Baby Moments

Quality Report

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

Ratings

Overall rating for this location	Requires improvement
Are services safe?	Requires improvement
Are services effective?	Not sufficient evidence to rate
Are services caring?	Good
Are services responsive?	Good
Are services well-led?	Requires improvement

Mental Health Act responsibilities and Mental Capacity Act and Deprivation of Liberty Safeguards

We include our assessment of the provider's compliance with the Mental Capacity Act and, where relevant, Mental Health Act in our overall inspection of the service.

We do not give a rating for Mental Capacity Act or Mental Health Act, however we do use our findings to determine the overall rating for the service.

Further information about findings in relation to the Mental Capacity Act and Mental Health Act can be found later in this report.

Summary of findings

Letter from the Chief Inspector of Hospitals

Baby Moments is operated by Baby Moments Limited. The service provides diagnostic pregnancy ultrasound, gynaecological and fertility scans and non-invasive prenatal testing to self-funding women predominantly across Oxfordshire and Berkshire but would accept women from across the UK.

The service provides diagnostic imaging for women aged 17 years and over. It is registered with the Care Quality Commission (CQC) to provide the regulated activity of diagnostic and screening procedures. It has one ultrasound machine with one waiting area.

We inspected this service using our comprehensive inspection methodology. We carried out the announced part of the inspection on 30 June 2019. We gave staff two working days' notice that we were coming to inspect to ensure the availability of the registered manager and clinics.

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

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

Services we rate

We have not previously inspected this service. At this inspection we rated it as **Requires improvement** overall.

We found the following issues that the service provider needs to improve:

- Although the registered manager had not received an appraisal they did appraise staff work performance annually and checked to make sure staff had the right qualifications for their roles.
- Although the service had policies that were current, and version controlled not all policies evidenced the latest national guidance.
- Ultrasound images were not independently reviewed to ensure they were of a good quality.
- The ultrasound machine was not password protected and therefore patient data was at risk of unauthorised access.
- The children's safeguarding policy did not reference child sexual exploitation and female genital mutilation (FGM) and the sonographer did not have knowledge of FGM and what actions to take if discovered.
- The service did not have the proper kit to safely clear any blood spillages.
- Although staff were able to identify risks within the service, these were not documented or reviewed on a regular basis.
- The service did not have a robust governance process to provide assurance of the quality of the service delivered.

However, we found the following areas of good practice :

- The service had enough staff with the right qualifications, skills, training and experience to keep people safe from avoidable harm and to provide the right care.
- Staff understood how to protect patients from abuse and the service worked well with other agencies to do so.
- The environment was appropriate and met the needs of the range of people who accessed the service, including toys for children to play with whilst waiting for parents' appointments and the service controlled infection risks well.
- Women could access services and appointments in a way and a time that suited them. The service used technology innovatively to ensure women had timely access to ultrasound scans.
- The service collected, analysed , managed and used information to support all its activities
- The service treated concerns and complaints seriously. The registered manager completed comprehensive investigations and shared lessons learnt with all staff.

Summary of findings

- The service improved service quality and safeguarded high standards of care by creating an environment for good clinical care.
- Staff were caring, compassionate, kind and engaged well with women and their families.
- The service took account of patient's individual needs for example if an early scan showed a miscarriage, if possible staff would request the next patient go for a coffee while the women who had miscarried had time to absorb the findings.
- Managers promoted a positive culture that supported and valued staff. Staff reported their team worked well together and staff trusted and respected each other.

Following this inspection, we told the provider that it must take some actions to comply with the regulations and that it should make other improvements, even though a regulation had not been breached, to help the service improve. We also issued the provider with four requirement notice(s) that affected diagnostic and screening. Details are at the end of the report.

Dr Nigel Acheson
Deputy Chief Inspector of Hospitals (London and South)

Summary of findings

Our judgements about each of the main services

Service	Rating	Summary of each main service
Diagnostic imaging	Requires improvement 	**This is a diagnostic imaging service run by Baby Moments Limited. The service is based in Didcot, Oxfordshire and serves the communities of Oxfordshire, Berkshire and beyond.** **We rated this service as requires improvement because it required improvements in the safe domain and well led domains. However, it was rated good for caring and responsive. We do not rate effective for this type of service.**

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Background to Baby Moments

Baby Moments is operated by Baby Moments Limited.

Baby Moments Limited opened in 2015 and provides diagnostic pregnancy ultrasound services to self-funding women, who are more than six weeks pregnant and aged 17 years and above. All ultrasound scans performed at Baby Moments Limited are in addition to those provided through the NHS.

The service is registered with the CQC to undertake the regulated activity of diagnostic and screening procedures. The service has had a registered manager in post since August 2015.

We have not previously inspected this service.

The service did not use or store any medications.

Our inspection team

The team that inspected the service comprised a CQC lead inspector, and an assistant inspector. The inspection team was overseen by Catherine Campbell, Head of Hospital Inspection for the South East.

Information about Baby Moments

The service provides diagnostic imaging service (ultrasound scans) to self-funding women across Oxfordshire and Berkshire. The service is situated on the first floor of a business unit within a shopping centre in Didcot in Oxfordshire. It can be accessed by a lift or stairs and is accessible for wheelchair users, with plenty of free parking.

Baby Moments offers many different scans and investigative tests including:

- A viability scan from as early as six- eight weeks gestation via the abdomen or trans-vaginal scan.
- A mini wellbeing scan (eight to 12 weeks) where the woman has already had the viability scan but wants further reassurance.
- Gender scans – Performed after 17 weeks and the baby and fluid are measured as part of the scan as well as the gender being revealed.
- 'Just a peek' scans – 23 to 36 weeks. The baby is measured, the position documented, and a 4D scan offered.
- Growth scans – 26 weeks plus. These are scans for reassurance if the NHS midwife has considered the baby big or small but there were not enough concerns for a referral.
- Wellbeing scans –10 to 16 weeks and 21 to 32 weeks. After the NHS 20-week anomaly scan, the service offered 4D scans and measurements.
- 4D scans
- Gynaecological scans predominantly related to Invitro Fertilisation treatment.
- Non-invasive prenatal testing (NIPTS) , Group B streptococcus testing and new born baby screening for allergies, medication induced deafness, intolerances and coeliac disease. (The CQC does not regulate new born baby screening services).

All women accessing the service self-refer to the clinic and are all seen as private (self-funding) patients.

The service runs three clinics a week. Tuesday afternoons, Thursday mornings and all-day Saturday.

At the time of our inspection, Baby Moments Limited employed a practice manager who was also the CQC's registered manager. A registered manager is a person

Summary of this inspection

who has registered with the Care Quality Commission (CQC) to manage a service. Like registered providers, they are 'registered persons. Registered persons have a legal responsibility for meeting the requirements of the Health and Social Care Act 2008 and associated regulations about how a service is managed. The service was staffed by the practice manager and two receptionists who were also scan assistants and the service had one sonographer, who was a director and the nominated individual.

During the inspection, we visited the registered location in Didcot. We spoke with three staff including the registered manager, nominated individual and receptionist/ scan assistant. We spoke with six women and their partners and observed six ultrasound scans. During our inspection, we reviewed 14 sets of patient records.

There were no special reviews or investigations of the service ongoing by the CQC at any time during the 12 months before this inspection. This was the services first inspection since registration with CQC in 2015.

Activity (January 2018 – January 2019)

- In the above reporting period, there were 1091 ultrasound scans, 16 NIPTS tests and five Strep B tests recorded at Baby Moments Limited.

Track record on safety for the period April 2018 to April 2019:

- No never events.
- No clinical incidents.
- No serious injuries.
- No incidences of hospital acquired Methicillin-resistant Staphylococcus aureus (MRSA), Methicillin-sensitive staphylococcus aureus (MSSA), Clostridium difficile (c. diff) or Escherichia coli (E-Coli).
- Five complaints.

Services provided at the provider under service level agreement:

- Clinical and or non-clinical waste removal.
- Maintenance of ultrasound equipment.
- Maintenance of fire extinguishers and smoke alarms.
- Non-invasive prenatal testing analysis.

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?

Are services safe?

Requires improvement

We rated it as **Requires improvement** because:

- Although staff understood how to protect women from abuse and the service worked well with other agencies to do so, the sonographer did not have knowledge of Female Genital Mutilation (FGM) and what actions to take if discovered. Therefore, not all staff had training on how to recognise and report abuse, and they did not know how to apply it.
- The service controlled infection risk well and kept equipment and the premises visibly clean. Staff mostly used equipment and control measures to protect women and their families, themselves and others from infection. However, they did not have the right equipment to clean blood spillages.
- Although staff kept detailed reports of women's scans. Not all records were stored securely as the ultrasound machine was not password protected. However, reports were clear, up-to-date, and easily available to all staff providing care.

However, we also found the following issues that the service provider did well:

- The service provided mandatory training in key skills to all staff and made sure everyone completed it.
- The design, maintenance and use of facilities, premises and equipment kept people safe. Staff and managed clinical waste well.
- Staff completed and updated risk assessments for each woman and removed or minimised risks.
- The service had enough staff with the right qualifications, skills, training and experience to keep women and their families safe from avoidable harm and to provide the right care and treatment.
- The service managed patient safety incidents well. Staff recognised and reported incidents and near misses. Managers investigated incidents and shared lessons learned with the whole team. When things went wrong, staff apologised and gave women and their families honest information and suitable support.

Summary of this inspection

- Staff supported women and their families to make informed decisions about their care and treatment. They followed national guidance to gain women's consent. They knew how to support women who lacked capacity to make their own decisions or were experiencing mental ill health.

Are services effective?

Are services effective?

Not sufficient evidence to rate

We do not rate effective for this type of service

- Staff monitored the effectiveness of care and treatment. They used the findings to make improvements and achieved good outcomes for women.
- The service made sure staff were competent for their roles for the most part. Managers planned to appraise staff's work performance and there were processes in place to assess the sonographer's competencies and suitability for their role.
- Staff of different kinds worked together as a team to benefit women and their families.
- Staff gave women and their families practical support and advice with regards to their pregnancy.
- Staff supported women and their families to make informed decisions about their care and treatment. They followed national guidance to gain women's consent. They knew how to support women who lacked capacity to make their own decisions or were experiencing mental ill health.

However, we also found the following issues that the service provider needs to improve:

- The service mostly provided care and treatment based on national guidance and evidence-based practice. Not all policies referenced up to date national guidance. Staff protected the rights of women in their care.

Are services caring?

Are services caring?

Good

We rated it as **Good** because:

- Staff treated patients with compassion and kindness, respected their privacy and dignity, and took account of their individual needs.
- Staff provided emotional support to patients, families and carers to minimise their distress. They understood patients' personal, cultural and religious needs.

Summary of this inspection

- Staff supported and involved patients, families and carers to understand their condition and make decisions about their care and treatment.

Are services responsive?

Good

Are services responsive?

We rated it as **Good** because:

- The service planned and provided care in a way that met the needs of the service users.
- The service was inclusive and took account of women's' individual needs and preferences. Staff made reasonable adjustments to help women access services.
- Women and their families could access the service when they needed it and received the right care in a timely way.
- It was easy for women and their families to give feedback and raise concerns about care received. The service treated concerns and complaints seriously, investigated them and shared lessons learned with all staff. The service included women and their families in the investigation of their complaint.

Are services well-led?

Requires improvement

We rated it as **Requires improvement** because:

- **The service had a governance process, however areas of the process needed strengthening. Staff at all levels were clear about their roles and accountabilities but had no regular opportunities to meet, discuss and learn from the performance of the service.**
- Leaders and teams did not use systems to manage performance effectively, but they were able to identify and manage relevant risks and issues and identified actions to reduce their impact. However, the risk management framework was not formalised, and they did not have plans to cope with unexpected events.

However, we also found the following issues that the service provider did well:

- Leaders had the integrity, skills and abilities to run the service. They understood and managed the priorities and issues the service faced. They were visible and approachable in the service for women, their families and staff.
- The service had a vision for what it wanted to achieve and a strategy to turn it into action.

Summary of this inspection

- Staff felt respected, supported and valued. They were focused on the needs of women receiving care. The service promoted equality and diversity in daily work. The service had an open culture where women, their families and staff could raise concerns without fear.
- The service collected, analysed, managed and used information well to support all its activities
- Leaders and staff actively and openly engaged with women, their partners, and the public. to plan and manage services.
- The service was committed to improving services by learning from when things went well or wrong and promoting training.

Detailed findings from this inspection

Overview of ratings

Our ratings for this location are:

	Safe	Effective	Caring	Responsive	Well-led	Overall
Diagnostic imaging	Requires improvement	Not rated	Good	Good	Requires improvement	Requires improvement
Overall	Requires improvement	Not rated	Good	Good	Requires improvement	Requires improvement

Requires improvement

Diagnostic imaging

Safe	Requires improvement
Effective	Not sufficient evidence to rate
Caring	Good
Responsive	Good
Well-led	Requires improvement

Are diagnostic imaging services safe?

Requires improvement

We rated safe as **requires improvement.**

Mandatory training

The service provided mandatory training in key skills to all staff and made sure everyone completed it.

- Mandatory training subjects included: infection prevention and control, fire safety, equality diversity and human rights, conflict resolution, safeguarding adults and children, personal safety and lone working, basic life support and the mental capacity act. This ensured all staff had information to care for people with a diverse range of needs.
- All staff we spoke with had completed mandatory training. Staff we spoke with said their mandatory training was easily accessible and time was available within working hours for them to complete it. The registered manager oversaw mandatory training requirements.
- The service provided mandatory training on a rolling programme basis and accessed it via e-learning modules.
- At the time of inspection all staff were 100% compliant with their required training modules.
- The sonographer completed their mandatory training at the substantive part time NHS trust place of employment. We saw evidence the sonographer had completed and was up to date with all required mandatory training. The sonographer completed fire awareness training locally with the service.

Safeguarding

Although staff understood how to protect women from abuse and the service worked well with other agencies to do so, the sonographer did not have knowledge of FGM and what actions to take if discovered. Therefore, not all staff had training on how to recognise and report abuse, and they knew how to apply it.

- There were clear safeguarding processes and procedures in place for safeguarding adults and children. A policy was available for staff in a paper format and all staff had signed to say they had read it.
- At the time of our inspection, 100% of staff were compliant with adult and children's safeguarding training. All staff we spoke with had received training in levels one and two for children's safeguarding. The registered manager was trained to level two and could access advice from the local council safeguarding teams if needed. This met the intercollegiate guidance 'Safeguarding children and young people: roles and competences for health care staff' (January 2019).
- However, we noted the children's safeguarding policy did not cover the different types of abuse, child sexual exploitation (CSE) or female genital mutilation (FGM). However, these topics were covered in the safeguarding level two online course staff completed. We also found the sonographer was unaware of the

reporting procedures of FGM which needed a safeguarding referral to be completed when FGM was identified. This meant the sonographer may not have made appropriate safeguarding referrals.

- Following the inspection, the sonographer sent us evidence that they has purchased an online course to strengthen their knowledge around FGM and accessed material available at the local NHS trust.
- Staff were able to describe the correct pathways as per the providers safeguarding policy to take in the event a safeguarding concern was identified. We saw one safeguarding referral had been made between April 2018 and April 2019. The referral was appropriate and followed the provider's safeguarding policy.

Cleanliness, infection control and hygiene

The service controlled infection risk well and staff kept equipment and the premises visibly clean. Staff mostly used equipment and control measures to protect women and their families, themselves and others from infection. However, they did not have the right equipment to clean blood spillages.

- We observed well-presented staff who kept the equipment and premises visibly clean. They used control measures to prevent the spread of infection.
- The ultrasound room had washable flooring and wipe-clean furnishings. The service used fresh paper towelling on the couch for each patient. The waiting room and reception area was carpeted, and the carpet appeared clean and intact.
- If the service needed to use any linens such as towels or pillow cases, these were washed by the directors following appropriate washing guidelines to prevent cross infection.
- We saw hand sanitiser dispensers placed in a prominent positions in the scanning room. We observed staff use the hand sanitiser appropriately.
- There was a hand wash basin in the ultrasound room and access to hand disinfectant. Hand washing guidance was posted above the basin which detailed the World Health Organisation's "five moments for hand hygiene" to remind staff of hand hygiene in line with best practice.
- However, the service did not complete any hand hygiene audits which would assure the service that staff were following the World Health Organisations "five moments for hand hygiene" recommendations.
- Staff completed daily checks to ensure the service remained clean which included cleaning surfaces, floors and the toys. We reviewed the checklists and found they were complete.
- During inspection we saw staff were compliant with the infection control policy. The policy instructed all staff involved in clinical work to be bare below the elbows and for long hair to be tied up, which followed good infection control practice. The infection prevention and control policy provided staff with guidance on such things as cleaning and waste control.
- Staff correctly cleaned and stored equipment such as probes used for intimate ultrasound investigations (for example, trans vaginal investigations). Staff covered the probes with an appropriate sheath during investigations and cleaned them with the recommended sporicidal wipes post ultrasound scan. This eliminated the risk of cross infection between patients.
- Personal protective equipment such as gloves were available when staff were taking blood for the non-invasive prenatal tests (NIPTs) tests. NIPTs can be used to assess if a woman's foetus is at a higher risk of having certain genetic and chromosomal conditions, using a venous blood sample taken from the pregnant woman. It is referred to as non-invasive because it does not involve the insertion of a needle into the woman's abdomen or cervix, as is the case with more invasive testing, where cells are taken from the amniotic sac or placenta.
- There had been no incidences of healthcare acquired infections at the service in the last 12 months.

Environment and equipment

The design, maintenance and use of facilities, premises and equipment kept people safe. Staff managed clinical waste well.

- Baby Moments was situated on the first floor of a large office complex which was accessible by a lift and stairs.

Diagnostic imaging

- Women and their partners and families arrived in the reception area. This was an open area which included one large sofa and some chairs, as well as a TV screen which displayed many example scan pictures at different stages of pregnancy. There was a kitchen area for staff and a scanning room.
- The scanning room could comfortably accommodate up to six people. It included a scan couch and some chairs. There was one large screen to view the images.
- The couch in the scan room could accommodate women with a weight of up to 160kg, which limited the clinic to accommodating women below this weight.
- Staff disposed of clinical waste safely. Clinical waste bags and sharps boxes were collected under contract with an external company. Staff disposed of clinical waste into orange bags and the service had a correctly assembled sharps box to dispose of needles used for the NIPTs.
- The ultrasound machine's manufacturer maintained and serviced it annually. We reviewed service records for the equipment, which detailed the maintenance history and service due dates. The machine was due for service the day after the inspection and we saw evidence it was booked with the service engineer. The service had systems in place to ensure machines or equipment were repaired on time, when needed. This ensured women would not experience prolonged delays to their care and treatment due to broken and out of use equipment.
- Due to the nature of the service they did not require a resuscitation trolley. However, they did have a sealed and in date first aid box. There was always a member of staff on duty who had adult and children first aid qualifications. In the case of an emergency the service would call 999.
- The service had access to a shared toilet within the unit which was clean and well-maintained.
- Fire extinguishers were accessible, stored appropriately, and were all up to date with their services.
- The service did not complete formal environmental risk assessments. However, some areas had risk assessments, such as water quality (legionnaire's disease) and Control of Substances Hazardous to Health (COSHH). The practice manager completed fire assessments monthly. The service held regular fire drills and documented each one.
- We observed all chemicals were stored appropriately with the appropriate documentation that risk assessed the chemicals. Staff securely stored all equipment to take blood in a locked cupboard in the kitchen including the sharps boxes. This prevented unauthorised access.

Assessing and responding to patient risk

Staff completed and updated risk assessments for each woman and removed or minimised risks.

- Staff told us what action they would take if a patient became unwell or distressed while waiting for, or during, an ultrasound scan. The action taken depended on the specific situation and staff provided examples which showed they would take appropriate action.
- Upon booking their appointment, the service asked women to bring their NHS pregnancy records with them. This meant the sonographers had access to the woman's obstetric and medical history. It also meant if there were any concerns staff could contact the women's relevant medical provider and GP. If the woman forgot her NHS records the sonographer would explain they could not comment on the findings of the scan without the NHS notes to compare it to.
- There were clear processes and pathways in place to guide staff on what actions to take if the sonographer found unusual findings on the ultrasound scan. When asked, staff were clear on what these actions were, and we reviewed the abnormal scans file which detailed the advice given to the women and referral letters to GPs, midwives or early pregnancy units. The advice given and documented mirrored the provider's policy on abnormal scans.
- Once the sonographer had identified an abnormal scan, they would create a report and with the mother's consent, the reception staff would write a referral letter to the appropriate healthcare professional. A

copy of the referral letter, along with the scan report, would be given to the woman for their NHS notes and the receptionist emailed or posted the referral letter to the onward service provider.

- The sonographer reported that they would often receive feedback from units or consultants they had referred to which verified the interpretation of the scan was the same as theirs.
- We saw the sonographer remind women about the importance of still attending their NHS scans and appointments. The sonographer made sure women understood the ultrasound scans they performed were in addition to the routine care they received as part of their NHS maternity pathway.
- To safeguard people against experiencing incorrect ultrasound scans staff asked patients to confirm their identify and date of birth. This evidenced staff followed best practice and used the British medical ultrasound society's (BMUS) 'paused and check' checklist.
- The sonographer reported they had not had a woman who requested frequent scans but they did advise women who wanted longer appointments that their scanning time was restricted to 10 -15 minutes as per the British medical ultrasound societies (BMUS) and followed the as low as reasonably achievable (ALARA) principles, outlined in the 'guidelines for professional ultrasound practice 2017' by the Society and College of Radiographers (SCOR) and BMUS. Details of this guidance were available for women upon request.
- The service included the latest information on their website from Public Health England about the potential risks associated with all types of scans that were carried out at the clinic.

Staffing

The service had enough staff with the right qualifications, skills, training and experience to keep women and their families safe from avoidable harm and to provide the right care and treatment.

- The service employed one practice manager on a 20 hour a week contract and two receptionists on part time contracts, who were also scan assistants. The sonographer jointly owned the business with a family member and held a substantive part time post working for a local NHS trust.
- The sonographer had completed a medical ultrasound degree level course.
- There were enough staff to cover the available clinics with no current staff vacancies.
- The service did not use bank or agency staff and if needed, the clinic would be cancelled if the sonographer was on annual leave or unwell. Clinics were planned around the sonographer's availability and to date the service had not cancelled any appointments.
- The registered manager communicated updates and shift cover requirements using an online application. All staff we spoke with reported this worked very well.
- All staff we spoke with felt the staffing levels were sufficient to cover the work required.
- The service's sickness rates from April 2018 to April 2019 was 0%.
- There was no formal induction process for new staff. The registered manager would supervise new staff until they felt confident in their role.
- Although there were rarely any staff working on their own during the clinic times, the service had a lone working policy, a safety alarm and a standard operating procedure about what to do when working alone. We saw evidence staff checked the safety alarm weekly. Staff would only be lone working when they went to the office to complete administration work outside of the clinic's active sessions.

Records

Although staff kept detailed reports of women's scans. They were not stored securely as the ultrasound machine was not password protected. However, reports were clear, up-to-date, and easily available to all staff providing care.

- Women having all types of scans would receive a report written by the sonographer at the time of the scan to add to their NHS notes. All NIPTs results were communicated to the woman and their GP.

Requires improvement

Diagnostic imaging

- Where appropriate, and with consent, the sonographer would also send a paper copy of the scan report to the woman's GP or another relevant healthcare professionals when making a referral.
- Staff saved the images and videos onto a memory stick which they passed on to the woman. Staff downloaded the images and reports each year from the ultrasound machine onto a compact disc and stored this securely in a locked cupboard within the kitchen area.
- We reviewed 12 ultrasound reports, including abnormal reports, and five referral letters. Staff recorded information in a clear and correct way. This included the reason for the scan, the findings, conclusions and recommendations.
- The service kept a years' worth of completed service users records securely in a locked cupboard within the premises, and the service stored all older records securely in a storage unit. Any electronic records or systems were password protected on the computer, although access to the ultrasound machine was not password protected. This resulted in the possibility of unauthorised access to women's ultrasound pictures and written reports. We raised this at the inspection and the sonographer reported a password would be set up immediately and verbally assured us post inspection the service engineer visited the next day and set up a password.

Medicines

The service did not store or administer any medicines.

Incidents

The service managed patient safety incidents well. Staff recognised and reported incidents and near misses. Managers investigated incidents and shared lessons learned with the whole team. When things went wrong, staff apologised and gave women and their families honest information and suitable support.

- The service used electronic and paper-based reporting systems and had an accident book available in the clinic for staff to access. The registered manager was responsible for handling investigations into all incidents. The registered manager used the incidents log to identify any themes and learning, and shared with staff through the electronic app.
- Staff we spoke with knew how to report incidents and could give examples of when they would do this. Managers investigated incidents and shared lessons learned with the whole team and the wider service. When things went wrong, staff apologised and gave patients honest information and suitable support.
- From April 2018 to April 2019 there were four incidents documented which included safeguarding, a broken fire alarm and staff giving the wrong photo to the wrong woman.
- Never events are serious patient safety incidents which should not happen if healthcare providers follow national guidance on how to prevent them. Each never event type has the potential to cause serious patient harm or death but neither need have happened for an incident to be a never event. From April 2018 to April 2019, the service did not report any incidents classified as a never event taking place in their diagnostics services.
- The service did not report any serious incidents from April 2018 to April 2019.
- Duty of candour is a regulatory duty that relates to openness and transparency and requires providers of health and social care services to notify patients (or other relevant persons) of certain 'notifiable safety incidents' and provide reasonable support to that person. Staff were able to tell us about a situation where they had carried out the duty of candour when staff gave a woman the wrong ultrasound scan picture. The registered manager contacted both the correct owner of the scan and the women who was given the wrong scan and apologised.
- Managers were aware of the requirements for reporting incidents and sending notifications to the CQC. However, at the time of inspection the registered manager had not been required to submit any notifications.

Are diagnostic imaging services effective?

Requires improvement

Diagnostic imaging

Not sufficient evidence to rate

We do not rate effective for this core service.

Evidence-based care and treatment

The service mostly provided care and treatment based on national guidance and evidence-based practice. Not all policies referenced up to date national guidance. Staff protected the rights of women in their care.

- The registered manager checked to make sure staff followed guidance. Staff had to sign and date a checklist to confirm they had read policies and when the service updated policies. We saw evidence of these completed checklists.
- We reviewed 17 policies which were version controlled and current. Some of the policies followed national guidance from the Royal College and Society of Radiographers, the foetal abnormality screening programme (FASP) standards and British Medical Ultrasound Society (BMUS). For example, the procedure to follow, following detection of abnormalities on the scan followed the FASP guidelines.
- However, not all policies referenced national guidance. For example, the safeguarding adults and children policy did not reference the 'Working together to safeguard children 2018' document nor did it include definitions of female genital mutilation (FGM) or child sexual exploitation (CSE). This meant staff were not following relevant up to date guidance.
- The service followed as low as reasonably achievable (ALARA) principles outlined by the Society and College of Radiographers. Sonographers did not scan for longer than 20 minutes and would not repeat scans within seven days of the earlier scan, which reduced any risks that prolonged scans may cause to the unborn baby.
- There were protocols for the non-invasive prenatal tests (NIPTS) provided by the suppliers of the blood sampling packs.

Nutrition and hydration

- Staff gave women information on drinking water before a scan to ensure they attended with a full bladder which enabled the sonographer to gain a better view of the unborn baby.
- The service offered cold bottled water to women who were required to have a fuller bladder at the time of the scan.

Pain relief

- Staff did not formally check pain levels as the procedure was pain free. However, we saw that staff asked women if they were comfortable during their scan.

Patient outcomes

Staff monitored the effectiveness of care and treatment. They used the findings to make improvements and achieved good outcomes for women and their families.

- The service monitored patient outcomes and experience through their monthly clinic audits and patient satisfaction feedback cards.
- When sonographers identified any unusual or abnormal images that needed further referral to NHS specialists, they followed up the outcomes to both offer support and to assess the accuracy of the diagnoses through a phone call or email communication.
- The sonographer reported a close working relationship with the foetal medicine department at the local NHS trust, who would report back to the sonographer about if their ultrasound reports revealed the same findings.
- The registered manager audited the sonographer's and receptionists' practice by completing monthly audits. Audit looked at how the sonographer interacted with the women and their families, consent form completion and the general experience of the women and their families.
- The service used three companies for non-invasive prenatal tests and each had their own packs and

processes for labelling and sending the bloods to the laboratory for analysis. The service tracked and recorded when these were sent and when the results were received.

Competent staff

The service made sure staff were competent for their roles for the most part. Managers planned to appraise staff's work performance and there were processes in place to assess the sonographer's competencies and suitability for their role.

- The registered manager was about to undertake the first appraisal of one of the receptionists as neither staff member had been in post for one year or more. We saw the pre and post appraisal paperwork which included reflections on performance and areas where individuals would like to develop.
- The registered manager reported they had not received an appraisal since starting their role in 2015. An appraisal is an opportunity for staff to discuss areas of improvement and development within their role in a formal manner. The registered manager reported this was done informally with the directors and not documented.
- The sonographer received an annual competency assessment and appraisal within their substantial post in the NHS Trust. As part of the assessment, the sonographer's NHS scans were reviewed to ensure the foetus was measured correctly and the report was detailed and complete. We saw evidence of two reviews where the sonographer had achieved maximum scores for scanning competency.
- The service had good links with the local NHS trust and reviewed and updated protocols based on those used within the NHS. They had systems for recording cleaning, incidents, complaints and patient feedback.
- However, the sonographer was unaware of the procedures to follow upon the discovery a women had been subject to FGM. This did not assure us the sonographer had received the right training for their role. This awareness was relevant and important as the sonographer regularly completed trans-vaginal scans.
- We saw confirmation of the sonographers' registration with the public voluntary register of sonographers. This was kept in the staff recruitment folder as well as displayed on the wall in the reception and scanning room.
- The registered manager was trained in phlebotomy (taking blood directly from a vein) and we saw evidence of their training which was adequate for their role and up to date. The registered manager reported they were planning to access yearly updates or sooner if the frequency of the non-invasive prenatal tests reduced.

Multidisciplinary working

Staff of different kinds worked together as a team to benefit women and their families.

- During the inspection we saw the team worked well together and saw positive communications between all members of the team.
- The service had liaised with local NHS trusts to ensure their referral pathways were effective and appropriate. Following feedback from midwifes had changed their practices to ensure consistency. For example, the service no longer gave expected delivery dates (EDD) from the growth scans and requested the women follow the NHS's suggested EDD following a midwife's request.
- The service ensured where the woman had consented for their information to be shared, GPs received a copy of the ultrasound report by post or electronically.
- The service had links with the cleft lip and palate association in Oxford and offered 4D scans, at a 50% discounted price, for women who had been told their baby had a cleft lip. The service told us this was to help the woman emotionally adjust and come to terms with the appearance of their baby before it was born.
- The service also liaised effectively with the non-invasive prenatal tests equipment providers, to ensure results were communicated promptly.

Seven-day services

- The service ran three clinics a week. These clinics took place on Tuesday afternoons, Thursday mornings and

all-day Saturday. Clinic sessions were designed to accommodate the needs of women and their families. For example, evening and weekend appointments enabled working mothers and siblings to attend.

Health promotion

Staff gave women and their families practical support and advice with regards to their pregnancy.

- The service provided families with two information leaflets about miscarriage and ectopic pregnancies produced by the miscarriage association. The sonographer would refer the women back to their NHS midwife, GP or trust if they had specific questions or concerns relating to their pregnancy.

Consent and Mental Capacity Act

Staff supported women and their families to make informed decisions about their care and treatment. They followed national guidance to gain women's consent. They knew how to support women who lacked capacity to make their own decisions or were experiencing mental ill health.

- For women aged 17 years the sonographer would not perform the scan without the written consent of a parent or responsible adult who must go with the young woman. The service had a specific consent form for young women aged under 18 years.
- Staff were able to verbalise the process to take when they believed a woman did not have the capacity to consent, which was in line with the service's consent policy. However, staff reported they had never had an incident of a women lacking capacity to consent.
- All women received written information to read and sign before their scan. This included a technology and safety briefing, terms and conditions, and information on scan limitations. The pre-scan questionnaire and declaration form included a self-declaration saying that the patient was receiving appropriate NHS pregnancy care and consented to share information with the NHS.
- We saw clear signed consent in 12 pre-scan questionnaires and foetal wellbeing reports we reviewed.
- All staff were aware of the importance of gaining consent from women before conducting an ultrasound scan. The sonographer confirmed names and spellings and dates of birth prior to the scan and obtained verbal consent to begin.
- All staff at the service received basic Mental Capacity Act (2005) training and the service held a policy which all staff had signed to say they had read it.

Are diagnostic imaging services caring?

Good

We rated caring as **good.**

Compassionate care

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

- Staff treated women and their families with compassion and kindness, respected their privacy and dignity, and took account of their individual needs.
- During our inspection we observed staff treating women and their families with privacy, dignity, kindness, compassion and respect. One of the questions on the service's feedback forms was: 'Do you feel your privacy and dignity was respected at Baby Moments?' Of the 20 feedback forms we reviewed, 100% of the respondents agreed with the question.
- The clinic played music in the waiting area and reception to minimise the risk of conversations being overheard. All other conversations during and after an appointment took place in a private room.
- During our inspection we spoke with three women and their families, and all described the service positively. For example, women commented the booking process was easy, the appointment times were flexible and accommodating, and they were well informed before the appointment.
- Women were able to give feedback through feedback forms in the service waiting area, an email to the service or via an open social media platform. Examples of feedback included: 'it was perfect- very

friendly, welcoming and professional', and 'they took the time needed and were friendly. A great service.' Of 73 reviews on the social media platform, the service was rated as 4.9 out of 5.

- The service gave women who attended the service (and were over 16 weeks pregnant) a complimentary gift bag with information booklets and a maternity pack.
- If women attended the clinic alone, staff would routinely offer a chaperone. However, no staff had received chaperone training.

Emotional support

Staff provided emotional support to patients, families and carers to minimise their distress. They understood patients' personal, cultural and religious needs.

- Women we spoke with during our inspection told us they felt reassured by the information they were given before their appointment and that it helped them prepare for their scan.
- During our inspection we observed five appointments. Throughout these appointments the sonographer described what they saw and explained findings in a way the women could understand. For example, we saw the sonographer measuring each part of the baby and clarifying their findings to reassure the women.
- Staff described how the sonographer explained distressing findings to the women following a scan. Staff acknowledged that at the time the women might not be able to process and understand what was being said. Therefore, staff said they always sent the women away with the report and information leaflets from the miscarriage association (if appropriate) and encouraged the women to ring the service for further explanation of the results if required.
- The service had leaflets outlining the three types of Non-invasive Prenatal Tests (NIPTs) they offered. Staff said they explained the differences and supported patients to make their own decision on which to choose. The blood test results were returned to the clinic, and if there was a raised risk of abnormality, the sonographers contacted the patients to explain the results and advise on next steps. If there was a low risk result, office staff contacted the women with the information. The service then sent the result by email, as confirmation. Staff told us they would refer the women back to NHS care and would let the GP or midwife know the result, with the women's consent.
- Staff also said they would follow up women who had received distressing news. For example, a feedback comment stated: 'The ladies here are so friendly and reassuring and make you feel at ease. My first appointment was bad news, but they showed great empathy and support. They even followed up after to make sure I was ok'.
- Staff described an occasion where distressing news was given to a woman who was particularly upset by the result. The practice manager said they asked the next women if they could go and have a coffee and then come back. This was to allow the woman more time and privacy to come to terms with the result.

Understanding and involvement of patients and those close to them

Staff supported and involved patients, families and carers to understand their condition and make decisions about their care and treatment.

- During our inspection we saw women and their partners or relatives treated with kindness and respect by staff. Staff welcomed women and their partners or relatives to the service and there was enough room to accommodate five guests with the mother in the clinic room.
- Staff took time to explain the procedure before and during the scan. We saw the sonographer fully explain what was going to happen throughout the scan. They used appropriate language to explain the position of the unborn baby and the images on the monitors. They asked women if they had any questions throughout and at the end of the scan.
- The staff gave the women the report from the scan, with photos if appropriate, during the appointment and explained the findings.
- When women and their families booked in for their scan the prices and scans were rechecked to ensure the women had booked the correct scan for their requirements.

Requires improvement

Diagnostic imaging

Are diagnostic imaging services responsive?

Good

We rated responsive as **good.**

Service delivery to meet the needs of local people

The service planned and provided care in a way that met the needs of the service users.

- The facilities and premises met the needs of women and families, including children, that accompanied the women to their scan. The large waiting area had children's toys which staff could move into the scanning room.
- Toilets were separate from the clinic and maintained by the building's management team.
- The clinic's location was close to public transport links and free parking was available. The service provided information on travelling to the clinic on their website.
- The service had a range of packages with different price options which it clearly displayed on the website. Women and their families could book appointments on line or over the phone. The service offered out of hours appointment times, in the evenings and on Saturdays. Staff covered the reception desk during those appointment times.
- Staff discussed the packages with the women and their partners upon entering the clinic. All packages included a wellbeing scan.
- Staff said that some NHS maternity staff and GPs also suggested patients attend the clinic if they wanted to have the NIPTs. They explained this might be because of a high-risk result from a 12-week nuchal translucency scan carried out within the NHS. The nuchal translucency scan detects cardiovascular abnormalities in a foetus, but a NIPT is a more accurate test for genetic and chromosomal conditions than the nuchal translucency scan.

Meeting people's individual needs

The service was inclusive and took account of women's individual needs and preferences. Staff made reasonable adjustments to help women and their families access services.

- The service was accessible to all including individuals who used wheelchairs. The building included a disabled toilet which was compliant with the Disability Discrimination Act (DDA). The reception area was large and there was plenty of room in the scanning room to accommodate at least three wheelchairs.
- Women and their partners could book appointments online or by telephone at a time to suit them.
- The ultrasound scan room provided a calm and relaxing atmosphere with relaxing music playing in the background. The room had dimmed lighting to enable the woman and her family to view the images.
- Staff gave information leaflets to women when they had a pregnancy of an unknown location. For example, an ectopic pregnancy, or scan that confirmed a complete miscarriage. The leaflets had a description of what the sonographer had found, advice, and the next steps they should take.
- The service also had information on display about the NIPTs and screening of Group B streptococcus in the waiting area.
- All women we spoke with reported their appointment times were long enough for them to ask questions and gain reassurance. The sonographer reported half an hour was allocated to each appointment slot to ensure women had time to complete their questionnaires and for the sonographer to complete the report. It also allowed time for the woman to go for a walk to encourage the foetus to move to improve the scan image.
- The service did not have access to translation services. Staff said they encouraged patients to bring friends or relatives with them if English was not their first language. Although they recognised there was a risk with this approach, the registered manager considered this was proportionate for this type of service. The registered manager reported the service was translating their consent forms in to a variety of languages and this was currently a work in progress.

Diagnostic imaging

- The practice manager carried an out-of-hours mobile phone for any urgent queries.

Access and flow

Women and their families could access the service when they needed it and received the right care in a timely way.

- The service did not have a waiting list for ultrasound appointments. Women could self-refer to the service on the same day, particularly for viability appointments. We saw the service accommodated four extra women for viability scans on the day of inspection. Women could book their scans through the website, or via telephone or email.
- Staffing hours covered the reception 36 hours per week to take calls and manage bookings. When closed, the service used an external company to pass on messages to the individual with the on-call phone, who would contact the women to make the appointments. This meant staff responded to all calls within 48 hours.
- The sonographer gave the results of the ultrasound scans to the women and their partners immediately after the scan.
- We saw women and their families arrive in the reception area and wait no longer than five minutes for their scan. However, the service did not audit patient waiting times in clinic. This would help identify any areas for service improvement.
- Waiting time for the NIPTs tests were between five to seven days depending on the company used.
- The registered manager explained the booking system was flexible and allowed changes to packages to meet women's choices. Women paid a small deposit upon booking the scan and could change the package when they attended for their scan appointment if they wished.
- From April 2018 to April 2019 the service had not cancelled any scans.

Learning from complaints and concerns

It was easy for women and their families to give feedback and raise concerns about care received. The service treated concerns and complaints seriously, investigated them and shared lessons learned with all staff. The service included women and their families in the investigation of their complaint.

- The service received five complaints in the period between April 2018 to April 2019 where the service upheld one complaint. (The service recognised they were at fault).
- The service had a policy for managing complaints, which included timescales for acknowledging a complaint (four days) and responding within 15 working days. We reviewed one complaint response and found the registered manager had responded to the complaint within the four and 15 working day rule. The complainant received a written response to their complaint which offered an apology, refund and we saw documented evidence of learning from the complaint.
- There was information for patients within the reception areas, leaflets and website on how to make a complaint.
- All women and their partners we spoke with during the inspection saw no reasons to make a complaint and could not suggest any improvements the service could make.
- Staff received mandatory training in conflict resolution and the practice manager encouraged staff to resolve complaints from women and their families promptly.
- Where any complaints have arisen from women due to their scan, the sonographer would take the report to her colleagues in the NHS Trust to review for advice and feedback.
- Staff reported an example of change in service because of a complaint. A woman who had miscarried requested further written information. As a result, the clinic introduced leaflets containing information about miscarriages and ectopic pregnancies.
- The registered manager shared complaints via the electronic application only as the service rarely held team meetings.

Are diagnostic imaging services well-led?

Requires improvement

Diagnostic imaging

Requires improvement

We rated well led as **requires improvement.**

Leadership

Leaders had the integrity, skills and abilities to run the service. They understood and managed the priorities and issues the service faced. They were visible and approachable in the service for women and staff.

- The registered manager oversaw the receptionists and handled the everyday running of the clinic. The registered manager shared business information with the directors.
- Baby Moments Limited had two directors, one of whom worked clinically as the sonographer. The sonographer was onsite for each of the clinics.
- Staff told us the registered manager was accessible and approachable if they wanted advice or to make suggestions. The registered manager kept staff informed of any changes or development for the service. Staff also reported the directors to be approachable and easy to work with.
- Staff told us the registered manager had the skills and experience to appreciate the roles they completed and offered valuable support.

Vision and strategy

The service had a vision for what it wanted to achieve and a strategy to turn it into action.

- The service aimed to ensure a high quality, safe and effective service and environment, and to provide healthcare which was available to clients whilst creating a partnership between the patient and health professions. This would ensure mutual respect, holistic care and continuous learning and training.
- Baby Moments Limited's vision was to increase the volume of scanning appointments to meet demand, with a longer-term vision to get a contract with the local NHS trust to provide gynaecological scans. The directors were also keen to employ an independent consultant to be available to review the gynaecological scans and therefore offer a complete service.

Culture

Staff felt respected, supported and valued. They were focused on the needs of women receiving care. The service promoted equality and diversity in daily work. The service had an open culture where women, their families and staff could raise concerns without fear.

- Staff told us they enjoyed working at the service, and there was a friendly, supportive culture where people were happy to raise concerns or make suggestions. The service had a whistleblowing policy that staff we spoke with were aware of.
- Staff told us they worked together well as a team and there was an open and honest culture. We saw a 'no blame' approach to the investigation of complaints and the registered manager addressed performance issues through open and honest one-to-one feedback with staff.
- All staff spoke proudly about their roles within the service and staff felt supported in their work. Staff told us they felt valued and supported by colleagues and the registered manager.
- There was a strong emphasis on the care of women and their families. Staff promoted openness and honesty and understood how to apply the duty of candour. All staff were aware of what the term 'duty of candour' meant.
- Throughout our inspection, the registered manager and sonographer responded positively to feedback. They assured us improvements would be made at once following our feedback. This showed a culture of openness and willingness to learn and improve.

Governance

The service had a governance process, however areas of the process needed strengthening. Staff at all levels were clear about their roles and accountabilities but had no regular opportunities to meet, discuss and learn from the performance of the service.

Requires improvement

Diagnostic imaging

- The service had some systems and processes to support the delivery of a safe and caring service. All staff had regular criminal safety checks and completed mandatory training appropriate to their role. However, the sonographer lacked knowledge regarding identification of female genital mutilation.
- There were policies and procedures for the operation of the service and these were available to staff in a folder in the clinic. All policies were up to date and reviewed annually, this was a shared responsibility between the registered manager and one of the directors. However, not all policies referenced up-to-date national guidance.
- Information was shared with team members using an electronic application and this included general service updates, incident and complaint outcomes and cover arrangements for the service.
- The registered manager did not have full oversight of the governance of the service. There were no formal minuted governance meetings. The registered manager told us conversations with the directors took place on an informal basis, therefore there was no record of discussion of risk management, quality monitoring and decision making.
- Staff understood their roles and only carried out scans and procedures in line with their competencies.
- Baby Moments Limited had indemnity and medical liability insurance which covered all staff working within the service for the case of a legal claim. It was in date.

Managing risks, issues and performance

Leaders and teams did not use systems to manage performance effectively, but they were able to identify and manage relevant risks and issues and identified actions to reduce their impact. However, the risk management framework was not formalised, and they did not have plans to cope with unexpected events.

- The registered manager and sonographer understood and were able to articulate the risks relating to the premises, service delivery and business, although there was no actual documented register of risk with mitigated actions clearly identified.
- There were no risk management processes in place to identify or manage potential risks. For example, there was no documentation regarding environmental risks such as slip hazards or risks relating to loss of staff or business.
- While there were a small number of audits being used to monitor the quality of the service and through discussion it was clear action would be taken to drive improvement, the lack of a robust audit programme did not assure us there was clear oversight of the quality of the service where risks were managed
- The ultrasound machine did not have a back up battery in the case of a power cut. It saved all information as it was inputted. However, this would not have a detrimental effect to woman, but it also did not assure us the sonographer could finish and report on a scan in the case of a power cut.
- The service did not have a business continuity plan. However, they did undergo six monthly fire alarm drills to ensure staff were aware of the process to take in case of an emergency.

Managing information

The service collected, analysed, managed and used information well to support all its activities.

- Women consented for the service to store their records. This was part of their signed agreement within the form detailing the ultrasound process. This showed the service's compliance with the General Data Protection Regulation (GDPR) 2018.
- There was enough information technology equipment for staff to work with across the service.
- The service had an up-to-date information governance policy for staff to refer to. The policy detailed staff responsibilities, documentation standards, and the retention of records.
- The sonographer could access reported ultrasound scans easily. The registered manager stored printed reports in a locked filing cupboard in the kitchen area for a one-year period, after which they were moved to the external storage site. All staff had access to the key.

Engagement

Requires improvement

Diagnostic imaging

Leaders and staff actively and openly engaged with women, their partners, and the public. to plan and manage services.

- The service asked women and their partners to fill in a comment card whilst they were waiting for their scan report. There were also opportunities for women and their partners to leave comments on social media pages and online review sites.
- The service had an easily accessible website where women and their families were able to leave feedback and contact the service. This showed patients were able to engage with the service online and verbally.
- Baby Moments Limited had received high levels of satisfaction ratings from their users. The social media page showed over 70 comments which were very complimentary. We also reviewed six comments from the comments box in the reception area, which were all also very complimentary about the service.
- The management team supported staff to give feedback and they were listened to.
- We saw effective management engagement with staff. All staff we spoke with told us the management was supportive accessible and visible.

Learning, continuous improvement and innovation

The service was committed to improving services by learning from when things went well or wrong and promoting training.

- Staff took pride in their work and aimed to make improvements where possible. The sonographer said that working in the NHS helped them to keep abreast of policy changes and so enabled continuous improvements for Baby Moments Limited.

Outstanding practice and areas for improvement

Areas for improvement

Action the provider MUST take to improve

- The provider must ensure the service has access to an appropriate blood spillage kit.
- The provider must ensure the sonographer has received training and is aware of actions to take if female genital mutilation is identified.
- The provider must ensure the ultrasound machine is password protected.
- The provider must check all risks have been identified and managed, through a formalised process

Action the provider SHOULD take to improve

- The provider should appraise the registered manager.
- The service should update all policies to reference and reflect up to date legislation and national guidance.
- The provider should consider completing risk assessments for the service's environment.
- The provider should develop a quality assurance process for ultrasound images.
- The provider should consider formal minuted team meetings to share feedback to all staff.

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 CQC (Registration) Regulations 2009 Statement of purpose **Regulation 12 HSCA 2008 (Regulated Activities) Regulations 2014 Safe care and treatment.** **Regulation 12 (1)(2)(c)(h)**

Regulated activity	Regulation
Diagnostic and screening procedures	Regulation 17 HSCA (RA) Regulations 2014 Good governance **Regulation 17 HSCA 2008 (Regulated Activities) Regulations 2014 Good governance** **Regulation 17(1)(2)(c)**