Brayford Studio Limited

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

Summary of findings

Letter from the Chief Inspector of Hospitals

Brayford Studio was operated by Brayford Studio Limited. The service was situated at ground level in a small building on an office park close to the City of Lincoln.

The service provided diagnostic imaging specifically for ultrasound scanning procedures. This included baby scans and gynaecological scans and for diagnostic purposes as well as keepsake for reassurance purposes. The provider refered clients to hospital or other services where required.

We inspected this service using our focused inspection methodology. We carried out the inspection on 13 May 2019.

During our inspection, we looked for improvements made following the issue of a warning notice dated 3 February 2019, following the inspection dated 22 January 2019. We did not provide an overall rating for this provider at this inspection as we did not carry out a comprehensive inspection. We looked at a number but not all of key lines of enquiry within the key question for safe and well led.

Services we rate

We found areas of practice that required improvement;

- There was no mandatory training programme in key skills for staff, and no induction programme.
- There was no safeguarding policy and no written protocols available for staff to be able to identify and manage any safeguarding concerns.
- There was a chaperone policy in place, however this did not include acknowldegment to a requirement of appropriate chaperone training or completion of any pre employment checks.
- The service did not control infection risk well. There was an infection prevention and control policy in place, however, it was limited and did not cover all areas of infection prevention and control. There was no standard cleaning schedule in place.
- There were no arrangements in place for maintenance and calibration of scanning equipment.
- There was no schedule or process for secure destruction of paper records in line with legislation. This posed a risk to the confidentiality of client information.
- There was not an effective governance framework in place to deliver good quality care.
- There were limited written policies, processes or protocols in place to govern and monitor activity.
- The provider did not ensure that all staff underwent appropriate checks as required by schedule 3 of the Health and Social Care Act (HSCA) 2008 (regulated activities) regulation 2014.
- There was no mechanism for monitoring the quality and safety of the provider's practice.
- The service had no systems in place to identify, record or manage risks and cope with both the expected and unexpected.
- There was no systematic programme of clinical and internal audits.

Following our inspection, we commenced further enforcement activity.

Name of signatory

Nigel Acheson – Deputy Chief Inspector of Hospitals.

Summary of findings

Contents

Brayford Studio Ltd

Services we looked at
Diagnostic imaging;

Summary of this inspection

Background to Brayford Studio Limited

Brayford Studio was operated by Brayford Studio Limited. Brayford Studio was an independent ultrasound service based in Lincoln. The service offered a range of obstetric and gynaecology ultrasound scans providing both medical and diagnostic scans, 4D bonding and pregnancy reassurance scans. People generally self referred to this service. Brayford Studio Limited had a registered manager who is also the provider and the only sonographer. At the time of our inspection, the provider employed a chaperone for all gynaecological and obstetrical scans, and a cleaner for services once a week.Following our inspection in January 2019 we subsequently imposed a condition on the providers' registration under 12(5)(b) of the Health and Social Care Act 2008. The registered provider must not perform gynaecological diagnostic scanning procedures.

Our inspection team

The team that inspected the service comprised Simon Brown, Inspection Manager and a CQC Assistant Inspector. The inspection team was overseen by Carolyn Jenkinson, Head of Hospital Inspection.

Information about Brayford Studio Limited

The clinic had one scanning room, a reception area, a waiting room and a kitchen/store room. The clinic also had a toilet facility available for staff, women and those who accompanied them. The premises were located on the ground floor of a business unit and was fully accessible. The clinic was registered to provide the following regulated activities:

- Diagnostic and screening procedures

All women accessing the service self-referred to the clinic at a time to suit them. The clinic operated five times a week excluding Wednesday and Sunday.

The clinic did not use or administer controlled drugs.

There was one registered manager and a chaperone under a service level agreement employed to work in this service.

We were unable to establish how many procedures the provider undertook in the year proceeding our inspection.

The service has been inspected three times, the most recent was 22 January 2019.

Services accredited by a national body:

- There were no services provided that were accredited by a national body.

Services provided at the clinic under service level agreement:

- A chaperone service.
- Clinical Waste Management.
- A cleaning service.

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?

- There was no safeguarding policy and no written protocols available for staff to be able to identify and manage any safeguarding concerns.
- There was a chaperone policy in place and there was access to a suitable chaperone for intimate gynaecological scans, however we were not assured this provided good quality care.
- The service did not control infection risk well. There was an infection prevention and control policy in place, however it did not include all elements of infection, prevention and control. There was no standard cleaning schedule.
- There were no arrangements in place for maintenance and calibration of scanning equipment.
- There were no schedules or processes for secure destruction of paper records in line with legislation. This posed a risk to the confidentiality of client information.

Are services well-led?

- We were not assured that there were effective governance systems in place to ensure the regulated activities were carried on in accordance with the regulations. This meant there was a risk the health, welfare and safety of people who used the service might not be protected.
- There was not an effective governance framework in place to deliver good quality care. There were no written policies, processes or protocols in place to govern and monitor activity.
- The provider did not ensure that all staff underwent appropriate checks as required by schedule 3 of the Health and Social Care Act (HSCA) 2008 (regulated activities) regulation 2014.
- There was no policy for the storage, security and destruction of records. There was no schedule or process for secure destruction of records in line with legislation. There was a risk of unauthorised access to these records. This posed a risk to the confidentiality of client information
- There was no mechanism for monitoring the quality and safety of the provider's practice.
- The service had no systems in place to identify, record or manage risks and cope with both the expected and unexpected.

Summary of this inspection

- There was no systematic programme of clinical and internal audit.

Diagnostic imaging

Safe	
Well-led	

Are diagnostic imaging services safe?

Safeguarding

- The provider did not fully understand how to protect patients from abuse and we were not assured that the service worked well with other agencies to do so. The provider demonstrated a lack of awareness for safeguarding, by informing us, women who attended the clinic did not present with any safeguarding concerns. The registered manager displayed no knowledge about Child Sexual Exploitation (CSE) and Female Genital Mutilation (FGM) and said 'it does not happen here'.
- There was no record of staff completing any safeguarding training. It is the duty of healthcare organisations to ensure that all health staff have access to appropriate safeguarding training to ensure staff understand the clinical aspects of child welfare and information sharing. The Safeguarding children and young people: roles and competences for health care staff intercollegiate document 2018, sets out the requirements related to roles and competencies of staff for safeguarding vulnerable children and young people. Level 2 training is required for all non-clinical and clinical staff that had any contact with children, young people and/or parents/carers. Whilst the service did not directly treat children, children may visit this service accompanying patients.
- At the time of our inspection, the registered manager was not aware they were the designated safeguarding lead and could not confirm they had received training to the correct level for both adults and children, did not know their responsibilities, how to recognise a potential safeguarding issue or know the actions they should take.
- The provider had failed to act on the warning notice issued on 3 February 2019, outlining the failure to comply with regulation due to not having a safeguarding policy in place. During this inspection, we did not see a safeguarding policy at the location and no written protocols available for staff to be able to identify and manage any safeguarding concerns.
- During our inspection we had a telephone conversation with the employed chaperone, who demonstrated appropriate knowledge on safeguarding and the pathway to follow should a safeguarding incident arise, despite having no safeguarding training provided by the service. They also confirmed they had not received specific chaperone training; however, said they would know if the procedure was being carried out in an inappropriate way due to their experience in early pregnancy scans and their midwifery training. We were not assured this would be the case as the chaperone's explanation of their clinical background did not include gynaecology scanning. Furthermore, they demonstrated little understanding of the action to take should they encounter an issue for example who and when to raise a concern in regard to any poor conduct or if the patient raised any concerns with regards to the carrying out of the procedure. The provider policies and procedures did not include information on how the chaperone should report issues and to whom.
- At our January 2019 inspection the provider did not employ a chaperone and did not have a chaperone policy in place. Following the January inspection we imposed a condition on the providers' registration so that it must not perform gynaecological diagnostic scanning.
- At our May 2019 follow up inspection we saw the service had written a chaperone policy, dated 1 March 2019, which we saw during our inspection. The policy detailed an impartial observer (chaperone) being offered to patients whenever an intimate examination was carried out. The chaperone policy did not include reference to what level chaperone training was required, what was expected of the chaperone or any required pre employment checks.

Diagnostic imaging

- During our inspection we saw, documented in the provider's hand written diary, eight out of a possible 12 trans-labial scans (four were DNA (did not attend)) had been completed between 26 January 2019 and 28 February 2019, without an appropriate chaperone. The provider previously, verbally informed us they would not perform any trans-labial scans without an appropriate chaperone present. We spoke with the provider about this, who stated women were accompanied by either their friend or relative who the provider deemed was an appropriate chaperone. A chaperone is usually a health professional who has knowledge of the chaperone role and familiar with the procedures involved in performing a routine intimate examination. We were not assured that the provider understood the role and remit of the chaperone role.
- The provider informed us, following the inspection, they would electronically send copies of a sample of patient consent forms. After formally requesting these documents we received a sample of eight patient consent forms by email on 17 May 2019. All eight forms contained reference to a chaperone and all were circled yes to the question, 'is chaperon present for you'. However this referred to a family or relative, not an appropriate employed chaperone.
- During our inspection we saw a blank copy of an updated pelvic trans-labial ultrasound consent form which included the option of having a chaperone present during the scan. The request required patients to circle either yes or no.

Cleanliness, infection control and hygiene

- Since our last inspection the service had written an infection prevention and control policy, dated 1 April 2019, which we saw during our inspection. We reviewed the policy, it did not have the required information within it to support staff in adopting best practice. The policy did not cover all the essential elements of the Health and Social Care Act 2008: Code of Practice for health and adult social care on the prevention and control of infections and related guidance. For example, it did not define specific roles and responsibilities for cleaning; cleaning routines; sufficient resources dedicated to keeping the environment clean. There was no auditing of compliance with the policy.
- There was a lack of personal protective equipment, we saw a small stock of disposable gloves and sheaths available in the ultrasound room, which included latex-free products for clients who had a latex allergy. We asked the provider if there were any aprons, the provider did not have any and did not routinely use these.
- We saw no standard cleaning schedule, and no evidence to suggest when the environment or equipment was last cleaned and by what means.
- The provider had employed a member of staff to complete cleaning duties, we saw a service level agreement, dated 5 March 2019, between the provider and a named person. The service level agreement documented cleaning services to be carried out once per week, however no specific details were listed, for example, no rooms, areas or equipment for cleaning required were recorded.
- The provider had a service level agreement with a specialist waste disposal and collection company, dated 1 March 2019, this included a 360 litre wheelie bin and a two litre sharps bin. The wheelie bin contained one clinical waste bag, it was located outside the premises and whilst the bin was locked, it was not securely locked to the wall, and there was a risk this could be removed. The registered manager did not understand the importance of ensuring the external clinical waste bin was secured. We saw the sharps bin located in the store room/kitchen. There were also a number of clinical waste bags stored in the store room/kitchen.
- The clutter in the scanning room had reduced since our previous inspection, however we saw a pile of paperwork under the computer desk. The scanning room floor was still carpeted, although the provider informed us a company was coming to measure to replace the carpet with washable floor to promote easy cleaning and adherence to infection prevention and control legislation.
- The provider informed us the couch covers were washed every other day, however there was no record documenting this. The infection prevention and control policy did not include details of this, or the temperature covers were washed at.

Diagnostic imaging

- The provider had installed a sink into the scanning room since our last inspection to enable effective hand washing within the clinical environment. The sink had hot running water.
- There had been no hand hygiene or cleaning audits conducted during the previous 12 months, the provider informed us plans to complete audits were being written although we did not see any evidence of this.

Environment and equipment

- The waiting area and reception area was comfortable and pleasant with sufficient seating for people waiting. There were toys available for young children. Since our previous inspection, the provider had replaced the sofas in the waiting area with wipable leather sofas, and removed the blankets.
- The corded window blinds we noted during our previous inspection were still in use in the waiting room where children waited. This provided a potential ligature risk for children.
- We did not see any first aid or emergency equipment at the premises and there was no risk assessment made to mitigate risk of emergency or collapse.
- The provider had two pieces of ultrasound equipment, the newest machine was kept in the scanning room. The provider showed us an email which confirmed completion on the new equipment. There were no service records or maintenance contract available on site, however the provider informed us that service and calibration of the equipment was completed once a year. The provider completed daily visual checks of the equipment, but did not keep any record of the checks. The provider informed us they would begin to document the checks completed on the equipment.
- The second ultrasound machine was kept in the waiting room with a cover over it. This had been serviced by an external company on 3 May 2019.

Records

- The provider had failed to act on the warning notice issued on 3 February 2019, outlining the failure to comply with regulation, relates to not having a schedule or process for secure destruction of records in line with legislation. At this inspection the provider informed us client records were stored in an off site storage unit, in a lockable cabinet. At our previous inspection, client records were kept in a locked cabinet in the reception area at the premises.
- We saw client records stored on a total of three memory sticks, which the provider informed us were kept in their pocket at all times. When we asked the provider if the memory sticks were encrypted, they were not aware of what this meant. During our inspection the provider misplaced one of the memory sticks, it was later found attached at the bottom of their trouser. There was no consideration made of the risks to information breaches, if the memory sticks were lost or stolen.

Are diagnostic imaging services well-led?

Governance

- There was no robust governance framework or management systems in place to support the delivery of good quality care. There was no evidence that the service had considered the risks and challenges of the service despite the previous concerns raised by the CQC with the registered manager. In particular the service did not have an agreed, shared and comprehensive definition of which incidents to report.
- There was no agreed policy which defined incidents, how to investigate them or communicate outcomes. As a result, the service did not have fully developed systems to record, analyse or learn from incidents, or a process for reporting them. There was no schedule of clinical and internal audit in place to monitor quality and systems to identify where action should be taken. The registered manager was unable to provide evidence of any audits.
- Following our Notice of Decision dated 27 March 2019 to impose a condition on the providers' registration so that it must not perform gynaecological diagnostic scanning, the service had written a chaperone policy, dated 1 March 2019, and an infection prevention and control policy, dated 1 April 2019, however we were not assured that either policy were effective to deliver

good quality care. These were the only two policies available to us on the day of our inspection, therefore suitable policies and procedures were not in place to govern the regulated activity.

- There was no infection control risk assessment to identify control measures staff should use to prevent the spread of infection and staff had not been trained in infection prevention or control practices as they had not had mandatory training. There was no system in place to ensure staff had received essential mandatory training such as fire safety, safeguarding and first aid. The registered manager had not undertaken any mandatory training and had not checked that the member of staff carrying out chaperoning had done so.
- The service did not ensure all staff underwent appropriate checks as required by schedule 3 of the Health and Social Care Act 2008 (regulated activities) Regulation 2014. The recruitment procedures were ineffective, for example, we asked the registered manager to look at the file for the chaperone they employed. There was no such file, the registered manager had not requested references. The provider had acted on the warning notice issued on 3 February 2019, outlining the failure to comply with regulation due to not ensuring staff had received a DBS (Disclosure and Barring Service) check. At the time of our inspection, the provider informed us they had seen the DBS check for the employed chaperone, however they did not have a record of this. A copy of the DBS certificate was later emailed to us, on 16 May 2019.
- There was no policy for the storage, security and destruction of records. There was no schedule or process for secure destruction of records. We also found the registered manager to be storing patient information on non-encrypted media sticks. We asked the registered manager if they were encrypted and they confirmed they were not. We further asked how the media sticks were stored, they informed us that "they were always kept on their person". During the process of our inspection, one media stick was misplaced for a short period of time, the registered manager showed little concern for this and said, "I am sure it will turn up". We later pointed out to the registered manager that the media stick could be seen hanging from the bottom of his trouser.
- The registered manager did not have the skills, knowledge or experience required to ensure provision of sustainable high-quality care. There had been a lack of action following our previous inspection. During this inspection we asked the registered manager if they understood their responsibilities in relation to reporting a notifiable safety incident to CQC, but they did not and did not answer our question. Furthermore, we noted on the provider website they were to commence services in Harley street. We asked the registered manager on behalf of the provider what the providers intentions were for this service, the registered manager informed us they were planning to carry out the same service operated at Brayford studio but in Harley street. We asked the registered manager if they had considered if this needed to be added as a registered location to their current registration and if they were considering applying, the registered manager did not respond to this, we asked again if they were going to update their statement of purpose, the registered manager asked what this was and how should they do this. During a further conversation during the inspection the registered manager demonstrated a lack of knowledge on the role of CQC by asking for clarification on who it was that could allow or disallow him from carrying on activity as a consultant, was it the CQC or the GMC. We reminded the registered manager of the role of the CQC and the meaning of regulated activities. This and other issues the registered manager required clarification on, demonstrated a lack of knowledge and understanding.

Managing risks, issues and performance

- The provider had failed to act on the warning notice issued on 3 February 2019, outlining the failure to comply with regulation due to not having a formal induction process for new staff including safeguarding training. During our inspection we had a telephone conversation with the employed chaperone, who confirmed they had not received a formal induction, however at the time of our inspection the member of staff had not began their role as chaperone.

Diagnostic imaging

- The service did not have robust systems to monitor, analyse or take action on safety, quality, performance or risk. There were no robust arrangements for identifying, recording and managing risks and mitigating actions or contingency plans. Risks we identified during our inspection for example the lack of safeguarding and mandatory training for staff, had not been identified by the service and therefore could not be mitigated. The registered manager demonstrated no understanding of the risk management process. This had not improved since our last inspection.
- There was no systematic programme of clinical and internal audits.
- **Learning, continuous improvement and innovation**
- There were no systems and processes for learning continuous improvement and innovation. There were no record of complaints or responses to them.

This section is primarily information for the provider

Enforcement actions

Action we have told the provider to take

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

Regulated activity	Regulation
Diagnostic and screening procedures	Regulation 17 HSCA (RA) Regulations 2014 Good governance We are currently taking enforcement action.