

Announced Inspection Report: Independent Healthcare

Service: Baby Stepps Pregnancy Ultrasound,

Glasgow

Service Provider: Baby Stepps Ltd

22 May 2025





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1 A summary of our inspection

Background

Healthcare Improvement Scotland is the regulator of independent healthcare services in Scotland. As a part of this role, we undertake risk-based and intelligence-led inspections of independent healthcare services.

Our focus

The focus of our inspections is to ensure each service is person-centred, safe and well led. We evaluate the service against the National Health Services (Scotland) Act 1978 and regulations or orders made under the Act, its conditions of registration and Healthcare Improvement Scotland's Quality Assurance Framework. We ask questions about the provider's direction, its processes for the implementation and delivery of the service, and its results.

About our inspection

We carried out an announced inspection to Baby Stepps Pregnancy Ultrasound on Thursday 22 May 2025. We received feedback from 15 patients through an online survey we had asked the service to issue to its patients for us before the inspection and feedback emails from two patients. This was our first inspection to this service.

Based in Glasgow, Baby Stepps Pregnancy Ultrasound is an independent clinic providing non-surgical treatments.

The inspection team was made up of one inspector.

What we found and inspection grades awarded

For Baby Stepps Pregnancy Ultrasound, the following grades have been applied.

Direction	How clear is the service's vision and pu supportive is its leadership and culture	urpose and how ??		
Summary findings	Grade awarded			
The service's vision statement was shared with patients and staff. The service should be assessed against its own key performance indicators. Staff meetings should be formalised. ✓ Satisfactory				
Implementation and delivery	How well does the service engage with and manage/improve its performance			
Staff kept up to date with developments in pregnancy ultrasound. Detailed patient information was available on the services website. A risk register helped the service to manage risks to staff and patients. Development of the emergency policy would help prepare for potential adverse events. A structured approach to obtaining patient feedback and a programme of audits would help demonstrate a proactive approach to service improvement. ✓ Satisfactory				
Results	How well has the service demonstrate safe, person-centred care?	d that it provides		
The clinic was clean, organised and well-maintained. All patient consultations, discussions and information must be documented in the patient care records to evidence safe care. Staff must receive performance reviews and should have ongoing safety checks.				

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:

<u>Guidance for independent healthcare service providers – Healthcare</u>

Improvement Scotland

Further information about the Quality Assurance Framework can also be found on our website at: <u>The quality assurance system and framework – Healthcare Improvement Scotland</u>

What action we expect Baby Stepps Ltd to take after our inspection

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.
- **Recommendation:** A recommendation is a statement which sets out what a service should do in order to align with relevant standards and guidance.

This inspection resulted in three requirements and seven recommendations.

Direction			
Requirements			
	None		
Recommendations			
а	The service should implement a process for monitoring and measuring the service against the key performance indicators (see page 10).		
	Health and Social Care Standards: My support, my life. I have confidence in the organisation providing my care and support. Statement 4.19		
b	The service should formalise its staff meetings, with a record of discussions and decisions reached at these meetings kept. These should detail staff responsible for taking forward any actions (see page 11).		
	Health and Social Care Standards: My support, my life. I have confidence in the organisation providing my care and support. Statement 4.19		

Implementation and delivery

Requirement

1 The provider must ensure that an emergency management policy is in place that clearly sets out how an emergency or adverse event would be dealt with (see page 15).

Timescale – immediate

Regulation 3(a)

The Healthcare Improvement Scotland (Requirements as to Independent Health Care Services) Regulations 2011

Recommendations

c The service should implement a structured approach to gathering and analysing patient feedback to demonstrate the impact of improvements made. Patients should be informed of the changes made as a result of their feedback (see page 13).

Health and Social Care Standards: My support, my life. I have confidence in the organisation providing my care and support. Statement 4.8

- **d** The service should ensure complaints are documented effectively to evidence that the complaints management procedure had been followed (see page 15).
 - Health and Social Care Standards: My support, my life. I have confidence in the organisation providing my care and support. Statement 4.19
- **e** The service should develop a list of mandatory training for staff to complete. This should include clinical training to ensure patient safety, as well as governance procedures, such as those for:
 - (a) complaints management
 - (b) duty of candour
 - (c) consent, and
 - (d) safeguarding (see page 15).

Health and Social Care Standards: My support, my life. I have confidence in the people who support and care for me. Statement 3.14

Implementation and delivery (continued)

- **f** The service should develop an audit programme to include audits of:
 - (a) patient care records
 - (b) staff files, and
 - (c) the clinic environment and equipment (see page 16).

Health and Social Care Standards: My support, my life. I have confidence in the organisation providing my care and support. Statement 4.19

Results

Requirements

2 The provider must ensure that patient care records contain appropriate patient information, consents and documentation of assessment, discussions, outcomes and aftercare advice (see page 19).

Timescale – immediate

Regulation 4(2)(a)(b)

The Healthcare Improvement Scotland (Requirements as to Independent Health Care Services) Regulations 2011

3 The provider must ensure that staff recruited in the provision of the independent healthcare service receive regular individual performance reviews and appraisals (see page 19).

Timescale – 22 August 2025

Regulation 12(c)(i)

The Healthcare Improvement Scotland (Requirements as to Independent Health Care Services) Regulations 2011

Recommendation

g The service should ensure that key ongoing checks on staff members are carried out to ensure they are safe to work in the service (see page 19).

Health and Social Care Standards: My support, my life. I have confidence in the organisation providing my care and support. Statement 4.24

An improvement action plan has been developed by the provider and is available on the Healthcare Improvement Scotland website:

<u>Find an independent healthcare provider or service – Healthcare Improvement</u>

Scotland

Baby Stepps Ltd, the provider, must address the requirements and make the necessary improvements as a matter of priority.

We would like to thank all staff at Baby Stepps Pregnancy Ultrasound for their assistance during the inspection.

2 What we found during our inspection

Key Focus Area: Direction

Domain 1: Clear vision and purpose Domain 2: Leadership and culture

How clear is the service's vision and purpose and how supportive is its leadership and culture?

Our findings

The service's vision statement was shared with patients and staff. The service should be assessed against its own key performance indicators. Staff meetings should be formalised.

Clear vision and purpose

The service told us its vision was to provide a family friendly, inclusive, accessible, pregnancy ultrasound service. The vision was displayed on its social media pages.

Key performance indicators were documented in the service's yearly business plan. The indicators included reviewing:

- any complaints received
- patient feedback
- the number of missed appointments
- the number of patients, and
- the number of returning patients.

What needs to improve

While the service had defined key performance indicators in place, we saw no evidence that these had been regularly evaluated to help measure how well the service was performing (recommendation a).

No requirements.

Recommendation a

■ The service should implement a process for monitoring and measuring the service against the key performance indicators.

Leadership and culture

The family-run service was owned and managed by a midwife sonographer and a business partner. They provided visible leadership in the service. At the time of our inspection, one other midwife sonographer and a radiographer also worked in the service under practicing privileges agreements (staff not employed directly by the provider but given permission to work in the service).

Staff involved in ultrasound scanning were registered with their professional body, the Nursing and Midwifery Council.

Policies were in place describing the procedure for staff to raise concerns, including a bullying and harassment policy and a whistleblowing policy.

What needs to improve

We were told the team had good face-to-face communication between its members and a handover message was sent in an online group chat at the end of each clinic day. However, we saw no evidence of formal communication between staff members (recommendation b).

■ No requirements.

Recommendation b

■ The service should formalise its staff meetings, with a record of discussions and decisions reached at these meetings kept. These should detail staff responsible for taking forward any actions.

Key Focus Area: Implementation and delivery

Domain 3: Domain 4: Domain 5: Co-design, co-production Quality improvement Planning for quality

How well does the service engage with its stakeholders and manage/improve its performance?

Our findings

Staff kept up to date with developments in pregnancy ultrasound. Detailed patient information was available on the services website. A risk register helped the service to manage risks to staff and patients.

Development of the emergency policy would help prepare for potential adverse events. A structured approach to obtaining patient feedback and a programme of audits would help demonstrate a proactive approach to service improvement.

Co-design, co-production (patients, staff and stakeholder engagement)

The service's website provided detailed information on the types of pregnancy ultrasound packages available, including cost, duration of the appointment and what is included in the package. The website also included an overview of the service, including staff experience and qualifications.

The service posted service information videos online so patients could see the staff and the clinic, as well as have an insight into what could be expected during the appointment.

The patients who responded to our online survey indicated they had felt fully informed and involved in decisions about their treatment. Comments included:

- 'Full explanation given but questions answered and encouraged.'
- 'Everything was always explained to us thoroughly. If we never understood anything, questions were always well received.'

The employed staff member was involved in service improvement and had suggested merchandise to sell in the clinic and topics to cover on social media information videos and posts.

Patients could provide feedback to the service through social media sites or contacting the clinic directly through email, text or verbally. We saw evidence that all reviews were positive.

What needs to improve

While the online method used to gather patient feedback was useful, it was difficult for the service to draw any conclusions or identify trends that could be used to help improve the service (recommendation c).

■ No requirements.

Recommendation c

■ The service should implement a structured approach to gathering and analysing patient feedback to demonstrate the impact of improvements made. Patients should be informed of the changes made as a result of their feedback.

Quality improvement

We saw that the service clearly displayed its Healthcare Improvement Scotland registration certificate and was providing care in line with its agreed conditions of registration.

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.

An infection prevention and control policy detailed the standard precautions that would be taken to reduce the risks of infection, such as hand hygiene and the use of personal protective equipment (such as disposable aprons, gloves and face masks). A contract was in place to make sure that waste was disposed of appropriately.

The service had a process in place to document and report accidents and incidents. We were told none had occurred to date.

A yearly fire risk assessment was carried out. Fire safety signage was displayed, fire safety equipment was in place and checked. The fixed electrical wiring and portable electrical appliances had received appropriate safety checks. A contract was in place for maintenance, serving and calibration of the ultrasound equipment.

A consent policy detailed how consent would be obtained from patients. A consent form was emailed to patients before their appointment and discussed in-person before the scan.

After their appointment, patients received contact details for the service to use if they had any queries or concerns following their scan.

All patients who responded to our online survey told us they had received adequate information about the scan procedure.

It was noted that the service's website made it clear that patients must still attend their NHS routine diagnostic scans and that the ultrasound scans that the service performed were non-diagnostic (keep-sake, souvenir scans) only. However, if the sonographer found something of concern a referral process was in place to direct patients to their local maternity hospital.

An adult protection policy was in place that described the reporting process for staff to follow if they had a safeguarding concern. The service had a privacy and dignity policy, as well as a chaperone policy in place. All patients who responded to our online survey felt they had been treated with dignity and respect.

Patient care records were stored on a password-protected electronic database. The service was registered with the Information Commissioner's Office (an independent authority for data protection and privacy rights) to make sure confidential patient information was safely stored.

A duty of candour policy was in place (where healthcare organisations have a professional responsibility to be honest with people when something goes wrong). A yearly duty of candour report was displayed in the clinic and had been published on the service's social media pages.

The service's complaints management process was also displayed in the reception area. The complaints information made clear that patients could make a complaint to Healthcare Improvement Scotland at any time.

The midwife sonographer and radiographer also worked in the NHS and were subject to the mandatory training and continued professional development in their NHS role and as part of their revalidation requirements for the professional register. They attended conferences, study days and were members of the British Medical Ultrasound Society. This made sure that the service kept up to date with changes in the maternity and sonography fields, legislation and best practice guidance.

What needs to improve

The service had an emergency policy in place that covered evacuation from the premises due to fire. However, it did not include other types of emergencies, such as medical or obstetric emergencies that may occur (requirement 1).

From email communication with the patient, we saw that one formal complaint had been received and resolved to the patient's satisfaction. However, we did not see any formal documentation to evidence that the complaints

management process had been followed. For example, we did not see an entry in a complaints log or any documented lessons learned for service improvement resulting from the complaint (recommendation d).

A refresher training session on the equipment and procedures was carried out every year. We were told that additional training was provided if changes were made to the equipment or the methods of measurement used in the scanning process. While we saw a training policy in place, it did not include a list of mandatory staff training that staff were required to have completed (recommendation e).

Requirement 1 – Timescale: immediate

■ The provider must ensure that an emergency management policy is in place that clearly sets out how an emergency or adverse event would be dealt with.

Recommendation d

■ The service should ensure complaints are documented effectively to evidence that the complaints management procedure had been followed.

Recommendation e

- The service should develop a list of mandatory training for staff to complete. This should include clinical training to ensure patient safety, as well as governance procedures, such as those for:
 - (a) complaints management
 - (b) duty of candour
 - (c) consent, and
 - (d) safeguarding.

Planning for quality

The service had a contingency plan in place with another Healthcare Improvement Scotland-registered service in case of emergencies, such as:

- flood
- power failure, or
- sickness.

This arrangement would provide patients with an option to arrange a scan with an alternative sonographer or radiographer.

Appropriate insurances were in-date and displayed in the service, such as public and employer liability insurance.

The service had a process in place to manage risk. General risks to patients and the day-to-day running of the clinic were detailed in a risk register with controls mitigating the risks documented. Business risks had been identified, assessed and documented in a yearly business plan. The risk register was updated when any changes occurred in the service or additional risks were identified and the business plan was updated every year.

Quality improvement is a structured approach to evaluating performance, identifying areas for improvement and taking corrective actions. Improvement activities were included in a documented quality improvement plan.

In addition, the quality of the service that patients received was reviewed at the end of each clinic day. Each scan image from every scan appointment was reviewed to help make sure that the quantity and quality of the images were appropriate. We saw evidence that patients were asked to return to the clinic for a complimentary scan to receive additional or better-quality scan images.

What needs to improve

While the scan images were audited each day, we saw no documented audits of the complete patient care record. The service also did not carry out audits on:

- environment and equipment (to ensure compliance with infection prevention and control, and health and safety), and
- staff files (to make sure all recruitment and ongoing checks could be evidenced) (recommendation f).
 - No requirements.

Recommendation f

- The service should develop an audit programme to include audits of:
 - (a) patient care records
 - (b) staff files, and
 - (c) the clinic environment and equipment.

Key Focus Area: Results

Domain 6: Relationships

Domain 7: Quality control

How well has the service demonstrated that it provides safe, person-centred care?

Our findings

The clinic was clean, organised and well-maintained. All patient consultations, discussions and information must be documented in the patient care records to evidence safe care. Staff must receive performance reviews and should have ongoing safety checks.

Every year, we ask the service to submit an annual return. This gives us essential information about the service such as composition, activities, incidents and accidents, and staffing details. The service submitted an annual return, as requested. As part of the inspection process, we ask the service to submit a self-evaluation. The questions in the self-evaluation are based on our Quality Assurance 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.

The clinic environment appeared modern, clean and well-equipped. Equipment was in good condition. Cleaning of the treatment rooms and equipment was carried out between patient appointments, as well as a full clean of the clinic every day. All patients who responded to our online survey said they were satisfied with the facilities and equipment in the environment they were treated in. Comments included:

- 'Baby Stepps is a lovely environment and I felt very relaxed and comfortable.
 I could not fault the facilities or equipment.'
- 'The equipment was excellent very clear pictures and videos which were then shared to our personal mobiles to keep forever!! The facilities were also great.'
- 'Very organised clean and tidy.'

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 and alcohol-based hand gel.

The recruitment of the one member of staff who worked in the service under a practicing privileges arrangement pre-dated registration with Healthcare Improvement Scotland. They worked with the registered manager of the service

in an NHS ultrasound department and so the registered manager was aware of their skills and experience. We saw appropriate insurance was in place and the member of staff had been checked under the Protecting Vulnerable Groups (PVG) Scheme from Disclosure Scotland. The PVG scheme helps make sure people who are unsuitable to work with children and protected adults cannot do regulated work with these vulnerable groups.

The service had a practicing privileges policy in place that would be followed if recruiting in the future.

What needs to improve

The process for documenting the patients and ultrasound scans did not include sufficient information for a patient care record. We were told that full discussions took place, that included:

- dates relevant to the pregnancy and scan (delivery due date, date of last menstrual period
- issues during the current pregnancy, and
- obstetric history (pervious pregnancies, deliveries).

We acknowledge that pregnancy ultrasound scans cannot be performed without some of this information. However, the information was not documented.

Patient care records also lacked documentation of:

- a next of kin or emergency contact
- consent for sharing information with other healthcare professionals (if an issue identified during the scan)
- GP details
- NHS maternity unit (if applicable for the stage of pregnancy) (requirement 2).

During our inspection, we found that regular performance reviews and yearly appraisals had not been carried out (requirement 3).

We saw no evidence that yearly checks of staff members' professional registration status had been carried out (recommendation g).

Requirement 2 – Timescale: immediate

■ The provider must ensure that patient care records contain appropriate patient information, consents and documentation of assessment, discussions, outcomes and aftercare advice.

Requirement 3 – Timescale: 22 August 2025

■ The provider must ensure that staff recruited in the provision of the independent healthcare service receive regular individual performance reviews and appraisals.

Recommendation g

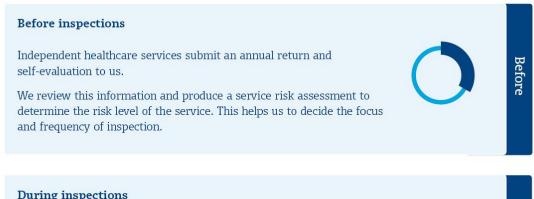
■ The service should ensure that key ongoing checks on staff members are carried out to ensure they are safe to work in the service.

Appendix 1 – About our inspections

Our quality assurance system and the quality assurance framework allow us to provide external assurance of the quality of healthcare provided in Scotland.

Our inspectors use this system 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.



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.

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.



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

Email: his.ihcregulation@nhs.scot

You can read and download this document from our website. We are happy to consider requests for other languages or formats. Please contact our Equality and Diversity Advisor on 0141 225 6999 or email his.contactpublicinvolvement@nhs.scot

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