice

Staff had the right qualifications to undertake non clinical scans and were updated through training. However there were concerns that staff worked outside their qualifications and expertise.

Informal protocols were in place for referring people back into the NHS antenatal system if required.

Consent forms were signed by all people having a scan but we could not assure ourselves that when they signed the form they had read it and understood it.

Information was available about the cost of the scans and option choices.

Are services caring?

We found that this service was providing caring services in accordance with the relevant regulations.

Feedback from people through completed comment cards was positive about their experience at the service.

People commented that they were listened to, treated with respect and were involved in the scanning process.

People also commented that the staff were caring and committed to their work and displayed empathy, friendliness and professionalism towards them.

We found staff spoke with knowledge and enthusiasm about their work.

Are services responsive to people's needs?

We found that this service was providing responsive care in accordance with the relevant regulations.

The facilities and premises were appropriate for the service which was delivered.

People were offered appointments to suit their preferences.

The provider informally gathered the views of its people through verbal feedback and social media posts.

Summary of findings

There was a complaints system in place.

Are services well-led?

We found that this service was providing well-led care in accordance with the relevant regulations.

Staff were supported by management and were clear about the line of accountability.

Records relating to the employment of staff included information relevant to their recruitment.

There was no evidence that service audits were being undertaken to assess the quality of the service.

Hello Baby

Detailed findings

Background to this inspection

We inspected this service as part of our new comprehensive inspection programme under Section 60 of the Health and Social Care Act 2008 as part of our regulatory functions. This inspection was planned to check whether the provider is meeting the legal requirements and regulations associated with the Health and Social Care Act 2008 (Regulated Activities) Regulations 2015, to look at the overall quality of the service.

We carried out an announced comprehensive inspection at Hello Baby on 31 March 2016 as a result of concerns being raised with the CQC about the service.

Our inspection team was led by a CQC Lead Inspector who was accompanied by a Specialist Advisor who had experience in Midwifery and antenatal care.

During our visit we:

• Spoke with the provider and a receptionist.

• Reviewed records and documents.

• Reviewed 50 comment cards where people shared their views and experiences of the service.

• Toured the premises.

To get to the heart of patients' experiences of care and treatment, we always ask the following five questions:

- Is it safe?
- Is it effective?
- Is it caring?
- Is it responsive to people's needs?
- Is it well-led?

These questions therefore formed the framework for the areas we looked at during the inspection.

Are services safe?

Our findings

Reporting, learning and improvement from incidents

The provider did not clearly understand their responsibilities in the recording of safety incidents, concerns and near misses, although they did report them externally where appropriate. The provider told us of two recent incidents where the scan had indicated that there could be a problem with the pregnancy. These incidents were not recorded in an incident log but were logged in the referral book. There was evidence that where concerns were identified people were referred to the relevant service, for example back to the NHS for further investigation. People were told verbally to refer themselves back into the NHS system. The provider followed this up with a phone call to the relevant service to explain their concerns.

There had been a number of complaints regarding the wrong sexing of the baby when scans were undertaken and the attitude of staff. The provider had taken appropriate action to resolve these complaints.

Reliable safety systems and processes (including safeguarding)

The service had information in place regarding safeguarding but staff had not received any form of training.

The information available to staff on how to identify and report safeguarding concerns was a nationally available document. However there was no local information regarding the referral process.

The scanning machine was not password protected which could mean data held on the machine could be accessed by anyone attending the service. The provider told us that people were rarely left alone in the scanning room but agreed to consult with the manufacturers on how a password could be installed.

On the booking system people's details were recorded. We saw that this was password protected to stop unauthorised viewing.

Medical emergencies

The service is a non-clinical service and therefore medical resuscitation equipment was not required. We saw that staff were booked onto a first aid course on 21 April 2016. The provider has been asked to send confirmation to CQC when this has taken place.

If a medical emergency did take place within the premises the staff would call the emergency NHS services to deal with it.

Staffing

All staff had received a disclosure and barring check (DBS check). (DBS checks identify whether a person has a criminal record or is on an official list of patients barred from working in roles where they may have contact with children or adults who may be vulnerable).

Monitoring health & safety and responding to risks

We saw that health and safety within the environment and risks to the unborn baby were not fully monitored.

Staff did not understand the standards and guidelines associated with ultrasound scanning. We found that the provider did not adhere to guidelines from the Royal College of Obstetricians, NICE guidelines or British Medical Ultrasound Society. When asked, the provider was unaware of any guidelines relating to how early a foetus should be scanned or how frequently scans should be carried out. They told us that scans were only performed from seven weeks and the actual scan took less than five minutes usually.

Although not legally required, the provider had let their registration to the British Medical Ultrasound Society (BMUS) lapse. Being a member of this group entitled people to receive updates on ultrasound scanning and a facility to improve their knowledge and skills.

Infection control

There were limited systems in place to manage infection prevention and control. We did not see an infection control policy for the premises. A hand washing poster was displayed near all hand wash sinks. Between each scan the paper covering the bed was removed and replaced. However we saw that there were also domestic towels and padding on the bed. The provider told us that these were changed every day. The provider also told us that they cleaned the scanning head between each scan and they used antibacterial wipes on the machine weekly.

Are services safe?

Staff had undertaken infection control training on 21 March 2016. However we did not see evidence of change of practice following this course for example, cleaning equipment was not stored safely and cleaning schedules had not been introduced.

The premises appeared clean and well maintained. We were told that the receptionists were responsible for cleaning the premises.There was a good supply of cleaning equipment and supplies; however these were not stored appropriately. The provider moved them to a more secure place when we pointed this out. We were not shown any cleaning schedules for the premises.

Premises and equipment

The service was run from a double fronted shop type building in the centre of the high street. Privacy was maintained in the scanning room and a separate private area was available for people to review their scans or share them with family.

All electrical equipment was checked to ensure the equipment was safe to use and the machine was checked to ensure it was working properly. There were systems in place to check all equipment had been serviced regularly. We were shown the annual servicing certificates which showed the service had a system in place to ensure all equipment in use was safe, and in good working order.

There was a system in place for the reporting and maintenance of faulty equipment. Records showed and staff confirmed repairs were carried out promptly which ensured there was no disruption in the delivery of the service.

Safe and effective use of medicines

No medicines were used or stored at the location.

Are services effective?

(for example, treatment is effective)

Our findings

Assessment and treatment

This service provided scans for entertainment value only. However systems were not in place to ensure that scanning was delivered in line with evidence based guidelines and standards. Staff did not understand the standards and guidelines associated with ultrasound scanning. We found that the provider did not adhere to guidelines from the Royal College of Obstetricians, NICE guidelines or British Medical Ultrasound Society.. When asked, the provider was unaware of any guidelines relating to how early a foetus should be scanned or how frequently scans should be carried out.

Staff training and experience

The provider was the only member of staff who carried out scanning. They were not trained as a diagnostic sonographer but had received training regarding the use of the scanning machine.

The provider understood their level of ability to perform scans and was aware that they were not offering diagnostic procedures. However CQC had received a number of concerns that indicated that on occasions diagnostic advice was being given to service users. When we discussed this we were told that the provider was using her experience gained during five years of providing this service.

Receptionists had received limited statutory training and training in customer care.

Working with other services

We were told that if the provider did suspect something was wrong with the pregnancy or with the baby they would refer the service user to NHS clinical services. There were systems in place to refer people back into the NHS for investigation.

We saw that the provider kept records of all people they had referred to the NHS and the reasons for the referral .

Consent to care and treatment

People who came for scans at Hello Baby had to sign a consent form. The consent confirmed that the scanning was for entertainment purposes only.

In signing the consent form people were agreeing that if the scan highlighted a potential problem then the person would be asked to attend their NHS antenatal team for further investigation. There was also a disclaimer that the ultrasound technician could not be held responsible for any complication or disorder that went unrecognised. The form also included disclaimers regarding the potential lack of clarify of early scan images. There was also a claim on the consent form that scans were provided within the guidelines set out by BMUS and scans included a foetal heartbeat check.

All consent forms were signed by people undergoing a scan but they were not given a copy. As the consent was very detailed it was as unclear if people actually read or understood the contents of the form or the advice given within it.

Are services caring?

Our findings

Respect, dignity, compassion & empathy

We received 50 completed CQC comment cards for this service. Every comment recorded was very positive about the way people had been treated.

All scans were undertaken in the private scanning room with the door closed. There was a separate area in the building where people could look at their scans and share these with their family.

Every comment card we received said that staff were friendly and welcoming and that they had a good experience when using the service.

We found the ultrasound technician treated people with compassion and empathy especially if they thought they may had noticed an abnormality in the scan. However the provider on occasions provided details about the pregnancy that they were not trained or registered to provide. .

Involvement in decisions about care and treatment

People attended the service voluntarily to obtain pictures of their unborn baby. They did not receive any care or treatment from the service.

Are services responsive to people's needs?

(for example, to feedback?)

Our findings

Responding to and meeting patients' needs

The service offered flexible appointments to meet the needs of the people requesting scans. The provision of services was kept under review to meet demand. Staff reported the service scheduled enough time for people to undergo the scan and review the pictures taken.

The facilities at the service complied with the Disability Discrimination Act 2005; they were comfortable and welcoming for patients, with a manned reception area and an appropriately decorated waiting area

The scanning room was small but was arranged with peoples comfort and needs in mind.

The service had effective systems in place to ensure the equipment and materials needed were always available.

Tackling inequity and promoting equality

The service was offered on a fee basis only and was accessible to people who chose to use it.

We asked staff to explain how they communicated with patients who had different communication needs such as those first language was not English. Staff told us they ensure that someone with them could speak English and was able to translate for them. The provider told us thatthe service treated everybody equally and welcomed patients from different backgrounds, cultures and religions.

Access to the service

Appointments were available at varied times throughout the week but were also dependent on the availability of the ultrasound technician.

The length of the appointment was specific to the package people agreed and paid for.

Concerns & complaints

Prior to the inspection CQC had received a number of concerns and complaints regarding this service.

On reviewing the complaints procedure for the service we found that there were systems in place for the handling of written and verbal complaints. The provider told us, however, that some people, if unhappy about the service, would place comments on the service's Facebook page. The lack of detail in some of these concerns made it hard for the provider to identify the concern and respond appropriately. We were told that any complaint would be reviewed openly and fairly and the provider strove to reach a satisfactory outcome.

When we reviewed five complaints received by the service. We saw that the provider had handled these complaints in line with their complaints process. The complaints raised with the CQC had not been raised directly with the provider.

Are services well-led?

(for example, are they well-managed and do senior leaders listen, learn and take appropriate action?)

Our findings

Governance arrangements

There were limited governance arrangements in the service. The service did not have written policies and procedures in place to cover all processes and procedures..The policies and procedures we saw had been reviewed but did not reflect current good practice guidance from for example the British Medical Ultrasound Society (BMUS).

The provider had responsibility for the day to day running of the service. They held quarterly staff meetings with the staff to discuss service provision. There was an agenda for these meetings but minutes of the meetings were not kept. There were only three members of staff employed so informal day to day discussions took place.

Leadership, openness and transparency

The provider was in day to day control of the service. During the inspection we spoke to two members of staff who told us they enjoyed working there and felt very supported by the provider. Staff told us there was an open culture within the service and they had the opportunity to raise any issues at any time with the provider. Staff were involved in discussions about how to run and

develop the service, and to identify opportunities to improve the service.

Learning and improvement

The management of the service was focused on achieving high standards of excellence and

provided daily supervision and support for staff. We found formal appraisal had been undertaken.

However there were limited systems in place that ensured the service regularly monitored the quality of the service provided and made any changes necessary as a result.

Provider seeks and acts on feedback from its patients, the public and staff

The provider usually sought feedback from people using social media. People were encouraged to write reviews on the providers Facebook page. The provider said they read these reviews and in the main everyone was positive about the service they received.

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 12 HSCA (RA) Regulations 2014 Safe care and treatment **Regulation 12**: Safe care and treatment. **How the regulation was not being met:** The provider did not systems in place to ensure that service was delivered in line with evidence based guidelines and standards to prevent avoidable harm or risk of harm. The provider could not demonstrate that staff have the qualifications, competence, skills and experience to keep people safe. 12 (1) (2) (b) (c)

Regulated activity	Regulation
Diagnostic and screening procedures	Regulation 11 HSCA (RA) Regulations 2014 Need for consent **Regulation 11: Need for consent** **How the regulation was not being met:** The provider did not systems in place to ensure that care and treatment of people must only be provided with the consent of the relevant person When a person is asked for consent information about the proposed care must be provided including information about the risks, complications and alternatives. 11 (1)

Regulated activity	Regulation
Diagnostic and screening procedures	Regulation 17 HSCA (RA) Regulations 2014 Good governance

This section is primarily information for the provider

Requirement notices

Regulation 17: Good governance

How the regulation was not being met:

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

17(2) (b)