

# Sussex Downs Fertility Centre

### **Inspection report**

6 Park View Alder Close Eastbourne BN23 6QE Tel: 07447429374

Date of inspection visit: 04 October 2022 Date of publication: 18/11/2022

This report describes our judgement of the quality of care at this service. It is based on a combination of what we found when we inspected, information from our ongoing monitoring of data about services and information given to us from the provider, patients, the public and other organisations.

### Ratings

Overall rating for this location	Requires Improvement	
Are services safe?	Requires Improvement	
Are services effective?	Requires Improvement	
Are services caring?	Good	
Are services responsive to people's needs?	Good	
Are services well-led?	Requires Improvement	

## Overall summary

#### This service is rated as Requires improvement overall.

The key questions are rated as:

Are services safe? – Requires improvement

Are services effective? - Requires improvement

Are services caring? - Good

Are services responsive? - Good

Are services well-led? – Requires improvement

We carried out this announced comprehensive inspection of Sussex Downs Fertility Centre on 4 October 2022 under Section 60 of the Health and Social Care Act 2008. This inspection was planned to check whether the service was meeting the legal requirements and regulations associated with the Health and Social Care Act 2008. This was the provider's first inspection of the service since it registered with the Care Quality Commission (CQC).

#### How we carried out the inspection:

This inspection was carried out in a way which enabled us to spend a minimum amount of time on site.

#### This included:

- Speaking with staff in person, on the telephone and using video conferencing.
- Requesting documentary evidence from the provider.
- A site visit.

We carried out an announced site visit to the service on 4 October 2022. Prior to our visit we requested documentary evidence electronically from the provider. We spoke to staff on the telephone and using video conferencing prior to our site visit.

Sussex Downs Fertility Centre is an independent provider of fertility services, located in Eastbourne. This service is registered with CQC under the Health and Social Care Act 2008 in respect of some, but not all, of the services it provides. These include pregnancy scans (post 12 weeks) and a range of women's health and gynaecological consultations and procedures, such as hysteroscopy. (A hysteroscopy is a procedure used to examine the inside of the uterine cavity).

There are some exemptions from regulation by CQC which relate to particular types of regulated activities and services and these are set out in Schedule 1 and Schedule 2 of The Health and Social Care Act 2008 (Regulated Activities) Regulations 2014. Sussex Downs Fertility Centre provides a full range of fertility services for NHS and private patients and holds a licence with the Human Fertilisation and Embryology Authority (HFEA) to enable them to carry out this work. Fertility services provided are not within CQC scope of registration. Therefore, we did not inspect or report on those services.

Sussex Downs Fertility Centre is registered with the Care Quality Commission to provide the following regulated activities: Treatment of disease, disorder or injury; Diagnostic and screening procedures; Surgical procedures.

## Overall summary

The service's managing director is the registered manager. A registered manager is a person who is registered with the Care Quality Commission to manage the service. Like registered providers, they are 'registered persons'. Registered persons have legal responsibility for meeting the requirements in the Health and Social Care Act 2008 and associated Regulations about how the service is run.

#### Our key findings were:

- There were some safeguarding systems and processes to keep people safe. However, there was no documented policy for the safeguarding of children.
- There were some comprehensive processes in place for the induction of staff and monitoring of role-specific competencies. However, some staff had not completed training in key areas.
- There was a lack of records to demonstrate that recruitment checks had been carried out in accordance with regulations for some staff.
- The monitoring and storage of staff documentation was not well managed and did not ensure leaders had clear oversight of their status.
- Arrangements for chaperoning were effectively managed.
- There were some processes to assess the risk of, and prevent, detect and control the spread of infection. However, staff immunisations were not monitored in line with current guidance.
- Cleaning and disinfection of intracavity ultrasound probes were not carried out in line with best practice guidance.
- There had been insufficient action taken to address and manage identified risks associated with Legionella bacteria.
- There were appropriate arrangements to manage medical emergencies and suitable emergency medicines and equipment were in place.
- Clinical record keeping was clear, comprehensive and complete, and in line with best practice guidance.
- There was evidence of clinical audit and auditing of clinical record keeping processes.
- There were effective governance, incident reporting and risk assessment processes in some areas. However, some identified risks were not always included in action planning or followed up in a timely manner.
- Leaders were focused upon staffing levels and stabilising the staff team following a period of high staff turnover.
- There was effective and open communication and information sharing amongst the staff team. There were regular team meetings and staff felt motivated to contribute to driving improvement within the service.
- Patients were asked to provide feedback on the service they had received, and the service acted promptly to respond to feedback. Complaints were managed appropriately.

The areas where the provider **must** make improvements as they are in breach of regulations are:

- Ensure care and treatment is provided in a safe way to patients.
- Establish effective systems and processes to ensure good governance in accordance with the fundamental standards of care
- Ensure persons employed in the provision of the regulated activity receive the appropriate support, training, professional development, supervision and appraisal necessary to enable them to carry out their duties.

(Please see the specific details on action required at the end of this report).

The areas where the provider **should** make improvements are:

• Review the complaints policy to provide information to support patients should their complaint remain unresolved.

#### Dr Sean O'Kelly BSc MB ChB MSc DCH FRCA

Chief Inspector of Hospitals and Interim Chief Inspector of Primary Medical Services

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### Our inspection team

Our inspection team was led by a CQC lead inspector and included a GP specialist advisor and a radiographer specialist advisor.

### Background to Sussex Downs Fertility Centre

Sussex Downs Fertility Centre is an independent provider of fertility services, located in Eastbourne. This service is registered with CQC under the Health and Social Care Act 2008 in respect of some, but not all, of the services it provides. These include pregnancy ultrasound scans (post 12 weeks) and a range of women's health and gynaecological consultations and procedures, such as hysteroscopy. The service offers consultations and treatments to people over the age of 18.

The Registered Provider is The Hospital Fertility Group Limited.

Sussex Downs Fertility Centre is located at 6 Park View, Alder Close, Eastbourne, BN23 6QE.

The service is open from 9am to 5pm on Monday to Friday. Out of hours support is available 24 hours per day, on 7 days per week, for those patients undergoing fertility treatments. Some Saturday appointments are available to meet the needs of individual patients' treatment plans.

The services also provides limited services from a satellite centre located at 18 Marine Parade, Kemptown, Brighton BN2

The service is run from self-contained, 2 storey premises which are owned by the provider. The service comprises a suite of consultation and treatment rooms, an operating theatre and recovery suite, a waiting room and reception area and administrative offices. Patients are able to access toilet facilities on the ground floor. Access to the premises at street level is available to patients with limited mobility.

Services are managed by the managing director, a centre manager and a quality manager, supported by a team of administrators. A medical director, who is a consultant gynaecologist and obstetrician, oversees the care provided by a team of specialist fertility consultants, a sonographer and nurses. The service employs consultant anaesthetists on a sessional basis to administer sedation to patients undergoing some procedures. Some staff work across multiple sites, including the satellite location in Brighton and another centre managed by the provider, located in Kent.

#### How we inspected this service

To get to the heart of patients' experiences of care and treatment, we always ask the following five questions:

- Is it safe?
- Is it effective?
- Is it caring?
- Is it responsive to people's needs?
- Is it well-led?

These questions therefore formed the framework for the areas we looked at during the inspection.



#### Safety systems and processes

#### The service had some systems to keep people safe and safeguarded from abuse.

- The service had systems and processes to safeguard vulnerable adults from abuse. The provider's safeguarding vulnerable adult's policy provided appropriate guidance for staff. Staff we spoke with had a clear understanding as to who was the safeguarding lead within the service and how to raise safeguarding concerns about a patient. Our review of training records confirmed that some staff had not received training in the safeguarding of vulnerable adults at a level appropriate to their role.
- Treatment was offered to those aged over 18 years of age and no children were treated by the service. However, in the event that children may attend the service whilst accompanying an adult, or staff may have contact with adults who may pose a risk to children, some staff had not received training in the safeguarding of children. There was no documented policy on the safeguarding of children to provide guidance to staff.
- We reviewed personnel files of 5 staff members employed by the service and found that some recruitment and monitoring checks had not been undertaken. For example, a DBS check had not been undertaken for 1 staff member. (DBS checks identify whether a person has a criminal record or is on an official list of people barred from working in roles where they may have contact with children or adults who may be vulnerable). References were not available for 2 staff members. There was no proof of identity held for 2 staff members.
- There was a lack of a clear approach to ensure that all required recruitment checks were completed. The monitoring and storage of staff recruitment documentation was not well managed and did not ensure leaders had clear oversight of their ongoing status. Some records were paper-based and others were stored electronically. There was a lack of an overarching view and monitoring of records held for each staff member.
- We saw there was signage on display within the service which invited patients to request a chaperone. All staff who acted as chaperones were trained for the role and had undergone a DBS check.
- The service had some systems to identify and manage health and safety risks within the premises, but these were not always followed up in a timely manner. For example, a Legionella risk assessment had been carried out by an external supplier in November 2021. (Legionella is a particular bacterium which can contaminate water systems in buildings). We found that the provider had not taken steps to address the actions identified as being required within the risk assessment. There was lack of monitoring of water temperatures within the premises and sampling of water supplies, in order to minimise the risk of Legionella contamination.
- There was guidance and information, including risk assessments and safety data sheets, available to staff to support the control of substances hazardous to health (COSHH). There were documented risk assessments in place to manage risks associated with the premises and general environment.
- There was a fire risk assessment in place and appropriate fire-fighting equipment located within the premises which was regularly serviced and maintained. We noted that fire extinguishers had been serviced in March 2022. The premises' fire alarm system had been serviced in June 2022 and was tested weekly. Staff had undertaken some fire safety training and had participated in a fire drill.
- The provider mainly ensured that facilities and equipment were safe, and that equipment was maintained according to manufacturers' instructions. We reviewed records to confirm that electrical equipment had undergone portable appliance testing in September 2022.
- However, we found that one ultrasound system, which had undergone servicing in February 2022, was reported as
  having a component which was faulty or corrupt. The provider had not explored the potential impact of this upon
  imaging quality or patient safety and had not sought to have the fault remedied. Immediately following our inspection,
  the provider obtained clarification from the servicing company. The fault was confirmed as a hard drive error which
  would not have any impact on imaging quality or patient safety but could mean the system stopped working without
  warning. We noted that the provider had a back-up system should this occur.



- There were some systems to manage infection prevention and control within the service. Cleaning and monitoring schedules were in place for clinical areas. The premises were clean and well maintained. Auditing of infection prevention processes was carried out every 3 months. However, the provider was unable to demonstrate that all staff had received training in infection prevention and control. Monitoring of hand hygiene techniques had not been undertaken to ensure staff followed recommended guidelines. We noted that the lead for infection prevention and control within the service had not completed training at an appropriate level to support their role.
- We reviewed processes for the cleaning and disinfection of ultrasound probes within the service. The service used some intracavity ultrasound probes which required high levels of disinfection. There was no system of assurance to ensure that all staff who used ultrasound probes were appropriately trained and consistent in their approach to decontamination processes.
- We found that cleaning and disinfection of transvaginal ultrasound probes were not carried out in line with best practice guidance. The service was using disinfectant wipes which were not suitable for this purpose. The provider told us this was due to a lack of availability of alternative disinfection systems during the COVID pandemic. We reviewed a risk assessment dated July 2021 which did not adequately assess the risks in this regard and was no longer applicable.
- The provider held a supply of appropriate disinfection systems which were not in use at the time of inspection. Immediately following our inspection, the provider provided evidence to confirm they had revised their approach and had implemented use of the alternative systems held, which ensured higher levels of disinfection in line with best practice guidance.
- There was a lack of records and tracking in relation to decontamination of transvaginal probes per individual patient, to ensure an audit trail of decontamination for each intracavity examination. Immediately following our inspection, the provider demonstrated they had implemented a tracking process, in line with current guidance.
- We reviewed the provider's ultrasound use policy and found that it did not provide sufficient guidance to staff or reflect best practice guidance in relation to ultrasound probe decontamination and tracking.
- The provider was unable to demonstrate that they held appropriate records relating to staff immunisations. We reviewed the service's staff screening policy dated July 2021. The policy did not reflect current guidance in relation to staff immunisation requirements. The policy stated that the service would monitor the vaccination status of all team members only with regard to hepatitis B, varicella and rubella. We reviewed records relating to 9 staff members and confirmed there were no immunisation records held for 6 of those staff. Four of those staff members were clinical staff. There were full immunisation records available, in line with current guidance, for 1 staff member only. Therefore, staff records we reviewed were not in line with national guidance or the provider's policy in monitoring the immunisation status of staff.
- There were systems for safely managing healthcare waste, including sharps items. We saw that clinical waste disposal was available in clinical rooms. We saw there were bins used to dispose of sharps items that were signed, dated and not over-filled. External, lockable bins were used to store healthcare waste awaiting collection by a waste management company.

#### **Risks to patients**

#### There were some systems in place to assess, monitor and manage risks to patient safety.

• There were arrangements for planning and monitoring the number and mix of staff required to meet patient needs. The service had experienced significant staff turnover in the 12 months prior to our inspection and resulting challenges in maintaining adequate staffing levels. The service had appropriately identified and monitored associated risks and had taken steps to address the staffing shortfalls. For example, some nursing staff who had been recruited from outside of the United Kingdom, worked as trainee fertility nurses whilst they developed required skills and awaited registration with the Nursing and Midwifery Council.



- There were comprehensive, role-specific induction processes in place and a plan of required training for staff to complete as part of the induction process. Clinical staff told us induction processes included clinical supervision and observation which required them to meet an extensive programme of competencies. Staff were keen to demonstrate their completed record of competencies during our inspection.
- Staff were required to complete training in key areas via an online platform. However, we reviewed training records of 9 staff and found that 3 had not completed training in some of those key areas. There was a lack of clear monitoring processes to ensure leaders had oversight of all training completed.
- We reviewed arrangements within the service to respond to medical emergencies. We found there were appropriate supplies of emergency medicines available to staff in the event of a medical emergency. There was an oxygen supply and a defibrillator available to support the management of medical emergencies, which were subject to regular checks. Staff had completed training in basic life support.
- The provider had in place a public and employer's liability insurance policy.

#### Information to deliver safe care and treatment

#### Staff had the information they needed to deliver safe care and treatment to patients.

- We reviewed clinical records relating to 10 patients who had received treatment within the service.
- The care records we saw showed that information needed to deliver safe care and treatment was available to relevant staff in an accessible way.
- Individual care records were written and managed in a way that kept patients safe. Clear, accurate and contemporaneous patient records were consistently kept. Treatment planning and information were fully documented. The provider utilised a clinical notes template to promote consistency of clinical record keeping.
- Consent processes were comprehensive and consistently applied. There was a documented consent policy. Patient records clearly documented the consent process and discussions between the practitioner and patient.
- The provider had undertaken auditing of clinical records to ensure completeness and consistency.
- The service had effective systems for sharing information with staff and other agencies, for example, the patient's NHS GP, to enable them to deliver safe care and treatment.
- Patients' NHS GP details were routinely recorded. Our review of clinical records confirmed that the service sought patient consent to share information with their GP and did so at all stages of treatment.
- The provider utilised a cloud-based, password protected, electronic system to ensure consistency and security of clinical record keeping. Historical paper-based records were stored securely in locked cupboards.
- The service had a system in place to retain medical records in line with Department of Health and Social Care (DHSC) guidance in the event that they cease trading.

#### Safe and appropriate use of medicines

#### The service had systems for the appropriate and safe handling of medicines.

- There were systems and arrangements for managing the safe handling of medicines and prescribing practices in a way which minimised risks to patients.
- The service undertook infrequent prescribing in relation to services which fell into scope of CQC registration, but ensured that when required, staff prescribed and administered medicines to patients, and gave advice on medicines, in line with legal requirements and current national guidance.
- Medicines requiring refrigeration were stored in a refrigerator which was monitored to ensure it maintained the correct temperature range for safe storage.
- Appropriate processes were in place for the ordering, receipt and monitoring of stock medicines held and staff kept accurate records of those medicines.



• Emergency medicines were readily available and in date and supplies were regularly checked. There were documented records of those checks.

#### Track record on safety and incidents

- There were some monitoring and auditing processes in place to provide assurance to leaders that systems were operating as intended. There were risk assessments in place in relation to safety issues to support the management of health and safety within the premises.
- There was some monitoring and review of activities to support the provider in identifying potential risks within the service. The provider utilised a corrective and preventive action process (CAPA) in order to identify and investigate risks and incidents and implement effective corrective or preventive actions to reduce the risk of recurrence.
- However, managers did not always respond promptly when safety concerns or risks were identified. For example, risks associated with the management of Legionella bacteria had not been addressed following a risk assessment undertaken; equipment servicing findings had not been addressed in a timely manner.

#### Lessons learned and improvements made

#### The service had systems to ensure they learned when things went wrong.

- There was a system for recording and acting on significant events. Staff understood their duty to raise concerns and report incidents and near misses. Leaders and managers supported them when they did so. The newly recruited staff team shared a consistent focus, at all levels, upon continuous improvement.
- There were adequate systems for reviewing and investigating when things went wrong. There was a low threshold for
  incident reporting which promoted a culture of openness and transparency. The service ensured timely and
  appropriate action was taken to make changes where necessary. For example, in response to complaints made, the
  provider had implemented additional staff training and reminders to staff to accurately record details of telephone
  conversations with patients onto their electronic patient records system, to ensure accuracy and consistency of
  information and guidance provided.
- The provider was aware of and complied with the requirements of the Duty of Candour. The provider encouraged a culture of openness and honesty.
- The service had systems in place for knowing about notifiable safety incidents. The service acted on and learned from external safety events as well as patient and medicine safety alerts. The service had an effective mechanism in place to disseminate alerts to all members of the team.



### Are services effective?

#### Effective needs assessment, care and treatment

#### The provider had systems to keep clinicians up to date with current evidence-based practice.

- Clinicians employed by the service had high levels of skills, knowledge and experience to deliver the care and treatment offered by the service. For example, the medical director was a consultant gynaecologist & obstetrician, specialising in reproductive health and surgery. Consultant anaesthetists were employed to deliver intravenous sedation to patients undergoing some procedures. Clinicians kept up to date with current evidence-based practice. We found that clinicians assessed needs and delivered care and treatment in line with relevant current legislation, standards and guidance.
- We reviewed clinical records relating to 10 patients who had received treatment within the service. We found there was a consistent approach to clinical record keeping and risks to the patient were comprehensively assessed, discussed and documented. Clear, accurate and contemporaneous clinical records were kept. Treatment planning and diagnostic information were fully documented.
- The service ensured they provided information to support patients' understanding of their treatment, including preand post-treatment advice and support. We saw that the service provided a series of comprehensive information leaflets for patients.
- In the event of concerns or complications, patients were able to access post treatment support via follow up appointments and also on the telephone. The service provided access to 24-hour telephone support to patients undergoing treatment.
- Staff assessed and managed patients' pain where appropriate. Patients were prescribed local anaesthetic medicines or intravenous sedation prior to some procedures, where appropriate. For example, patients undergoing hysteroscopy.
- We saw no evidence of discrimination when making care and treatment decisions.

#### Monitoring care and treatment

#### The service was able to demonstrate some quality improvement activity.

- The service used information about care and treatment to assess the need to make improvements.
- Staff employed by the service and those working on a sessional basis under practising privileges, were subject to review of their performance within the service. There was a programme of clinical supervision of staff which included monitoring and assessment of defined clinical competencies.
- Staff of all levels participated in a weekly clinical, multi-disciplinary team meeting, in which care and treatment of individual patients was reviewed and discussed in order to promote optimum treatment outcomes and to share learning.
- There was a developing programme of quality improvement activity within the service. For example, the service undertook quarterly auditing of infection prevention and control and clinical record keeping processes. The service employed a quality manager who worked in conjunction with the centre manager, medical director and managing director to promote improvement and implement quality monitoring activities.
- The provider implemented a series of processes and activities which enabled them to identify and monitor incidents, non-conformities and near misses and resulting corrective and preventative actions.
- However, staff told us of significant staff changes which had occurred within the service over the previous 12 months which had impacted upon the continuation of some quality assurance processes. For example, the monitoring and review of some equipment and premises risk assessments.
- The provider was required to implement a comprehensive programme of quality assurance processes in relation to their delivery of fertility services and to meet the requirements of their HFEA licence. These services fell outside of CQC regulation.



### Are services effective?

#### **Effective staffing**

#### Staff had some skills, knowledge and experience to carry out their roles.

- There were comprehensive, generic induction days, followed by role-specific induction processes in place, and a plan of required shadowing and training for staff to complete as part of the induction process. Induction processes for clinical staff included clinical supervision and observation which required them to meet an extensive programme of competencies. We noted that the service had established competency frameworks for individual roles which reflected best practice guidance. For example, the nurse and health care assistant competency framework had been developed with reference to guidance and codes of conduct from HFEA, the Royal College of Nursing (RCN) and the Nursing and Midwifery Council (NMC). We saw evidence of the detailed documentation held to confirm competencies had been achieved.
- The provider had clearly set out the training all staff were required to complete in key areas, via an online platform. For example: vulnerable adult and child safeguarding, infection control, information governance, health and safety, basic life support, confidentiality, and the Mental Capacity Act 2005. However, there was a lack of monitoring processes to ensure leaders had oversight of all training completed and training was not always completed in a timely manner. We reviewed training records of 9 staff and found that 3 had not completed training in many of those key areas.
- The provider demonstrated some understanding of the individual learning needs of staff and provided protected time and training to meet them. For example, nursing staff who had been recruited from outside of the United Kingdom, were supported to develop their skills and to achieve registration with the NMC. However, we found that the lead staff member for infection prevention and control within the service had not completed training at an appropriate level to support their role.
- There was regular review of individual performance of staff employed by the service. Staff underwent one-to-one review meetings with their line manager and annual appraisal. Staff who had completed their probationary period were subject to a probationary review.
- The service held records which confirmed medical professionals were registered with the General Medical Council (GMC) and Nursing and Midwifery Council (NMC) and were up to date with revalidation. The service had recently become a designated body in order to provide appraisal and revalidation support to medical professionals working there. The service had identified an external responsible officer for doctors employed by the service. (A responsible officer evaluates the fitness to practice of doctors with whom the designated body has a prescribed connection and makes a recommendation to the GMC regarding revalidation).

#### Coordinating patient care and information sharing

#### Staff worked well with other organisations, to deliver effective care and treatment.

- Patients who used the service received coordinated and person-centred care. Staff referred to, and communicated effectively with, other services where appropriate. For example, the provider worked closely with an external pathology laboratory to ensure blood testing results were processed in a safe and timely manner.
- Our review of care records confirmed that before providing treatment, doctors at the service ensured they had adequate knowledge of the patient's health, previous medical and medicines history.
- Patient information was shared routinely with patient consent, and the information needed to plan and deliver care and treatment was available to relevant staff in a timely and accessible way.
- All patients were asked for consent to share details of their consultation and treatment, with their GP, when they registered with the service. Clinicians routinely dictated letters to be typed and sent to the patient's GP, following consultation or treatment, where the patient had given their consent.
- There were effective arrangements for supporting patients to access care with other related services. For example, patients were provided with information to promote access to counselling and support networks.



### Are services effective?

#### Supporting patients to live healthier lives

#### Staff empowered patients and supported them to manage their own health and maximise their independence.

- Patients were provided with extensive information about procedures, including the benefits and risks of treatments provided. The service provided access to timely advice and support to patients, including out of hours support.
- In the event that patients presented with concerns or complications post treatment, appropriate support and advice was provided. Staff told us that patients would be promptly reviewed within the service if required.
- Where patients' needs could not be met by the service, staff told us they redirected them to the appropriate service for their needs.

#### Consent to care and treatment

#### The service obtained consent to care and treatment in line with legislation and guidance.

- Staff we spoke with understood the requirements of legislation and guidance when considering consent and decision making. Staff had completed training in the Mental Capacity Act 2005. Staff described processes for the assessment of patients' suitability for treatment which included their psychological well-being, mental capacity and vulnerability. Staff told us they would not agree to treat patients about whom they had any concerns.
- There was a documented consent policy. Consent processes were comprehensive and consistently applied. Patient records we reviewed clearly documented the consent process and discussions between the practitioner and patient.



## Are services caring?

#### Kindness, respect and compassion

#### Staff treated patients with kindness, respect and compassion.

- The service gave patients timely support and information in relation to their care and treatment.
- Staff understood patients' personal, cultural, social and religious needs. They displayed an understanding and non-judgmental attitude to patients.
- The service actively invited feedback on the quality of care patients received via a satisfaction survey sent out to patients following their treatment. Patients were also able to complete the survey whilst at the service, utilising an electronic hand-held device.
- The survey provided patients with the opportunity to provide feedback and make suggestions for improvements to services. The service collated this information in order to identify areas for improvement and feedback which required a direct response to the patient.
- The service's website also included links to encourage patients to provide reviews on Google, Facebook and the HFEA website.

#### Involvement in decisions about care and treatment

#### Staff helped patients to be involved in decisions about care and treatment.

- We saw that the service provided comprehensive information about the service and treatments offered, on their website and within the centre. We noted that information on display within the patient waiting area included for example, the provider's complaints procedure and confidentiality statement.
- The service ensured that patients were provided with all the information they required to make decisions about their treatment prior to treatment commencing. The service provided comprehensive verbal and written pre- and post-treatment advice and support to patients.
- Some information about pricing was available to patients on the service's website and within the service. Patients were provided with individual quotations for their treatment following their first consultation.
- Translation services were available for patients who did not have English as a first language. Staff within the service were able to speak several languages. There was a hearing loop in place and reception staff could support patients in its use.

#### **Privacy and Dignity**

#### The service respected patients' privacy and dignity.

- Staff recognised the importance of people's dignity and respect. Consultations and treatments took place behind closed doors and conversations could not be overheard.
- Patients were collected from the waiting area by the clinician and escorted into the consultation room.
- Chaperones were available should a patient choose to have one. There were signs on display within the service to encourage patients to request a chaperone. Staff who provided chaperoning services had received training to carry out the role.
- Reception staff were aware that if patients wanted to discuss sensitive issues or appeared distressed, they could offer them a private room to discuss their needs.
- Staff complied with the service's information governance arrangements. Processes ensured that all confidential electronic information was stored securely on computers. All patient records and information kept as hard copies was stored in locked cupboards within a locked room. Staff working in the reception area operated a clear desk policy and hard copy documents were promptly locked away.



## Are services responsive to people's needs?

#### Responding to and meeting people's needs

### The service organised and delivered services to meet patients' needs. It took account of patient needs and preferences.

- The provider understood the needs of their patients and arranged services in response to those needs. For example, some Saturday appointments are available to meet the treatment needs of individual patients. Appointments were available to patients at an alternative satellite location in order to promote ease of access to services.
- The facilities and premises were maintained to a high standard and were appropriate for the services and treatments delivered. Services were delivered over 2 floors. Patients with limited mobility were able to access the premises at street level.
- Reasonable adjustments had been made so that people in vulnerable circumstances could access and use services on an equal basis to others. For example, there was a hearing loop and translation support services were available.
- Patients were directed to NHS services if they required treatment for certain conditions and for urgent assistance when the service was closed.

#### Timely access to the service

### Patients were able to access care and treatment from the service within an appropriate timescale for their needs.

- Appointments could be booked in person or by telephone. Patients usually had appointments within a short time from their request. Weekend appointments were available to accommodate required treatment scheduling.
- Waiting times, delays and cancellations were minimal and managed appropriately.
- Referrals to other services were undertaken in a timely way and were managed appropriately. For example, where patients required ongoing referral to secondary care services.

#### Listening and learning from concerns and complaints

### The service took complaints and concerns seriously and responded to them appropriately to improve the quality of care.

- Information about how to make a complaint or raise concerns was available within the service. There was a patient charter and information about how to make a complaint on the provider's website.
- Staff treated patients who made complaints compassionately.
- The service was able to demonstrate how appropriate and timely actions were taken in response to a complaint. However, our review was limited, as complaints received related mainly to services and treatments which fell outside of CQC regulation.
- There was evidence that complaints had been discussed and the learning shared across the organisation. Complaints were discussed at regular team and operational meetings.
- However, there was a lack of arrangements in place to signpost patients who may not be satisfied with the response to
  a complaint. The service's written complaints policy did not include clear information to support patients should their
  complaint remain unresolved.



#### Leadership capacity and capability:

#### Leaders had demonstrated some capacity and skills to deliver high-quality, sustainable care.

- Leaders demonstrated the capacity to implement systems and processes to support the delivery of high-quality care. Leaders had awareness and understanding of the issues and priorities relating to the quality and future of the service.
- Leaders within the service were visible and approachable. They worked closely with the team of staff and others and told us they prioritised compassionate and inclusive leadership.
- There was a staffing structure in place across the service and staff were aware of their individual roles and responsibilities. The provider had identified individual members of staff to assume lead roles in key areas. For example, centre management, quality management, safeguarding and infection prevention and control.
- There were formal and informal lines of communication between staff working within the service. Staff spoke of team meetings they attended, and we saw records of those meetings.

#### Vision and strategy

- The provider had a vision and desire to provide a high-quality service that put caring at its heart, and which promoted good outcomes for patients.
- Staff we spoke with were consistent in their awareness and understanding of the vision, values and strategy of the service and their role in achieving them. Staff felt motivated to contribute to driving improvement within the service.

#### **Culture**

#### There were some systems and processes to support a culture of high-quality sustainable care.

- Leaders and managers encouraged behaviour and performance consistent with the vision and values.
- The service was focused upon the needs of patients and ensuring the best possible outcomes.
- The service had experienced significant staff turnover within the previous 12 months and leaders were focused upon stabilising and developing the newly recruited staff team.
- We noted that at the time of our inspection the provider continued to recruit to only a small number of roles.
- Staff we spoke with told us they felt respected, supported and valued. Staff at all levels were fully engaged in ensuring the promotion of optimum outcomes for patients.
- Staff were recognised for their achievements. We noted the provider had introduced a monthly staff recognition award.
- Staff told us they could raise concerns and suggestions for improvement and were encouraged to do so.
- The provider was aware of and had systems to ensure compliance with the requirements of the duty of candour.
- There were some processes for providing staff with the development they needed. Staff employed by the service had received regular review of their performance in the form of one-to-one review, assessment of competencies and annual appraisal. There were clear opportunities for staff to progress within the organisation. However, some staff had not completed required training in key areas. There was a lack of clear monitoring processes to ensure leaders had oversight of all training completed.
- Clinical staff were supported to meet the requirements of professional revalidation where necessary. The service had recently become a designated body in order to provide appraisal and revalidation support to medical professionals working there. Nurses recruited from outside of the United Kingdom had been supported to develop their skills and achieve NMC registration.
- There was a strong emphasis on the well-being of all staff. We saw records which confirmed all staff had participated in one-to-one review meetings with their line manager. Newly recruited staff had undergone a probationary review and been formally confirmed in post.



- The service actively promoted equality and diversity. Staff had received equality and diversity training. Staff felt they were treated equally.
- There was a culture of promoting positive relationships and prompt and effective communications between staff. Staff team meetings were held regularly. For example, staff participated in a weekly clinical, multi-disciplinary team meeting, in which care and treatment of individual patients was reviewed and discussed in order to promote optimum treatment outcomes and to share learning.
- Organisational communications were shared effectively across the team. The provider had developed a staff newsletter to promote information sharing across the team and other sites.
- The provider implemented an online platform in which they stored for example, organisational policies, records of meetings, clinical protocols and staff newsletters. The software package provided a secure place to store, organise, share, and access information from any device.

#### **Governance arrangements**

### Responsibilities, roles and systems of accountability to support good governance and management were not always effective.

- Structures, processes and systems to support good governance and management were clearly set out and understood for some areas of the service.
- Leaders held regular update meetings to discuss and review the service.
- There was an effective staff meeting structure and systems for cascading information within the organisation.
- The provider had appointed a quality manager who worked alongside the centre manager to implement governance processes and policy development.
- There were mainly appropriate policies, procedures and activities to ensure the safety of staff and patients. However, there were some instances where processes were not operating as intended and did not ensure safe care and treatment. For example, there was a lack of records to demonstrate that recruitment checks had been carried out in accordance with regulations for some staff; some staff had not completed training in key areas; the monitoring and storage of staff documentation was not well managed and did not ensure leaders had clear oversight of their ongoing status
- Some policies and procedures, for example, with regard to infection prevention and control processes, did not reflect
  best practice guidance. The provider's staff screening policy dated July 2021 did not reflect current guidance in relation
  to staff immunisation requirements. The provider's ultrasound use policy did not provide sufficient guidance to staff to
  ensure decontamination and tracking of intracavity ultrasound probes were carried out in line with best practice
  guidance.
- The provider utilised a corrective and preventive action process (CAPA) in order to identify and investigate risks and
  incidents within the service. However, some identified risks were not always included in action planning or followed up
  in a timely manner. For example, risks associated with the management of Legionella bacteria had not been addressed
  following a risk assessment undertaken in November 2021; equipment servicing findings had not been addressed in a
  timely manner.
- There were some monitoring and auditing processes in place. However, these had not always identified when systems were not operating as intended or in line with current guidance. For example, infection prevention and control audits had not identified risks and shortfalls associated with Legionella management, staff immunisation requirements or the decontamination of ultrasound probes.
- Staff clearly understood their individual roles and responsibilities and were well supported by the centre manager and other leaders in fulfilling those roles. Appropriate role-specific guidance was provided for staff. For example, there were comprehensive induction processes and competency frameworks for each role. However, we noted that the lead for infection prevention and control within the service had not undergone appropriate training to support the role.



- There were arrangements in line with data security standards for the availability, integrity and confidentiality of patient identifiable data, records and data management systems.
- The service submitted data or notifications to external organisations as required.

#### Managing risks, issues and performance

#### There were some processes for managing risks, issues and performance.

- There were some governance processes to ensure leaders were able to identify, understand, monitor and address current and future risks including risks to patient safety.
- There was clear evidence of a commitment to change services to improve quality where necessary. Immediately following our inspection, and in response to initial feedback of our findings, the provider took prompt action to begin to address some findings. For example, with regard to decontamination of ultrasound probes.
- Leaders had oversight of safety alerts, incidents, and complaints. There was a system for recording and acting upon significant events. Staff understood their duty to raise concerns and report incidents and near misses. Leaders and managers supported them when they did so.
- Auditing of patient records was undertaken to review compliance with the provider's expected standards of clinical record keeping.
- Staff told us they regularly attended staff meetings. We saw documented evidence of staff meetings, where for example, updates, incidents and complaints had been discussed and outcomes from the meetings cascaded to staff.
- The provider had business continuity processes in place. We noted that the service had an emergency power generator on site.

#### **Appropriate and accurate information**

#### There was a lack of appropriate and accurate information available in some areas.

- Quality and operational information was used to monitor performance and drive improvement.
- The service used feedback from patients combined with performance information, to drive improvement.
- There was a lack of records to demonstrate that recruitment checks had been carried out in accordance with regulations for some staff. Staff immunisations were not monitored in line with current guidance.
- The monitoring and storage of staff documentation was not well managed and did not ensure leaders had clear oversight of their ongoing status.
- Individual care records were written and managed in a way that kept patients safe. The care records we saw showed that information needed to deliver safe care and treatment was available to relevant staff in an accessible way. Clear, accurate and contemporaneous patient records were kept. Treatment planning and treatment records were fully documented.
- Staff told us they had attended regular staff meetings. We saw documented evidence of staff meetings, where for example, updates, patient feedback and complaints had been discussed, and outcomes and learning from the meetings cascaded to staff.
- There were arrangements in line with data security standards for the availability, integrity and confidentiality of patient identifiable data, records and data management systems. Processes ensured that all confidential electronic information was stored securely on computers. All patient information kept as hard copies was stored in locked cupboards within a locked room. Staff demonstrated a good understanding of information governance processes.
- The provider ensured document management protocols were followed, which included version control, author and review dates.

#### Engagement with patients, the public, staff and external partners



#### The service involved patients, staff and external partners to support sustainable services.

- The service encouraged and valued feedback from patients, the public and staff. Feedback was closely monitored and acted upon to shape services.
- Staff could describe to us the systems in place for them to give feedback.
- The service was transparent and open with stakeholders about the feedback received.

#### **Continuous improvement and innovation**

- There was evidence of improvements made to the service as a result of feedback received. For example, staff spoke of a focus upon improvements to communication amongst the staff team and with patients.
- Leaders and managers encouraged staff to review individual and team objectives, processes and performance.
- There was some evidence of quality improvement activity and ongoing review of quality improvement processes.
- The service had achieved International Organisation for Standardisation (ISO) 9001 accreditation for quality management. (ISO supports the development of standards to ensure the quality, safety and efficiency of products, services and systems.)

## 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 Surgical procedures Treatment of disease, disorder or injury	Regulation 12 HSCA (RA) Regulations 2014 Safe care and treatment
	The provider had not done all that was reasonably practicable to ensure care and treatment was provided in a safe way for service users.
	In particular:
	<ul> <li>To ensure staff have access to policy guidance and training in the safeguarding of children.</li> <li>To ensure cleaning and disinfection of intracavity ultrasound probes in line with best practice guidance.</li> <li>To ensure tracking in relation to decontamination of transvaginal ultrasound probes per individual patient, to ensure an audit trail of decontamination for each intracavity examination.</li> <li>To implement monitoring of hand hygiene techniques to ensure staff follow recommended guidelines.</li> <li>To ensure action is taken to address and manage identified risks associated with Legionella bacteria.</li> <li>To ensure required recruitment checks are carried out for all staff.</li> <li>To ensure the monitoring of staff immunisations in line with current guidance.</li> </ul>
	This was in breach of regulation 12(1)(2) of the Health and

Regulated activity	Regulation
Diagnostic and screening procedures  Surgical procedures  Treatment of disease, disorder or injury	Regulation 17 HSCA (RA) Regulations 2014 Good governance  The provider was unable to demonstrate that systems and processes were in place to assess, monitor and mitigate the risks relating to the health, safety and welfare of service users and others who may be at risk which arise from the carrying on of the regulated activity.

2014.

Social Care Act 2008 (Regulated Activities) Regulations

### Requirement notices

The provider was unable to demonstrate that systems and processes were implemented effectively to assess, monitor and improve the quality and safety of the services provided in the carrying on of the regulated activities.

#### In particular:

- To adequately assess, monitor and respond to identified risks to ensure premises and equipment are safe and suitable for use.
- To adequately identify, assess and monitor infection prevention and control risks within the service.
- To ensure policies and procedures provide sufficient guidance to staff and reflect current best practice guidance.
- To implement effective monitoring and storage of staff documentation in relation to staff recruitment, immunisation and training, to ensure leaders had clear oversight of their ongoing status and associated risks.

This was in breach of regulation 17(1)(2) of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014.

### Regulated activity

Diagnostic and screening procedures

Surgical procedures

Treatment of disease, disorder or injury

### Regulation

Regulation 18 HSCA (RA) Regulations 2014 Staffing

The provider had failed to ensure that persons employed in the provision of a regulated activity received such appropriate support, training, and professional development, as was necessary to enable them to carry out the duties they were employed to perform.

#### In particular:

- To ensure monitoring of training undertaken by staff employed within the service.
- To ensure staff complete training in all required areas in a timely manner.
- To provide training for staff who lead infection prevention and control processes within the service, at an appropriate level to support their role.
- To ensure that all staff who use ultrasound probes are appropriately trained and consistent in their approach to decontamination processes.

This section is primarily information for the provider

## Requirement notices

This was in breach of regulation 18(1)(2) of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014.