

Announced Inspection Report: Independent Healthcare

Service: ABC4D Antenatal Baby Scan Clinic, Edinburgh

Service Provider: ABC 4D Limited

19 January 2023

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1 Progress since our last inspection

What the provider had done to meet the requirements we made at our last inspection on 23 August 2019

Requirement

The provider must ensure all clinical waste is disposed of safely.

Action taken

Clinical waste such as gloves and probe covers were now disposed of in an appropriate clinical waste bin, and a waste contract for collection and disposal of all clinical waste was in place. **This requirement is met.**

Requirement

The provider must ensure that all staff receive a regular documented performance review to give staff the opportunity to discuss progress in their role or raise any concerns.

Action taken

We saw evidence that formal performance reviews were now carried out for sonographer staff (staff who use ultrasound equipment). However, formal performance reviews were still not carried out for reception staff. **This requirement is not met** and is reported in Quality indicator 7.1 (see requirement 1).

What the service had done to meet the recommendations we made at our last inspection on 23 August 2019

Recommendation

The service should obtain structured feedback from patients, and develop and implement a participation policy to direct the way it engages with its patients and uses their feedback to drive improvement.

Action taken

A participation policy had now been developed. We were told the service was planning to use an online survey to collect structured patient feedback. However, this was not yet in place. This recommendation is reported in Quality indicator 2.1 (see recommendation a).

Recommendation

The service should ensure that information about how to make a complaint about the service is easily available to patients.

Action taken

Information on how to make a complaint was now available on the service's website.

Recommendation

The service should develop and implement a duty of candour policy.

Action taken

A duty of candour policy had now been developed and an annual report produced.

Recommendation

The service should carry out a regular audit of patient care records.

Action taken

Regular audits of scan reports and images were now carried out and actions to be taken recorded where applicable. However, more areas of patient documentation could be audited. This recommendation is reported in Quality indicator 5.2 (see recommendation e).

Recommendation

The service should develop and implement a quality improvement plan.

Action taken

A quality improvement plan had now been produced.

2 A summary of our inspection

The focus of our inspections is to ensure each service is person-centred, safe and well led. Therefore, we only evaluate the service against key quality indicators which apply across all services. However, depending on the scope and nature of the service, we may look at additional quality indicators.

About our inspection

We carried out an announced inspection to ABC4D Antenatal Baby Scan Clinic Edinburgh on Thursday 19 January 2023. We spoke with the medical director during the inspection. We received feedback from one patient through an online survey we had asked the service to issue for us before the inspection. We asked the service to provide contact details of patients who had agreed to be contacted by telephone to gather their views on the service. We were not provided with any contact details.

The inspection team was made up of one inspector.

As part of the inspection process, we asked the service to submit a self-evaluation. The questions in the self-evaluation are based on our Quality Framework and ask the service to tell us what it does well, what improvements could be made and how it intends to make those improvements. The service submitted a satisfactory self-evaluation.

What we found and inspection grades awarded

For ABC4D Antenatal Baby Scan Clinic Edinburgh, the following grades have been applied to the key quality indicators inspected.

Key quality indicators inspected		
Domain 2 – Impact on people experiencing care, carers and families		
Quality indicator	Summary findings	Grade awarded
2.1 - People's experience of care and the involvement of carers and families	Clear information about the types of scans and tests provided was available on the service's website. Management of complaints followed the complaints policy. A structured patient feedback questionnaire would help to further evaluate the service and identify any areas for improvement. Staff should be trained in duty of candour and safeguarding.	✓ Satisfactory

Key quality indicators inspected (continued)		
Domain 5 – Delivery of safe, effective, compassionate and person-centred care		
Quality indicator	Summary findings	Grade awarded
5.1 - Safe delivery of care	Infection prevention and control measures and an equipment maintenance programme were in place. A range of policies helped manage risks and maintain a safe environment. An audit of the environment would provide assurance that standards are maintained.	✓ Satisfactory
Domain 9 – Quality improvement-focused leadership		
9.4 - Leadership of improvement and change	There is visible leadership within the service, and staff are kept updated with industry guidelines and developments. A quality improvement plan helped to measure the quality, safety and effectiveness of the service delivered, and included a record of planned and completed service improvements. Formal minutes should be produced following directors' or management meetings.	✓ Satisfactory

The following additional quality indicators were inspected against during this inspection.

Additional quality indicators inspected (ungraded)	
Domain 5 – Delivery of safe, effective, compassionate and person-centred care	
Quality indicator	Summary findings
5.2 - Assessment and management of people experiencing care	Patient care records showed consent was sought before any scans took place. Appropriate policies were in place to ensure the confidentiality and security of patient data. A more comprehensive audit of patient care records should be introduced.

Additional quality indicators inspected (ungraded) (continued)	
Domain 7 – Workforce management and support	
Quality indicator	Summary findings
7.1 - Staff recruitment, training and development	An induction process was in place for all new staff, and ongoing training provided when required. Staff files should contain all relevant information to provide assurance that safe recruitment and ongoing checks are carried out. Performance reviews must be provided for all staff.

Grades may change after this inspection due to other regulatory activity. For example, if we have to take enforcement action to improve the service or if we investigate and agree with a complaint someone makes about the service.

More information about grading can be found on our website at:
http://www.healthcareimprovementscotland.org/our_work/inspecting_and_regulating_care/ihc_inspection_guidance/inspection_methodology.aspx

Further information about the Quality Framework can also be found on our website at:
https://www.healthcareimprovementscotland.org/our_work/governance_and_assurance/quality_of_care_approach/quality_framework.aspx

What action we expect ABC 4D Limited to take after our inspection

This inspection resulted in one requirement and nine recommendations. Requirements are linked to compliance with the National Health Services (Scotland) Act 1978 and regulations or orders made under the Act, or a condition of registration. See Appendix 1 for a full list of the requirements and recommendations.

An improvement action plan has been developed by the provider and is available on the Healthcare Improvement Scotland website:
www.healthcareimprovementscotland.org/our_work/inspecting_and_regulating_care/independent_healthcare/find_a_provider_or_service.aspx

ABC 4D Limited, the provider, must address the requirement and make the necessary improvements as a matter of priority.

We would like to thank all staff at ABC4D Antenatal Baby Scan Clinic Edinburgh for their assistance during the inspection.

3 What we found during our inspection

Outcomes and impact

This section is where we report on how well the service meets people's needs.

Domain 2 – Impact on people experiencing care, carers and families

High performing healthcare organisations deliver services that meet the needs and expectations of the people who use them.

Our findings

Quality indicator 2.1 - People's experience of care and the involvement of carers and families

Clear information about the types of scans and tests provided was available on the service's website. Management of complaints followed the complaints policy. A structured patient feedback questionnaire would help to further evaluate the service and identify any areas for improvement. Staff should be trained in duty of candour and safeguarding.

Bookings could be made over the telephone, by email or through the service's website. Information about the different types of tests and scan packages was clearly displayed on the service's website including:

- details of what the scan procedure involves
- expectations of what can be seen on the scan
- qualifications of staff performing the scan, and
- costs.

Information leaflets were also available in the clinic. The patient who responded to our online survey indicated they had felt fully informed and involved in decisions about their treatment.

We saw that feedback was received from patients verbally, from social media reviews and from an online review website. All patient feedback was documented and reviewed every 3 months, with action taken to improve the service or patient experience, where necessary. For example, following feedback from patients, the service simplified the scan packages on offer and included detailed information on its website about each scan to help manage patient expectations.

A complaints policy detailed the process for managing a complaint and provided information on how a patient can make a complaint to the service or directly to Healthcare Improvement Scotland at any stage of the complaints process. Contact details for patients to make a complaint were available on the service's website. The complaints policy was included in the staff manual which all staff signed to confirm they had read and understood.

A complaints log was used to record the details of any complaints, the resolution and any subsequent actions taken by the service. For example, complaints had been received in the Glasgow service about how test results were given to patients. This led a protocol being developed for how communication with patients should be carried out, which was implemented in both the Edinburgh and Glasgow services.

The service also had a chaperone policy, and a dignity and respect policy. The patient who responded to our survey said they were treated with dignity and respect.

A duty of candour policy was in place (where healthcare organisations have a professional responsibility to be honest with people when something goes wrong). An annual duty of candour report had been produced. Although it had not yet been published, this was documented as being in progress on the service's quality improvement plan.

A safeguarding (public protection) policy, which included the local safeguarding contact, ensured a clear protocol was in place to respond to any adult or child protection concerns.

What needs to improve

Since our last inspection in 2019, the service had developed a participation policy. However, patient reviews and feedback were still received in a free text format with no structured questions asked. Therefore, while the information was useful, it may be difficult for the service to draw any conclusions that could be used to drive improvement. We noted that the development of a structured patient feedback survey was documented as being in progress on the service's quality improvement plan (recommendation a).

We were told the service had not had any instances requiring the need to implement duty of candour principles. However, the service could not be assured of this as there was no evidence that staff had completed duty of candour training (recommendation b).

There was also no evidence that staff had completed safeguarding (public protection) training (recommendation c).

- No requirements.

Recommendation a

- The service should obtain structured feedback from patients to direct the way it engages with its patients and uses their feedback to drive improvement.

Recommendation b

- The service should ensure that staff are trained in the principles of duty of candour.

Recommendation c

- The service should ensure that staff have received safeguarding (public protection) training.

Service delivery

This section is where we report on how safe the service is.

Domain 5 – Delivery of safe, effective, compassionate and person-centred care

High performing healthcare organisations are focused on safety and learning to take forward improvements, and put in place appropriate controls to manage risks. They provide care that is respectful and responsive to people's individual needs, preferences and values delivered through appropriate clinical and operational planning, processes and procedures.

Our findings

Quality indicator 5.1 - Safe delivery of care

Infection prevention and control measures and an equipment maintenance programme were in place. A range of policies helped manage risks and maintain a safe environment. An audit of the environment would provide assurance that standards are maintained.

The clinic environment was clean. Equipment was in good condition and maintenance contracts in place, where appropriate. Appropriate insurances were in-date, such as public and employer liability insurance.

An infection prevention and control policy and effective measures were in place to reduce the risk of infection and cross-contamination. For example, the service had a good supply of personal protective equipment (such as disposable aprons, gloves and face masks) and alcohol-based hand gel. An appropriate waste management contract was in place and sharps were well managed in the service. The clinical wash hand basin in the scanning room was not compliant with national guidance about sanitary fittings. However, a documented risk assessment for the continued use of the clinical wash hand basin had been carried out.

Treatment rooms and equipment were cleaned between patient appointments, as well as a full clean of the clinic at the end of the day. Completed and up-to-date cleaning schedules were in place. The correct cleaning products were used in line with national guidance, for example for cleaning clinical wash hand basins and any blood contamination.

Staff were issued with contact numbers of duty managers and directors in the event of any issues arising which they cannot deal with themselves. The sonographers (staff who use ultrasound equipment) had the medical director's

contact details in case they needed advice on any clinical matters. Any woman whose pregnancy may have a potential complication was given a detailed report with instructions on which health professional they should contact (usually their named midwife) and a timescale of urgency. The service had developed a referral pathway for women with early pregnancy complications to the local NHS maternity hospital.

The range of patient safety policies were reviewed regularly and updated to reflect current legislation and best practice. Policies included:

- infection prevention and control
- health and safety
- safeguarding, and
- clinical governance, including risk management.

We saw that all staff were required to sign to say they had read and understood the policies.

A system was in place for recording accidents or incidents. Monthly audits took place of patient care records and any actions to be taken were documented.

A fire risk assessment was completed every year, and fire safety signage was displayed. Fire safety equipment was serviced every year. Electrical equipment had been tested, and a safety certificate was in place for the fixed electrical wiring.

The service was aware that, as a registered independent healthcare service, it had a duty to report certain matters to Healthcare Improvement Scotland, as detailed in our notifications guidance.

What needs to improve

No auditing of the environment was taking place to provide assurance of the standards within the clinic, such as ensuring compliance with infection prevention and control precautions, and health and safety measures. An audit would provide oversight of cleaning standards and maintenance of the building and equipment (recommendation d).

The gas boiler did not have a current safety certificate in place. Following the inspection, we were provided with evidence that a contractor had been requested to carry out a safety check. This type of issue could have been identified through an environmental audit process. We will follow this up at future inspections.

- No requirements.

Recommendation d

- The service should carry out regular audits of the environment.

Our findings

Quality indicator 5.2 - Assessment and management of people experiencing care

Patient care records showed consent was sought before any scans took place. Appropriate policies were in place to ensure the confidentiality and security of patient data. A more comprehensive audit of patient care records should be introduced.

The four patient care records we reviewed were fully completed. Records consisted of patient consent, the scan report and test results, if applicable. Patients' GP details were included in the record and also if a follow-up appointment by NHS maternity services was required.

Patient care records were paper based and taken to the provider's head office in Ayr to be filed and stored securely. Until then, the records were stored in a locked cabinet in the service. Scan images were stored on a secure database and sent directly to patients' mobile phones or emailed to them. The service was registered with the Information Commissioner's Office (an independent authority for data protection and privacy rights). The service's information management policy detailed the storage, retention and destruction of information held by the service. A data protection policy also detailed how the service would meet its legal obligations for confidentiality and information security standards.

Patient care records showed that patients signed to consent to the type of scan they were to receive, and to the terms and conditions of the scan. This included information on:

- quality of scan images
- gender identification
- when a rescan may be required, and
- the use of scan images for marketing purposes.

What needs to improve

Monthly audits of the scan reports and images were carried out by the medical director. These were to check if they were being fully and consistently completed, and that scan recordings were accurate. Where issues had been identified, actions taken were documented. However, the monthly audits did not document that other aspects of the patient care record had been completed, for example:

- patient contact details
- last menstrual period and gestation of pregnancy
- GP contact details, and
- dating and signing of reports (recommendation e).

■ No requirements.

Recommendation e

- The service should carry out a more detailed audit of patient care records.

Domain 7 – Workforce management and support

High performing healthcare organisations have a proactive approach to workforce planning and management, and value their people supporting them to deliver safe and high quality care.

Our findings

Quality indicator 7.1 - Staff recruitment, training and development

An induction process was in place for all new staff, and ongoing training provided when required. Staff files should contain all relevant information to provide assurance that safe recruitment and ongoing checks are carried out. Performance reviews must be provided for all staff.

Policies were in place for recruitment, training and granting practicing privileges (staff not employed directly by the provider but given permission to work in the service).

We reviewed staff files for two employed staff members who had been through a formal recruitment process. Induction topics for all new staff, including those with a practicing privileges agreement, included awareness of the service's policies and the services offered, and the staff manual.

The staff manual included all of the service's policies, and information on the service's vision and approach to quality. We saw evidence that reception staff were trained on company administrative procedures and when changes were introduced. We were told that face-to-face training was carried out on new equipment. We also saw evidence of the directors emailing staff with relevant updates about the service.

The patient who responded to our survey said they had confidence in the staff.

What needs to improve

During the last inspection in 2019, a requirement was made to ensure that all staff received a formal staff performance review. Although these had now taken place for the sonographers, there was no documented evidence of any performance review for reception staff (requirement 1).

Sonographers worked under a practicing privileges agreement and appropriate contracts were in place. However, staff files for these members of staff were not available. Therefore, there was no evidence that they had been safely recruited, and that relevant pre-employment checks were completed before they started working in the service. This should include evidence of:

- two references
- qualifications
- a risk-based Disclosure Scotland background check, and
- a fitness to practice check for healthcare practitioners.

There was also no evidence available of regular checks on staff to ensure they remained safe to continue working in the service such as an annual check of their professional registration (recommendation f).

Requirement 1 – Timescale: by 18 July 2023

- The provider must ensure that all staff receive a regular documented performance review to give staff the opportunity to discuss progress in their role or raise any concerns.

Recommendation f

- The service should ensure that staff files are kept to show that all appropriate recruitment and relevant annual checks are carried out and documented for all staff.

Vision and leadership

This section is where we report on how well the service is led.

Domain 9 – Quality improvement-focused leadership

High performing healthcare organisations are focused on quality improvement. The leaders and managers in the organisation drive the delivery of high quality, safe, person-centred care by supporting and promoting an open and fair culture of continuous learning and improvement.

Our findings

Quality indicator 9.4 - Leadership of improvement and change

There is visible leadership within the service, and staff are kept updated with industry guidelines and developments. A quality improvement plan helped to measure the quality, safety and effectiveness of the service delivered, and included a record of planned and completed service improvements. Formal minutes should be produced following directors' or management meetings.

The medical director regularly attended industry conferences and subscribed to relevant professional journals to keep informed and up to date of any changes in industry best practice or legislation. Any learning from these sources was shared with staff. We were told scans were provided in line with national guidelines, for example from the British Medical Ultrasound Society and the Royal College of Radiologists.

There was visible leadership within the service. The medical director attended each of the provider's clinics and was available to sonographers if they required clinical advice on scans. We were told another director visited each of the clinics approximately every 6 months to speak with staff. We saw evidence that the directors emailed staff to share relevant information.

Agendas for regular directors' meetings included topics such as:

- health and safety
- staff training
- performance of each clinic
- business development, and
- patient reviews of the service.

Quality improvement is a structured approach to evaluating performance, identifying areas for improvement and taking corrective actions. A quality improvement plan helped the service to demonstrate a culture of continuous improvement. We saw documented evidence of areas for improvement being added to the quality improvement plan from audit findings, patient feedback and complaints.

What needs to improve

During the previous inspection in 2019, we were told the service planned to implement a staff survey to gather anonymous views from staff about working in the service and to share any areas for improvement. This had not yet been implemented (recommendation g).

Although we were provided with agendas for the directors' meetings, we were told these meetings were not formally minuted (recommendation h).

Due to the work patterns of staff, the service had not been able to arrange staff meetings (recommendation i).

- No requirements.

Recommendation g

- The service should implement a staff survey to obtain feedback about working in the service.

Recommendation h

- The service should formally record the minutes of directors' and management meetings. These should include any actions taken and those responsible for the actions.

Recommendation i

- The service should hold formal staff meetings, either in person or online. Minutes should be recorded and include any actions taken and those responsible for the actions, and should be shared with all staff.

Appendix 1 – Requirements and recommendations

The actions that Healthcare Improvement Scotland expects the independent healthcare service to take are called requirements and recommendations.

- **Requirement:** A requirement is a statement which sets out what is required of an independent healthcare provider to comply with the National Health Services (Scotland) Act 1978, regulations or a condition of registration. Where there are breaches of the Act, regulations, or conditions, a requirement must be made. Requirements are enforceable at the discretion of Healthcare Improvement Scotland.
- **Recommendation:** A recommendation is a statement that sets out actions the service should take to improve or develop the quality of the service but where failure to do so will not directly result in enforcement.

Domain 2 – Impact on people experiencing care, carers and families	
Requirements	
None	
Recommendations	
a	<p>The service should obtain structured feedback from patients to direct the way it engages with its patients and uses their feedback to drive improvement (see page 11).</p> <p>Health and Social Care Standards: My support, my life. I have confidence in the organisation providing my care and support. Statement 4.8</p> <p>This was previously identified as a recommendation in the August 2019 inspection report for ABC4D Antenatal Baby Scan Clinic Edinburgh.</p>
b	<p>The service should ensure that staff are trained in the principles of duty of candour (see page 11).</p> <p>Health and Social Care Standards: My support, my life. I have confidence in the organisation providing my care and support. Statement 4.4</p>
c	<p>The service should ensure that staff have received safeguarding (public protection) training (see page 11).</p> <p>Health and Social Care Standards: My support, my life. I have confidence in the people who support and care for me. Statement 3.20</p>

Domain 5 – Delivery of safe, effective, compassionate and person-centred care	
Requirements	
None	
Recommendations	
d	<p>The service should carry out regular audits of the environment (see page 14).</p> <p>Health and Social Care Standards: My support, my life. I have confidence in the organisation providing my care and support. Statement 4.19</p>
e	<p>The service should carry out a more detailed audit of patient care records (see page 15).</p> <p>Health and Social Care Standards: My support, my life. I have confidence in the organisation providing my care and support. Statement 4.19</p> <p>This was previously identified as a recommendation in the August 2019 inspection report for ABC4D Antenatal Baby Scan Clinic Edinburgh.</p>

Domain 7 – Workforce management and support	
Requirement	
1	<p>The provider must ensure that all staff receive a regular documented performance review to give staff the opportunity to discuss progress in their role or raise any concerns (see page 16).</p> <p>Timescale – by 18 July 2023</p> <p><i>Regulation 12(c)(i)</i> <i>The Healthcare Improvement Scotland (Requirements as to Independent Health Care Services) Regulations 2011</i></p> <p>This was previously identified as a requirement in the August 2019 inspection report for ABC4D Antenatal Baby Scan Clinic Edinburgh.</p>

Domain 7 – Workforce management and support (continued)	
Recommendation	
f	<p>The service should ensure that staff files are kept to show that all appropriate recruitment and relevant annual checks are carried out and documented for all staff (see page 16).</p> <p>Health and Social Care Standards: My support, my life. I have confidence in the organisation providing my care and support. Statement 4.24</p>

Domain 9 – Quality improvement-focused leadership	
Requirements	
None	
Recommendations	
g	<p>The service should implement a staff survey to obtain feedback about working in the service (see page 18).</p> <p>Health and Social Care Standards: My support, my life. I have confidence in the organisation providing my care and support. Statement 4.19</p>
h	<p>The service should formally record the minutes of directors' and management meetings. These should include any actions taken and those responsible for the actions (see page 18).</p> <p>Health and Social Care Standards: My support, my life. I have confidence in the organisation providing my care and support. Statement 4.19</p>
i	<p>The service should hold formal staff meetings, either in person or online. Minutes should be recorded and include any actions taken and those responsible for the actions, and should be shared with all staff (see page 18).</p> <p>Health and Social Care Standards: My support, my life. I have confidence in the organisation providing my care and support. Statement 4.19</p>

Appendix 2 – About our inspections

Our quality of care approach and the quality framework allows us to provide external assurance of the quality of healthcare provided in Scotland.

Our inspectors use this approach to check independent healthcare services regularly to make sure that they are complying with necessary standards and regulations. Inspections may be announced or unannounced.

We follow a number of stages to inspect independent healthcare services.

Before inspections

Independent healthcare services submit an annual return and self-evaluation to us.

We review this information and produce a service risk assessment to determine the risk level of the service. This helps us to decide the focus and frequency of inspection.



Before

During inspections

We use inspection tools to help us assess the service.

Inspections will be a mix of physical inspection and discussions with staff, people experiencing care and, where appropriate, carers and families.

We give feedback to the service at the end of the inspection.



During

After inspections

We publish reports for services and people experiencing care, carers and families based on what we find during inspections. Independent healthcare services use our reports to make improvements and find out what other services are doing well. Our reports are available on our website at: www.healthcareimprovementscotland.org

We require independent healthcare services to develop and then update an improvement action plan to address the requirements and recommendations we make.

We check progress against the improvement action plan.



After

More information about our approach can be found on our website:

www.healthcareimprovementscotland.org/our_work/governance_and_assurance/quality_of_care_approach.aspx

Complaints

If you would like to raise a concern or complaint about an independent healthcare service, you can complain directly to us at any time. However, we do suggest you contact the service directly in the first instance.

Our contact details are:

Healthcare Improvement Scotland

Gyle Square
1 South Gyle Crescent
Edinburgh
EH12 9EB

Telephone: 0131 623 4300

Email: his.ihcregulation@nhs.scot

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or email his.contactpublicinvolvement@nhs.scot

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