

The Fetal Medicine Centre

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

Good 

Are services safe?

Good 

Are services effective?

Are services caring?

Outstanding 

Are services responsive?

Good 

Are services well-led?

Good 

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

The Fetal Medicine Centre is operated by The Fetal Medicine Centre Limited. The service provides ultrasound examinations and invasive testing for fetal abnormalities and pregnancy complications for adults.

We inspected diagnostic imaging facilities.

We inspected this service using our comprehensive inspection methodology. We carried out the unannounced inspection on 22 November 2018.

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 (MCA).

The main service provided by this unit was ultrasound scanning.

Services we rate

This was the first inspection of this service. We rated it as **Good** overall.

We found good practice in relation to diagnostic imaging:

- There were effective systems to keep people protected from avoidable harm.
- There were sufficient numbers of staff with the necessary skills, experience and qualifications to meet patients' needs.
- There was a programme of mandatory training which all staff completed, and systems for checking staff competencies.
- Staff had the right skills and training to undertake ultrasound scans, this was closely reviewed at the service as part of their fellowship training and at an NHS Trust.
- Equipment was maintained and serviced appropriately and the environment was visibly clean.
- Staff were trained and understood what to do if a safeguarding issue was identified.
- Records were up to date and complete and kept protected from unauthorised access.
- Incidents were reported, investigated and learning was implemented.
- The service had implemented a programme of audits, that included audits relating to patient outcomes
- Staff demonstrated a kind and caring approach to their patients and supported their emotional needs.
- Appointments were available during the evening, at weekends and at short notice if required.
- The referral to scan times and scan to reporting times were appropriate and well within expected ranges. Complaints from patients were taken seriously and acted upon.
- The service had supportive and competent managers. Staff understood and were invested in the vision and values of the organisation. The culture was positive and staff demonstrated pride in the work and the service provided.

Summary of findings

- Risks were identified, assessed and mitigated. Performance was monitored and performance information was used to make improvements.

Dr Nigel Acheson

Deputy Chief inspector of Hospitals (London and the South East)

Overall summary

The Fetal Medicine Centre was located in the basement at 137 Harley Street, London. The service had a reception on area. There were six scan rooms in the premises as well as a small laboratory for blood collection and blood processing. The laboratory was located at the back of the reception area. The service had five toilets three of these being in scan rooms. The service also had offices for the doctors/management and a telephone switchboard room with backrooms used for storage and for record keeping.

The service has had a registered manager in post since 2012.

The Fetal Medicine Centre was registered to provide the following regulated activities:

- Diagnostic and screening procedures

During the inspection we spoke with four staff including; the deputy manager, consultant and two sonographers. We also spoke with four patients.

There were no special reviews or investigations of the unit ongoing by the CQC at any time during the 12 months before this inspection.

The service conducted 700 scans per month. Staff in the service consisted of one whole time equivalent (WTE) registered manager, 1 WTE deputy manager, 1 WTE team leader, 1 WTE laboratory technician and 6 WTE receptionists. There were six consultants that currently provide services to the Fetal Medicine Centre as well as several doctors undergoing postgraduate training in Fetal Medicine at an NHS trust in London. The Nominated Individual also worked one day each week.

Every year The Fetal Medicine Foundation awards a two-year training fellowship in fetal medicine. The

practical training is undertaken at the Fetal Medicine units at an NHS trust.. Some fellows will be selected to provide services at the Fetal Medicine Centre and as part of their development they provide their services free of charge at the service.

The aim of the Fetal Medicine Foundation is to assess the risk for pregnancy complications at such an early time in pregnancy that this may give doctors the chance to reassure patients, and to prevent pre-eclampsia and premature birth, which are major contributors to maternal and neonatal morbidity and mortality.

Track record on safety

- No Never events.
- No serious injuries.
- No incidences of healthcare acquired Meticillin-resistant Staphylococcus aureus (MRSA).
- No incidences of healthcare acquired Meticillin-sensitive staphylococcus aureus (MSSA).
- No incidences of healthcare acquired Clostridium difficile (c. diff).
- No incidences of healthcare acquired Escherichia coli (E-Coli).
- No deaths.

Services provided under service level agreement:

- Clinical and or non-clinical waste removal
- Building Maintenance
- Laundry

Summary of findings

Our judgements about each of the main services

Service	Rating	Summary of each main service
Diagnostic imaging	Good 	We rated this service as good because it was safe, caring and responsive and well led. We do not rate effective in this type of service.



Summary of findings

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Good 

The Fetal Medicine Centre

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Summary of this inspection

Background to The Fetal Medicine Centre

This report relates to diagnostic imaging services provided by The Fetal Medicine Centre.

The Fetal Medicine Centre (FMC) opened in 1996 and since then has provided ultrasound examinations and invasive testing for fetal abnormalities and pregnancy complications. The FMC profits are donated to a U.K. charity. The founder and director of the FMC is Professor Kypros Nicolaides, who was also the Nominated Individual for the service. There are six other consultants that currently provide services to the FMC as well as several doctors undergoing postgraduate training in Fetal Medicine at a NHS Trust in London. Since 2012, the service began offering non-invasive prenatal testing (NIPT) which is a screening test that uses maternal blood to screen for the most common syndromes that are

detected during pregnancy. Patients with high risk pregnancies or NIPT results are examined by ultrasound and when necessary they undergo invasive procedures in order to try and provide a definite diagnosis.

The service provides ultrasound examinations to private patients for people attending from all over the United Kingdom.

The Care Quality Commission (CQC) report from the last inspection, published in January 2015 showed The Fetal Medicine Centre met the five standards inspections, taken from the essential standards as described in the Health and Social Care Act 2008 (Regulated Activities) Regulations 2010 and the Care Quality Commission (Registration) Regulations 2009.

Our inspection team

The team that inspected the service comprised a CQC lead inspector, and an ultrasound specialist advisor. Specialist advisers are experts in their field who we use to inform our inspection of services. The inspection was overseen by Nicola Wise Head of Hospital Inspection.

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?

We rated safe as **Good** because:

- There was an open incident reporting culture within the unit and an embedded process for staff to learn from incidents.
- All staff demonstrated an understanding of the duty of candour and the principles behind this.
- Staff were knowledgeable about safeguarding processes and what constitutes abuse.
- Many of the sonographers at the FMC were qualified Obstetricians (in other countries) therefore they demonstrated good knowledge and understanding of patient risk.
- Each patient had a referral form and we saw that any risks were identified or documented.
- Equipment was serviced and there were processes to ensure all items were well maintained.
- The environment was visibly clean.

Good



Are services effective?

We do not currently rate effective for diagnostic imaging.

- Policies, procedures and guidelines were up to date and based on National Institute for Health and Care Excellence (NICE) guidelines, relevant regulations and legislation.
- Staff worked collaboratively as part of a multi-professional team to meet patients' needs.
- There were systems to show whether staff were competent to undertake their jobs and to develop their skills or to manage under-performance.
- There was effective multidisciplinary team working throughout the unit and with other providers.
- The service had implemented a programme of audits, that included audits relating to patient outcomes, such as an independent six-monthly review of all scans undertaken at the service. As sonographers were undertaking fellowships at the Fetal Medicine Foundation all their work was regularly reviewed as part of ongoing development. We found that audits were discussed at team meetings.
- Information provided by the unit demonstrated 100% of staff had been appraised.

Are services caring?

We rated caring as **Outstanding** because:

Outstanding



Summary of this inspection

- Patients were treated with kindness, dignity and respect. This was reflected in feedback we received from patients.
- Patients received information in a way which they understood and felt involved in their care. Patients were always given the opportunity to ask staff questions, and patients felt comfortable doing so.
- People told us 'It seems really good here', 'We came here on a recommendation we have had a number scans we would recommend it'. Other people in feedback to the service said, 'Coming to the Fetal Medicine Centre and seeing the doctor has been the best decision we have made so far' and another said, 'The doctor has provided us with all the necessary information and have been excellent in their approach.'
- Staff provided patients and those close to them with emotional support; staff were supportive of anxious or distressed patients

Are services responsive?

We rated responsive as **Good** because:

- It offered numerous scans for pregnant women such as, viability, nuchal, cardiac and wellbeing. It also offered a test, which analyses cell free DNA in maternal blood and gives a strong indication of whether the fetus is at high risk of having trisomy 21 (Down syndrome) trisomy 18 (Edwards syndrome) or trisomy 13 (Patau syndrome). The test can be performed in women carrying one or two fetus' at any stage in their pregnancy from 10 to 32 weeks.
- Patient complaints and concerns were managed according to the Fetal Medicine Centre policy.
- The service told us that if there were no appointment slots available and the patient felt they required urgent attention then the service would request doctors to stay over the normal opening hours to accommodate the patient.
- Complaints were investigated and learning was identified and shared to improve service quality.

Good



Are services well-led?

We rated well-led as **Good** because:

- Staff said managers were visible and approachable. Staff informed us they felt supported by the management team.
- We were told that on a daily basis there is always one consultant subspecialist in fetal medicine present in the clinic and a staff manager to provide leadership and motivation to the doctors and rest of the staff. All the staff we spoke with were positive about the management of the service.





Good



Summary of this inspection

- There was a clear governance structure, which all members of staff were aware of.
- The unit had its own risk register and managers had clear visibility of the risks and were knowledgeable about actions to mitigate risks.
- There was a culture of openness and honesty supported by a whistle blowing policy.

Diagnostic imaging

Safe	Good 
Effective	
Caring	Outstanding 
Responsive	Good 
Well-led	Good 

Are outpatients and diagnostic imaging services safe?

Good 

Mandatory training

The service had systems in place to ensure staff had received mandatory training in key skills and made sure that everyone had completed it.

Annual mandatory training courses were undertaken and regularly updated. Fellows had received their training at an NHS Trust in London and at the service whilst other non-clinical staff received training solely at the service. The service provided us with its training matrix which showed staff received mandatory training in; fire safety and evacuation, health and safety in healthcare, equality and diversity, infection prevention and control, safeguarding adults, safeguarding children level 2, customer care and complaints, basic life support (BLS) and data security awareness.

Mandatory training rates were reviewed yearly. At the time of this inspection records we viewed demonstrated 100% of staff had completed mandatory training. All staff were required to complete the service's mandatory training programme as well as the training programme at an NHS Trust

Safeguarding

Staff understood how to protect patients from abuse. Staff had training on how to recognise and report abuse and knew how to apply it.

The lead for adults and children's safeguarding was the clinic manager who was trained to level three.

Staff were trained to recognise adults and young people at risk and were supported by the FMC safeguarding adults' and children's policy.

The provider had developed safety and safeguarding policies in place. The provider had an adult and child safeguarding policy that staff were familiar with and had access to it on the intranet. Both policies were up to date and reviewed yearly. The policies were clear, thorough and covered all types of abuse including female genital mutilation (FGM). They also clearly outlined staff responsibilities and how they should raise a safeguarding concern as well as immediate action to be taken where concerns related to a child. The provider had a separate domestic abuse policy and a separate Prevent policy. 'Prevent' is part of the government's counter terrorism strategy and is about identifying, safeguarding and supporting people who are at risk of being drawn into terrorist or extremist activity.

Staff we spoke with demonstrated they understood their responsibilities and adhered to the company's safeguarding policies and procedures.

Staff knew how to report a safeguarding concern but there were no safeguarding concerns raised from September 2017 to September 2018.

All staff received training in safeguarding children and young people level two as it was possible that children may attend the service with parents. This met intercollegiate guidance: 'Safeguarding Children and Young People: Roles and competencies for Health Care

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Staff; March 2014. Guidance states all non-clinical and clinical staff that have any contact with children, young people, parents or carers should be trained to level two safeguarding.

FMC did not provide services for children or patients under the age of 18 years. However, we saw contact phone numbers for local authority adult and children's safeguarding teams were in the unit's office.

Cleanliness, infection control and hygiene

The service controlled infection risk well. Staff kept themselves, equipment and the premises clean. They used control measures to prevent the spread of infection.

The service had an infection prevention and control (IPC) policies and procedures which provided staff with guidance on appropriate IPC practice in for example, communicable diseases and isolation.

During this inspection we saw all areas of the service were visibly clean. An external cleaning company cleaned the scanning rooms each day according to the services cleaning manual and room specifications document. This was recorded on a daily check spreadsheet and was reviewed by the clinic manager each week.

Staff followed manufacturers' instructions and the FMC guidelines for routine disinfection. This included the cleaning of the medical devices between each patient and at the end of each day. We saw staff cleaning equipment and machines following each use, this included such things as covers for the transvaginal probe used for internal examinations. We reviewed all machines in use during this inspection, and saw where appropriate, disinfection of the machines had taken place and a weekly check of each machine was available.

Between September 2017 and September 2018 there had been no incidences of health care acquired infection in the unit.

The clinic manager observed staff compliance towards hand hygiene, and infection prevention and control audits during their overall monthly audit of the service, although the service did not conduct specific hand hygiene audits to measure staff compliance with the World Health Organisation's (WHO) '5 Moments for Hand

Hygiene.' These guidelines are for all staff working in healthcare environments and define the key moments when staff should be performing hand hygiene to reduce risk of cross contamination between patients.

Staff had access to hand washing facilities. Throughout the inspection we found all staff were compliant with best practice regarding hand hygiene.

Staff were bare below the elbow and had access to a supply of personal protective equipment (PPE), including gloves and aprons. We saw staff using PPE appropriately.

Waste was handled and disposed of in a way that kept people safe. Waste was labelled appropriately and staff followed correct procedures to handle and sort different types of waste we saw that sharps bins were emptied each morning with waste being stored in a room behind the manager's office and collected each day.

Environment and equipment

The service had suitable premises and equipment and looked after them well.

The layout of the unit was compatible with health and building notification (HBN06) guidance. Access to the service was via Harley Street. There was a reception area with a reception desk that was staffed during opening hours. The reception area provided a range of magazines, refreshments and toilet facilities for patients and relatives. The service was located in the basement and access could be gained by either a lift or stairs.

The provider's maintenance and use of their facilities kept people safe. Waiting areas were visibly clean and tidy throughout. Treatment rooms were spacious and well-lit. The condition, maintenance and appearance of the environment was good and information was clearly displayed.

The service had six ultrasound machines and two blood sample analysing machines. All equipment was maintained and regularly serviced by the manufacturers. We saw that the service completed United Kingdom National External Quality Assessment Schemes (UKNEQAS) testing on a monthly basis. We reviewed service records for the equipment, which detailed the maintenance history and service due dates of equipment. There were systems to ensure repairs to machines or

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equipment, when required, were timely. This ensured patients would not experience prolonged delays to their care and treatment due to equipment being broken and out of use.

Staff had sufficient space to move around the ultrasound machines for scans to be carried out safely and there were comfortable couches for patients and stools for the operator.

All equipment conformed to relevant safety standards and non-medical portable appliance electrical equipment was tested.

We reviewed the October 2018 environment and health and safety audit which found the service to be compliant in all areas.

Assessing and responding to patient risk

Staff reviewed and updated risk assessments for each patient via the referral forms.

The service was 95% self-referral with only 5% being a request for a further opinion. Patients were asked to complete their demographic information, reasons for a scan and consent. The referral form included prompts to ensure risks and any special needs (such as support with language) were identified and included details of the type and purpose of the scan. This was to

ensure the type of scan was appropriate for the investigation or examination required. The majority of self-referred reasons were due to previously experienced miscarriages.

Many of the sonographers at the FMC were qualified Obstetricians therefore they demonstrated good knowledge and understanding of patient risk. Each patient had a referral form and we saw that any risks were identified or documented.

Patients we spoke with said they had discussed the relative risks and benefits with sonographers, should patients wish a reduction in pregnancy the service referred the patient to a NHS Trust for counselling.

There were processes to ensure the correct person got the correct scan at the right time. We observed the reception team booking a patient in, checking name,

date of birth, address and type of scan. We later observed the same checks being made by the sonographer prior to scan. If a patient required a blood test we saw a further check being conducted.

We were told that if the sonographers observed areas of a scan that could indicate concerns, this would be confirmed with the consultant present to confirm diagnosis. The consultant would review all non-routine scans, if any abnormalities were found during scans patients were given appointments the following Wednesday to see the Nominated Individual.

If the sonographers observed a fetal abnormality that required urgent further investigation and management, the service had arrangements for such patients to be seen within 24 hours at the fetal medicine unit at an NHS Trust. Examples of this were; severe fetal anaemia requiring blood transfusion, severe twin to twin transfusion requiring endoscopic laser placental separation or major fetal abnormality where the parents may request pregnancy termination.

Patients with severe fetal problems that required further management would be referred to their local hospitals for further investigations and management.

The service conducted analysis of blood samples with regard to the Nuchal test, the Harmony test (Harmony checks for Trisomy 21 (Downs syndrome) Trisomy 13 (Edwards syndrome) and Trisomy 18 (Patau's syndrome)) and Toxo, Rubella, Cytomegalovirus (CMV), Herpes (TORCH) screening. We were told that blood scans were completed before the scan so both test results would be available to following the ultrasound scan. The doctor could then give both scan and test results following the scan.

Medical emergency procedures were regularly audited. We viewed the unit's medical emergency audit dated October 2018. There were procedures for removal of a collapsed patient and staff had received training in basic life support. All clinical staff were basic life support (BLS) trained, and they told us if a patient required more urgent treatment they would call 999.

Staffing

The service had enough staff with the right qualifications, skills, training and experience to

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keep people safe from avoidable harm and to provide the right care and treatment.

At the time of the inspection there were four sonographers, two consultants, laboratory technician, clinic manager and reception / administration staff present. The service had 53 appointments booked throughout the day and sufficient staffing to manage appointments. The service did not use agency staff.

The clinic manager was responsible for monitoring the hours worked by staff and ensuring they did not exceed working time limits. This included ensuring staff working longer than 6 hours at a time received a 20-minute rest break. Workers were entitled to a daily rest period of at least 11 hours uninterrupted rest in every 24-hour period, as well as a weekly rest period of 24 hours uninterrupted in every seven-day period. The clinic manager was able to adjust staffing numbers to meet demand.

There were business continuity plans to guide the service when responding to changing circumstances. For example, sickness, absenteeism and workforce changes.

The recruitment processes for staff included employment checks to ensure they were safe and suitable to work for the service. For example, there was evidence in personnel files of identity checks, Disclosure and Barring Service (DBS) check and checks of professional qualifications, which if obtained in other countries had been translated into English.

All staff we spoke with felt staffing was managed appropriately

Records

Staff kept and updated individual patient care records in a way that protected patient's confidentiality. Patient care records were accessible to staff.

The service sought confirmation from patients that they had the opportunity to consider the information provided in the information sheet, been provided the opportunity to ask questions, discuss the test and have had any questions satisfactorily answered. Patients were also asked to consent to personal information being stored and accessed on systems outside the EU. This was because the service sent a blood sample along with personal information to a company in the United States, who extracted cell-free DNA from blood samples.

Patients' personal data and information were kept secure. Only authorised staff had access to patients' personal information. Staff training on information governance and records management was part of the mandatory training programme.

We reviewed five patient care records during this inspection and saw records were accurate, complete, legible and up to date. Reports of the scans were given to the patient directly.

Medicines

Medicines were not used at the Fetal Medicine Centre with the exception of a medication used to numb tissue in a specific area (local anaesthetic) due to the service having a remit to provide scanning for low risk patients. We found this to be stored and used appropriately. An anaphylactic kit was available, this was sealed and tagged appropriately with records of checks being in place.

All patient allergies were documented and checked on arrival in the unit.

Incidents

The service had systems to manage patient safety incidents.

The service had an incident reporting policy and procedure to guide staff in the process of reporting incidents. Staff understood their responsibilities to raise concerns, to record safety incidents and investigate and record near misses. An accident and incident book was kept in the clinic manager's office to which all staff had access. We reviewed the accident and incident book and found that staff had been completing it appropriately, the service recorded all low level incidents and near misses within the book.

Between September 2017 and September 2018, the service reported one incident through its reporting system. We reviewed this incident and found that it had been thoroughly investigated with the findings resulting in a change of practice when conducting ultrasound examinations. The incident was also treated as a complaint by the service. We saw that learning from this incident was shared with staff during a staff meeting.

During the period September 2017 to August 2018 there had been no serious incidents requiring investigation.

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Serious incidents are events in health care where the potential for learning is so great, or the consequences to patients, families and carers, staff or organisations are so significant, they warrant using additional resources to mount a comprehensive investigation.

There had been no 'never events' in the previous 12 months prior to this inspection. Never events are serious incidents that are entirely preventable as guidance, or safety recommendations providing strong systemic protective barriers, are available at a national level, and should have been implemented by all healthcare providers.

There had been no notifiable safety incidents that met the requirements of the duty of candour regulation in the 12 months preceding this inspection. The 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.

We were told that any incident would be immediately reviewed by the clinic manager, registered manager and nominated individual.

An organisational policy and procedure was available to staff providing guidance on the process to follow if an incident was to occur that met the requirements of the duty of candour regulation. Staff we spoke with demonstrated they understood the requirements of the duty of candour regulation. Incidents involving patient or service user harm were assessed with the 'notifiable safety incident' criteria as defined within regulation 20 of the Health and Social Care Act 2008 (regulated activities) Regulations 2014. Incidents meeting this threshold were managed under the organisations 'adverse events (incident) reporting and management policy' and 'Duty of Candour, procedure for the notification of a notifiable safety incident' standard operating procedure.

Are outpatients and diagnostic imaging services effective?

Evidence-based care and treatment

The service provided care and treatment based on national guidance and evidence of its effectiveness. Managers checked to make sure staff followed guidance.

Patients care and treatment was delivered and clinical outcomes monitored in accordance with guidance from the National Institute for Health and Care Excellence (NICE). NICE guidance was followed for diagnostic imaging pathways as part of specific clinical conditions. For example, NICE CG62 Screening for clinical conditions.

Staff assessed patients' needs and planned and delivered patient care in line with evidence-based, guidance, standards and best practice. Audits was carried out annually to assess clinical practice in accordance with local and national guidance, such as scan imaging audits.

Nutrition and hydration

Patients had access to water and hot drinks whilst awaiting their scan. During our inspection we observed staff offering patients drinks before and after they were scanned. Patients could also help themselves to hot and cold drinks in the main reception area.

Pain relief

Pain assessments were not undertaken at the Fetal Medicine Centre.

Patient outcomes

Managers monitored the effectiveness of care and treatment and used the findings to improve them.

The service had implemented a programme of audits, that included audits relating to patient outcomes, such as an independent six-monthly review of all scans undertaken at the service. As sonographers were undertaking fellowships at the Fetal Medicine Foundation all their work was regularly reviewed as part of ongoing development. We found that audits were discussed at team meetings.

The service conducted a monthly audit of delays in scans, we saw that each month the service performed mostly in line with its 10% target. We also reviewed the service patient satisfaction survey result January – June 2018 of the 417 questionnaires received by the service 100% rated in at good.

The service audited individual areas including, patient experience, health and safety, safeguarding, equipment and privacy and dignity and we saw good audit results indicated positive patient outcomes.

Competent staff

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The service made sure staff were competent for their roles. Managers appraised staffs work performance and provided support. All staff had completed a structured induction programme for the service, which included the use of equipment and office systems, sonographers had also completed a further induction programme at an NHS Trust.

Staff had the right skills and training to undertake ultrasound scans, this was closely reviewed at the service as part of their fellowship training and at an NHS Trust. We were told the sonographers who worked at the Fetal Medicine Centre had been selected because of their expertise and experience as they were considered to be highly skilled. Many of the people working in the role of sonographers were qualified doctors.

Administrative staff received a formal appraisal yearly. This was a two-way process with staff and their manager discussing aspects of performance, such as attendance and attitude as well as developmental objectives. We also saw that feedback from complaints was fed back during supervision sessions. Records we checked confirmed staff appraisals were up to date. Sonographers received ongoing professional review as part of their fellowship training programme.

Multidisciplinary working

Staff at the service told us that their aim was to work closely with patients to support a seamless treatment pathway. If concerns were identified from a scan these were escalated to the consultant in charge who would review their findings.

The service had good relationships with other external partners such as a local NHS Trust and the Fetal Medicine Foundation itself.

Seven-day services

The service was operational from 9am to 6pm Monday to Friday and 9am to 5pm on Saturdays.

Appointments were flexible to meet the needs of patients, and appointments were available at short notice.

Health promotion

Information leaflets were provided in the unit for patients on what the scan would entail and what was expected of them prior to a scan. Such as the information regarding the Harmony test.

Consent and Mental Capacity Act

Staff understood how and when to assess whether a patient had the capacity to make decisions about their scan.

Patients completed an informed consent form, consisting of patients' answers to the Harmony Prenatal Test, this is a test that analyses cell free DNA in maternal blood and gives a strong indication of whether the fetus is at high risk of having Trisomy 21 (Downs syndrome) Trisomy 18 (Edwards syndrome) or Trisomy 13 (Patau syndrome). The test can be performed in women carrying one or two foetuses at any stage in their pregnancy from 10 to 32 weeks.

Staff understood their responsibility to gain consent from patients before they performed an ultrasound scan. They recognised and respected a patient's choice if they decided not to have a scan after arriving for an appointment.

Staff informed us they explained the imagining procedure to patients and as well as requiring patients to completed an informed consent form a verbal request was also made. Staff we spoke with had knowledge of the requirements of the Mental Capacity Act 2005 (MCA).

During this inspection there were no patients who lacked capacity to make decisions in relation to consenting to treatment. We were told that they had not had experience of supporting a patient assessed as lacking capacity to make decisions about the scanning procedure.

Are outpatients and diagnostic imaging services caring?

Outstanding



Compassionate care

Diagnostic imaging

During this inspection we saw all staff treating patients with dignity, kindness, compassion, courtesy and respect. Staff introduced themselves prior to the start of a patient's treatment, interacted well with patients and included patients in general conversation.

In the interactions we saw during this inspection, and feedback provided by patients we spoke with, staff demonstrated a kind and caring attitude to patients. Staff introduced themselves and explained their role and explained to patients what would happen next.

During this inspection we spoke with three patients about various aspects of the care they received at the Fetal Medicine Centre. Feedback was wholly positive about staff and the care they delivered.

People told us 'It seems really good here', 'We came here on a recommendation we have had a number scans we would recommend it'. Other people in feedback to the service said, 'Coming to the Fetal Medicine Centre and seeing the doctor has been the best decision we have made so far' and another said, 'The doctor has provided us with all the necessary information and have been excellent in their approach.'

Staff ensured patients' privacy and dignity was maintained during their time in the unit and during scanning.

Patient satisfaction was formally measured through completion of the patient survey following their examination. Between January 2018 and June 2018 patients provided 100% positive feedback about the service they received at the Fetal Medicine Centre. This was based on 417 returned questionnaires which was 10% of the patients seen during this period.

We found that all members of staff we spoke with during the inspection shared the aim of the service to improve the health of pregnant women and their babies through research and training in fetal medicine and spoke with passion about delivering this.

Emotional support

Staff provided emotional support to patients to minimise any distress.

Staff supported people through their scans, ensuring they were well informed and knew what to expect. Staff provided reassurance and support for nervous and

anxious patients. They demonstrated a calm and reassuring attitude so as not to increase anxiety in nervous patients. All patients we spoke with told us staff had been supportive.

Staff provided reassurance throughout the scanning process, they updated the patient on the progress of the scan and how long they had before their treatment was complete

We spoke with staff who felt recognising and providing emotional support to patients was an important aspect of the work they did, patients could be taken to a quiet room to discuss difficult matters if need. The service told us that for patients who attended alone and were emotional after receiving exceptionally bad news, the service would call their next of kin and arrange for a taxi to ensure that they arrived home safely. Staff recognised the level of distress people may experience and considered patient's emotional and social needs as important as their physical needs. We were told that should a patient be in distress staff would stay late within the service to scan the patient at short notice.

Ongoing support was offered to women post-appointment and after discussion to ensure their emotional needs were met by referring them to a professional psychoanalyst specialising in the field of pregnancy.

Understanding and involvement of patients and those close to them

Staff involved patients and those close to them in decisions about their care.

Staff communicated with patients in a manner to ensure they understood the reasons for attending the unit. All patients were welcomed into the reception area and reassured about their procedure.

People could recontact the service, to clarify their understanding of results and discuss options available to them.

Staff recognised when patients or relatives needed additional support to help them understand and be involved in their care and treatment. Staff enabled them to access this, including access to interpreting and translation services.

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Patients and relatives could ask questions about their scan. A range of ultrasound related leaflets were available to patients in the service. Patients could also access information on different types of scans, packages from the Fetal Medicine Centre website.

The service encouraged partners to be present with the patient for the scan.

Are outpatients and diagnostic imaging services responsive?

Good 

Service delivery to meet the needs of local people

The diagnostic service was located in the basement of the building, and patients and visitors to the unit could access the unit via a lift or staircase.

The service provided payment details in a confirmation email prior to each patient's attendance.

These included a clear price list and different options for payment. The service was registered with most UK insurers.

The service offered numerous scans for pregnant women such as, viability, nuchal, cardiac and wellbeing. The Fetal Medicine Centre opened in 2012. There were six scan rooms in the premises as well as a small laboratory for blood collect and blood processing. The laboratory was located at the back of the reception area. The service had five toilets three of these being located in scan rooms. The service also had offices for the doctors/management and a telephone switchboard room with backrooms used for storage and for record keeping.

The service provided evening and Saturday appointments to accommodate the needs of patients who were unable to attend during the weekdays.

The service was located on Harley Street, it was accessible by public transport with a number of London underground stations being located close by on bus routes and the service could be access by vehicle. The service provided information on travelling to the centre on its website.

The environment was patient centred. The unit had comfortable sufficient seating in reception areas. Toilets

and drinks machines were available to patients and visitors in the main reception waiting area. Snacks could be provided upon request or if a patient was feeling unwell and needed to boost their blood sugars.

Meeting people's individual needs

Staff had an understanding of the cultural, social and religious needs of patients. For example, there was a diverse staff group with multilingual and diverse faith backgrounds.

During scanning, staff made patients comfortable. Patients were advised if they wanted to stop their scan, staff would assist them and discuss choices for further imaging or different techniques or coping mechanisms to complete their imaging. Patients and relatives could be present in the scanning room if required.

Explanations were given post examination on aftercare and follow up appointments were made should these be required. Patients with mobility needs could access the unit via a lift. Couches were suitable for bariatric patients.

Staff explained the referrer would inform them if translation services were required and they would

organise this in advance, however in most cases, patients were accompanied by a partner or relative who could translate for them. Easy to read leaflets and large print patient information was available and braille could be provided on request.

Access and flow

In 95% of cases patients self-referred, with only 5% of people attending for a second opinion. Patients could book appointments through several media platforms including, telephone and email and through the Fetal Medicine Centre website. Patients' appointments were usually made by telephone at a time and date agreed by them.

In the case of a requirement to conduct an urgent scan the service told us that it would attempt to make an appointment as soon as possible. The service told us that if there were no appointment slots available and the patient felt they required urgent attention then the service would request doctors to stay over the normal opening hours to accommodate the patient.

Waiting times in the service were usually met. There were very few delays and appointment times were closely

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adhered to. The service audited delays and found that the common theme for delays was due to additional time being given to explain scan results to patients. Diagnostic reports were produced and shared in a timely fashion, on the same day.

From September 2017 to September 2018 no planned examinations were cancelled for non-clinical reasons and no planned examinations had been delayed in the same period.

The service did not routinely record the data for patients who did not attend, we were told that if a person did not attend, or cancelled, they would be contacted to ascertain the reasons for their non-attendance and an appointment would be re-booked if necessary.

Learning from complaints and concerns

Staff were encouraged to resolve complaints and concerns locally. The Fetal Medicine centre had a complaints handling policy and all had staff completed a mandatory training course on customer care and complaints.

The unit had a complaints log. This recorded the unit had received 12 complaints in the period September 2017 to September 2018. All were managed through the informal complaints procedure. The complaints log recorded actions the unit had taken in response to the complaint. The log recorded when patients had received a verbal apology from the service. Most complaints related to appointments overrunning.

The complaints procedure was displayed for patients and relatives to read in the main reception area although the complaints leaflet required updating as it referred to the Healthcare Commission.

Are outpatients and diagnostic imaging services well-led?

Good 

Leadership

The Fetal Medicine Centre was managed by the registered manager, with support from the Nominated Individual and the Fetal Medicine Foundation. The registered manager had taken up the role in August 2012.

The management structure within the service consisted of an registered manager supported by a clinic manager. Staff also had specialist lead roles within the unit. For example, the registered manager was the lead for health and safety, safeguarding, and infection prevention and control (IPC).

Staff said managers were visible and approachable. Staff informed us they felt supported by the management team.

We were told that on a daily basis there was is always one consultant subspecialist in fetal medicine present in the clinic and a staff manager to provide leadership and motivation to the doctors and rest of the staff. All the staff we spoke with were positive about the management of the service.

Vision and strategy

The service's vision and aims were to improve the health of pregnant women and their babies through research and training in fetal medicine. Staff spoke passionately about these values and without exception identified with the services values and aims.

All staff were introduced into these values during induction when first employed during the corporate induction. The appraisal process for staff were also aligned to these values and fellows received ongoing personal professional development objectives which were linked to the objectives.

Culture

Managers and staff promoted a positive culture, creating a sense of common purpose based on shared values.

All of the staff we spoke with were very positive and happy in their roles and stated the service was a good place to work. Staff told us that the manager was flexible in their approach to running the service, stating that the manager was considered a friend.

Most staff we spoke with told us they felt supported, respected and valued. They were actively encouraged to make suggestions about changes and improvements to the services provided.

Staff demonstrated pride in their work and the service they delivered to patients and their service

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partners. Staff told us they had sufficient time to support patients.

Staff told us there was a positive approach in regard to incidents and they always received feedback from incidents.

Formal minuted team meetings were held monthly. We were provided with minutes from these meetings which included; how the unit was progressing in regards to the company strategy, performance, policies, and reviews of incidents and complaints and any lessons learnt. Information was also shared during a two-way process with clinicians at a NHS Trust by means of a monthly newsletter.

Equality and diversity were promoted within the service and were part of mandatory training. The diverse staff team promoted inclusive and non-discriminatory practices.

A whistle blowing policy and a duty of candour policy were in place. Staff told us they had attended duty of candour training and described to us the principles of duty of candour.

Governance

The provider systematically improved service quality and safeguarded high standards of care. There was a robust governance framework which oversaw service delivery and quality of care.

The Fetal Medicine Centre operated a clinical governance framework which aimed to assure the quality of services provided. The policies were available on line for staff to read and there was a system to monitor when staff had read the policies.

The clinic manager reviewed risk and governance within the service we saw that the service monitored such things as complaints, litigation, and incidents. The manager also ensured that regular health and safety audits were conducted on a monthly basis. This ensured actions to improve services were recorded and monitored to completion.

Managing risks, issues and performance

Performance was monitored at a local level. Progress in delivering services was monitored through key

performance indicators (KPI). The service monitored monthly its performance regarding delayed appointments. Dashboards and reports were produced and enabled comparisons and benchmarking.

There was a robust local risk assessment system which included a process of escalation to capture risks onto the corporate risk register. The local risk register was reviewed and updated monthly and new risks added regularly, these covered hazards and precautions in relation to a range of factors, including infection control, electrical safety, fire safety and substances hazardous to health.

The audit programme showed a wide range of audits planned and conducted for the service. This included a six-monthly independent review of scans and a monthly audit of scan delays and opportunities from learning were identified.

There was a business continuity policy which highlighted key hazards and mitigations, contact

details and relevant staff and an emergency response checklist.

Managing information

The provider collected, analysed, managed and used information to support all its activities, using secure electronic systems with security safeguards.

Staff told us there were sufficient numbers of computers in the unit. This enabled staff to access the computer system when they needed to.

All staff we spoke with demonstrated they could locate and access relevant information and records easily, this enabled them to carry out their day to day roles. Patient records could be accessed easily but were kept secure to prevent unauthorised access to data.

Information from scans could be reviewed remotely by referrers to give timely advice and interpretation of results to determine appropriate patient care.

Engagement

The service did not routinely undertake staff satisfaction surveys, it was explained that because the service had a relatively small number of permanent employees that numbers would not produce meaningful data. It was explained that staff had access to the clinic and

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registered manager together with the nominated individual all of whom operated an open-door policy. They told us that regular supervision and appraisal ensured the service provided staff with the opportunity to comment on the service.

The service also enabled patients to provide feedback by email or comment cards. We reviewed the feedback received by the service from patients which was wholly positive.

Learning, continuous improvement and innovation

The Fetal Medicine Centre, as part of the Fetal Medicine Foundation, was at the forefront of research into fetal medicine, hosting events such as the Fetal Medicine Foundation World Congress in 2019, and taking part in trials.

Outstanding practice and areas for improvement

Outstanding practice

Staff had the right skills and training to undertake ultrasound scans, this was closely reviewed at the service as part of their fellowship training and at an NHS Trust. We were told the sonographers who worked at the Fetal Medicine Centre had been selected because of their expertise and experience as they were considered to be highly skilled. Many of the people working in the role of sonographers were qualified doctors.

The service told us that patients who attended alone and were emotional after receiving exceptionally bad news, the service would call their next of kin and arrange for a

taxi to ensure that they arrived home safely. Staff recognised the level of distress people may experience and the bad news people may receive and considered patient's emotional and social needs as important as their physical needs and we were told that should a patient be in distress staff would stay late within the service to scan the patient at short notice.

The Fetal Medicine Centre as part of the Fetal Medicine Foundation was at the forefront of research into fetal medicine, hosting events such as the Fetal Medicine Foundation World Congress in 2019.