134 Harley Street

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?	**Not sufficient evidence to rate**
Are services caring?	**Not sufficient evidence to rate**
Are services responsive?	**Good**
Are services well-led?	**Good**

Overall summary

134 Harley Street is operated by Harley Street Fertility Clinic. The service has no overnight beds. Facilities include one operating theatre, outpatient and diagnostic facilities. The service provides surgical procedures.

We inspected surgery.

We inspected this service using our comprehensive inspection methodology.

We carried out an unannounced inspection on 2 October 2019.

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.

Summary of findings

Our rating of this hospital/service stayed the same. We rated it as **Good** overall because:

- The service had enough staff to care for patients and keep them safe. Staff had training in key skills. Staff assessed risks to patients, acted on them and kept good care records. The service managed safety incidents well and learned lessons from them. Staff collected safety information and used it to improve the service.
- Staff provided good care and treatment, gave patients enough to eat and drink, and gave them pain relief when they needed it. Managers monitored the effectiveness of the service and made sure staff were competent. Staff worked well together for the benefit of patients, advised them on how to lead healthier lives, supported them to make decisions about their care, and gave them access to good information. Key services were available six days a week.
- Staff treated patients with compassion and kindness, respected their privacy and dignity, took account of their individual needs, and helped them understand their conditions. They provided emotional support to patients, families and carers.
- The service planned care to meet the needs of local people, took account of patients' individual needs, and made it easy for people to give feedback. People could access the service when they needed it and did not have to wait too long for treatment.
- Leaders ran services well using reliable information systems and supported staff to develop their skills. Staff understood the service's vision and values, and how to apply them in their work. Staff felt respected, supported and valued. They were focused on the needs of patients receiving care. Staff were clear about their roles and accountabilities. The service engaged well with patients to plan and manage services and all staff were committed to continuously improving services.

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

- The safeguarding policy did not reflect most recent national best practice guidance. This was action we had previously told the provider to take on our last inspection.
- The service could not be assured that staff always controlled infection risk well. Staff used equipment and control measures to protect patients, themselves and others from infection, but these were not always consistently used or reliable. Not all staff at the service were bare below the elbow, and leaders had not completed the action plan from the most recent infection prevention and control audit.
- We found one instance where the disposal of a controlled drug was not recorded correctly.

Following this inspection, we told the provider that it should make improvements, even though a regulation had not been breached, to help the service improve. Details are at the end of the report.

Nigel Acheson

Summary of findings

Deputy Chief Inspector of Hospitals (South & London)

Summary of findings

Our judgements about each of the main services

Service	Rating	Summary of each main service
Surgery	Good 	We found good practice in the safe, responsive and well led domains. We did not rate effective or caring due to the small size of the service, which meant there was insufficient information to make a judgment.

Summary of findings

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Good

134 Harley Street

Services we looked at
Surgery

Summary of this inspection

Background to 134 Harley Street

134 Harley Street is operated by Harley Street Fertility Clinic. Harley Street Fertility Clinic is a private, specialist-led fertility clinic in Central London. 134 Harley Street undertakes diagnostic tests, including ultrasounds and blood tests as well as fertility treatments and hysteroscopy.

The hysteroscopy service is the only service which is subject to regulation by the Care Quality Commission (CQC). The service is also licensed by the Human Fertilisation and Embryology Authority (HFEA).

134 Harley Street opened in 2014. It is a private clinic in central London. The clinic primarily serves the communities of the London and surrounding areas. It also accepts patient referrals from outside this area.

The clinic has had a registered manager in post since 2014.

Our inspection team

The team that inspected the service comprised a CQC lead inspector, and a specialist advisor with expertise in surgery and theatres.The inspection team was overseen by Nicola Wise, Head of Hospital Inspection.

Information about 134 Harley Street

The clinic has is registered to provide the following regulated activity:

• Surgical procedures

Our inspection was unannounced, to allow us to observe routine activity. During the inspection, we visited the recovery area, theatre and one consulting room. We spoke with six members of staff including; registered nurses, a consultant, a health care assistant, the director and the general manager. We spoke with two patients who were attending the clinic for appointments (but were not receiving a hysteroscopy at the time of the inspection), and one other patient over the telephone.

During our inspection, we reviewed four sets of patient records, and other documentation provided to us.

There were no special reviews or investigations of the clinic on going by the CQC at any time during the 12 months before this inspection. The service was previously inspected on 21 December 2016.

Activity (July 2018 to June 2019)

- In the reporting period July 2018 to June 2019, there were 38 day case episodes of hysteroscopy recorded at the clinic; of these 0% were NHS-funded and 100% funded by other means.
- Two surgeons and eight anaesthetists worked at the clinic in relation to hysteroscopy surgical procedures under practising privileges. 134 Harley Street employed five registered nurses, three healthcare assistants and two receptionists, as well as having its own bank staff of anaesthetists. The accountable officer for controlled drugs (CDs) was the Nominated Individual.

Track record on safety

- No Never events
- No Clinical incidents relating to surgery.
- No incidences of hospital acquired meticillin-sensitive Staphylococcus Aureus (MSSA)
- No incidences of hospital acquired Clostridium difficile (c.diff)
- No incidences of hospital acquired E-Coli
- No complaints relating to surgical procedures

Summary of this inspection

Services accredited by a national body:

- Licensed and regulated by the Human Fertilisation and Embryology Authority (HEFA)

Services provided at the hospital under service level agreement:

- Clinical and or non-clinical waste removal
- Translation services
- Laundry
- Maintenance of medical equipment
- Pathology and histology
- Decontamination of hysteroscopes

The five key questions about service

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?

Good

Our rating of safe stayed the same. We rated it as **Good** because:

- The service delegated the provision mandatory training in key skills to all staff to an external company and made sure everyone completed it.
- The design, maintenance and use of facilities, premises and equipment kept people safe. Staff were trained to use them. Staff managed clinical waste well.
- Staff completed and updated risk assessments for each patient and removed or minimised risks. Staff identified and quickly acted upon patients at risk of deterioration.
- The service had enough nursing and support staff with the right qualifications, skills, training and experience to keep patients safe from avoidable harm and to provide the right care and treatment. Managers regularly reviewed and adjusted staffing levels and skill mix, and gave bank and agency staff a full induction.
- The service had mostly reliable systems and processes to safely prescribe, administer and store medicines, although we found one instance where controlled drugs were not recorded correctly.
- Staff kept detailed records of patients' care and treatment. Records were clear, up-to-date, stored securely and easily available to all staff providing care.
- The service managed patient safety incidents well. Staff were trained to recognise and report incidents and near misses. Managers investigated incidents and shared lessons learned with the whole team and the wider service.

However:

- The safeguarding policy did not reflect most recent national best practice guidance. This was action we had previously told the provider to take on our last inspection.
- The service could not be assured that staff always controlled infection risk well. Staff used equipment and control measures to protect patients, themselves and others from infection, but these were not always consistently used or reliable. Not all staff at the service were bare below the elbow, and leaders had not completed the action plan from the most recent infection prevention and control audit.
- We found one instance where the disposal of a controlled drug was not recorded correctly.

Summary of this inspection

Are services effective?

Not sufficient evidence to rate

We did not have sufficient evidence to rate effective. However, we found the following:

- The service provided care and treatment based on national guidance and evidence-based practice. Managers checked to make sure staff followed guidance.
- Staff assessed patients' food and drink requirements to meet their needs during their time at the clinic for a day case procedure. The service made adjustments for patients' religious, cultural and other needs.
- Staff assessed and monitored patients regularly to see if they were in pain and gave pain relief in a timely way.
- Staff monitored the effectiveness of care and treatment. They used the findings to make improvements and achieved good outcomes for patients.
- The service made sure staff were competent for their roles. Managers appraised staff's work performance and held supervision meetings with them to provide support and development.
- Nurses and other healthcare professionals worked together as a team to benefit patients. They supported each other to provide good care.
- Key services were available six days a week, with extended hours, to support timely patient care.
- Staff gave patients practical support and advice to enhance their health and wellbeing, before, during and after surgical procedures.
- Staff supported patients to make informed decisions about their care and treatment. They followed national guidance to gain patients' consent.

Are services caring?

Not sufficient evidence to rate

We did not have sufficient evidence to rate caring. However, we found the following:

- Staff treated patients with compassion and kindness, respected their privacy and dignity, and took account of their individual needs.
- Staff provided emotional support to patients, families and carers to minimise their distress. They understood patients' personal, cultural and religious needs.
- Staff supported and involved patients, families and carers to understand their condition and make decisions about their care and treatment.

Summary of this inspection

Are services responsive?

Good

Our rating of responsive stayed the same.We rated it as **Good** because:

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

Are services well-led?

Good

Our rating of well-led stayed the same.We rated it as **Good** because:

- Leaders had the integrity, skills and abilities to run the service. They understood and managed the priorities and issues the service faced. They were visible and approachable in the service for patients and staff.
- The service had a vision for what it wanted to achieve and a strategy to turn it into action.
- Staff felt respected, supported and valued. They were focused on the needs of patients receiving care.
- Leaders operated mostly effective governance processes, throughout the service and with partner organisations. Staff at all levels were clear about their roles and accountabilities and had opportunities to meet, discuss and learn from the performance of the service.

However:

- Governance meetings were infrequent.
- Leaders did not always take timely action to address areas for improvement. For example, the safeguarding policy did not reflect most recent national best practice guidance. This was action we had previously told the provider to take on our last inspection.

Detailed findings from this inspection

Overview of ratings

Our ratings for this location are:

	Safe	Effective	Caring	Responsive	Well-led	Overall
Surgery	Good	Not rated	Not rated	Good	Good	Good
Overall	Good	Not rated	Not rated	Good	Good	Good

Good

Surgery

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

Are surgery services safe?

Good

Our rating of safe stayed the same.We rated it as **good.**

Mandatory training

- **The service delegated the provision mandatory training in key skills to all staff to an external company and made sure everyone completed it.**
- The service held mandatory training days once per year, where the service was closed in order to ensure all staff were available. Subjects staff were expected to complete included for example; health and safety awareness, COSHH, equality and diversity, Infection prevention and control, safeguarding, mental capacity act (MCA) and deprivation of liberty safeguards (DoLS) and manual handling.
- The external company provided a mandatory training handbook which staff could refer to upon completion of their mandatory training.
- All clinical staff were certified in intermediate life support.
- The service provided us with records to show that 100% of clinical staff were compliant with their mandatory training.
- Consultants completed their mandatory training at the NHS establishment they routinely worked at. They were required to provide evidence of completion of mandatory training. The service provided information which demonstrated those consultants had completed up to date mandatory training.
-

Safeguarding

- **Staff has received training how to protect patients from abuse, and the clinic had policies outlining how they would work with other agencies to do so if necessary. However, this policy did not reflect most recent national best practice guidance.**
- On our last inspection we found the clinic had a safeguarding policy entitled 'Safeguarding Children and Adults Policy' dated 24 May 2013, and staff we spoke with were aware of its contents. However, the safeguarding policy was not updated to reflect the intercollegiate document from 2014. As a result, the latest guidance was not included, particularly with respect to female genital mutilations, Prevent, child exploitation situations, domestic violence and abuse. Since our last inspection, a further intercollegiate document was issued in 2018. On this inspection, we viewed the 'Safeguarding Children and Adults Policy', which was still dated as issued on 24 May 2013. The policy also did not contain any reference to female genital mutilation, Prevent, child exploitation situations, domestic violence and abuse. We asked the general manager about the date on the policy, who told us the policy had been updated, but dates on which policies were updated were kept on a separate log. The general manager told us policies were reviewed annually. We viewed a copy of this log which showed the safeguarding policy had been reviewed in August 2019 by the general manager and registered manager. However, the policy still did not reflect the most up to date guidance.
- Despite this, safeguarding was part of the annual mandatory training bundle, which all staff were compliant and up to date with.
- Staff could escalate any concerns about patients being at risk from abuse or neglect by speaking to the nurse in

charge or general manager. In turn, the nurse in charge or General manager would report to the registered manager, who would then escalate any concerns to the local safeguarding manager of the Local Safeguarding Children Board.

Cleanliness, infection control and hygiene

- **The service could not be assured that staff always controlled infection risk well. Staff used equipment and control measures to protect patients, themselves and others from infection, but these were not always consistently used or reliable. For example, not all staff at the service were bare below the elbow and leaders had not completed the action plan from the most recent infection prevention and control audit. However, staff kept equipment and the premises visibly clean.**
- The provider had an Infection Prevention and Control (IPC) policy, which included guidance on hand washing, management of personal protection equipment, management of needle stick injuries, management of airborne viruses and decontamination. Staff were able to access the policy.
- The hysteroscopes used within the service were decontaminated off site at an external organisation. On our previous inspection, we viewed the service level agreement between the clinic and the organisation that provided decontamination services and found this to be robust. On this inspection, we found this good practice remained the same.
- The recovery area and consultation rooms were visibly clean and well maintained. The clinic delegated responsibility for cleaning to a contractor, who visited the clinic six days a week, in the evenings to minimise disruption to clinic activity. The contractor completed a cleaning checklist, which was submitted to the clinic. We viewed this checklist and saw it was fully completed for the previous two months, signed and dated. The general manager also monitored cleaning standards by doing spot checks. They told us they would speak directly to the cleaner if there was a problem. Cleaning staff had received training and were supplied with nationally recognised colour-coded cleaning equipment. This enabled them to follow best practice with respect to minimising cross-contamination.
- The clinic arranged for an annual deep clean, carried out by an external company. The clinic provided us with evidence to show the most recent deep clean had taken place on 15 December 2018.
- We saw personal protective equipment such as aprons was readily available to all staff. Equipment such as disposable gloves were available to protect staff from exposure to potential infections whilst examining or providing treatment for patients.
- Staff screened patients for MRSA when they attended a pre-admission clinic. As part of the hysteroscopy pathway, staff also screened patients for human immunodeficiency virus (HIV), hepatitis B, hepatitis C, chlamydia, gonorrhoea and any risk of Ebola virus.
- The service provided was very small in terms of the numbers of patients seen and surgical procedures completed. No surgical site infections were recorded or monitored, as there were no systems in place to do so. The only way the clinic would know if a surgical site infection occurred, was if the patient informed them. However, there were clean and dirty zones in the treatment area and all work surfaces were clutter free, which was good practice to help to limit cross-infection. As there were no patients receiving care during our inspection we were not able to observe clinical practice related to the procedure.
- Equipment and materials were stored away in closed cupboards. There were disposable curtains in the recovery area which had been changed within the previous three months and had dates listed for when they should be changed in the future. The examination tables and recovery beds/chairs were provided with disposable paper covers.
- Clinical waste was disposed of correctly, in clinical waste bags and stored safely in a locked cupboard until collected by a specialist waste company, who collected on a weekly basis.
- Staff disposed of sharps, such as needles and glass ampoules safely. We viewed two sharps bins in theatre and recovery area and saw they were not overfilled, were signed and dated when brought in to use, and had a disposal date listed. This was an improvement upon our previous inspection, where we noted there was no disposal date listed on the sharps bin in theatre.
- The lead nurse carried out an annual infection control audit covering the clinic environment, waste disposal, handling of sharps, care of equipment, hand hygiene, clinical practises and documentation. The most recent

audit was carried out in June 2019, and the score was 84%, just above the pass mark of 80%. The lead nurse had drawn up an action plan as a result of the audit, including the corrective or preventative action to be taken, and the date to complete which was 31 July 2019. However, the action plan had not been filled in to show whether the actions had been completed or not. This meant the service could not be assured that corrective action had been taken to address these issues.

- Three of the five nursing and healthcare assistant staff we observed were not bare below the elbow in line with the clinic's infection control policy, by wearing wristwatches. It is important that staff are bare below the elbow, as items such as wristwatches can obstruct thorough handwashing which is vital to prevent the spread of infections. We raised this with the lead nurse, who was also the infection control lead, who told us they would speak to staff and remind them of the policy. We also noted that staff had been wearing wristwatches during the infection control audit carried out in June 2019, a copy of which the provider had submitted to us through the pre inspection information request. This meant the service did not have reliable systems to ensure all staff complied with the clinic policy and best practice infection prevention and control guidelines.

Environment and equipment

- **The design, maintenance and use of facilities, premises and equipment kept people safe. Staff were trained to use them. Staff managed clinical waste well.**

- The environment in which patients received their consultations, treatment and surgical procedures were suitably arranged to ensure their safety. There were separate consultation rooms, a designated minor procedure theatre with an adjacent preparation/ recovery room. Separate areas were provided for storage of equipment and administrative purposes.
- Resuscitation equipment was accessible in the recovery area. The resuscitation trolley was sealed with a tag. Staff checked the contents of the resus trolley once a month and whenever the seal was broken. We viewed these monthly checklists for the four months prior to our inspections and saw these were fully completed, signed and dated. Staff checked items placed on top of the resus trolley daily, such as the defibrillator and anaphylaxis kit, and we saw records which confirmed this.
- The theatre had piped oxygen available via flow meters to support patients who had difficulty breathing.
- Staff carried out daily checks of theatre equipment, including anaesthetic machine, anaesthetic equipment and patient monitors. We saw these checks were fully completed and records were signed and dated to demonstrate this. The clinic had service level agreements for equipment servicing. Staff told us if they ever had an issue with equipment, they could access engineers easily and quickly.
- On our last inspection, we saw within the theatre was a white board fixed to the wall and it was used to record the needles, swabs and other equipment used for each operation. This was done to confirm everything was accounted for at the end of the procedure and formed part of the safety checks. On this inspection, we saw this good practice remained the same.

Assessing and responding to patient risk

- **Staff completed and updated risk assessments for each patient and removed or minimised risks. Staff identified and quickly acted upon patients at risk of deterioration.**
- On our last inspection, we found the surgical pathway checklist used by the service was not based on the World Health Organisation (WHO) guidance and told the service they should review this. On this inspection, we saw this had been reviewed and had brought the checklist in line with the WHO five steps for safer surgery. We reviewed the documentation used and noted the use of the sign in and time out. There was a section named 'doctor's procedure notes' where the surgeon was required to record the name of the procedure, a description, further instructions and theatre pack used. Therefore, we were assured that the service had brought the pathway checklist in to line with the WHO guidance.
- We saw evidence within the patient notes review of risk assessments relevant to the patient's needs having been carried out. Staff carried out these risk assessments were in the three months prior to the patient undergoing the hysteroscopy procedure, and the pre-assessment was also confirmed for accuracy on the day of the procedure. All patients undergoing

hysteroscopy procedures were risk assessed for Venous Thromboembolism (VTE). VTE is a collective term for deep vein thrombosis, a blood clot that forms in the veins. Of the four records we reviewed, all patients had received a VTE risk assessment.

- The general manager told us that the main risk they encountered for patients was obesity. Staff recorded the weight in kilograms for all patients. The anaesthetist conducted an additional review on all patients with a body mass index (BMI) of 35 or over and did not carry out procedures on patients with a BMI of 40 or over.
- Surgical procedures carried out on-site were performed under local anaesthetic or conscious sedation. The anaesthetist was required to remain with the patient until the patient was awake and orientated after each procedure where conscious sedation was used. Conscious sedation is defined as 'a technique in which the use of a drug or drugs produces a state of depression of the central nervous system enabling treatment to be carried out, but during which verbal contact with the patient is maintained throughout the period of sedation. The drugs and techniques used should carry a margin of safety wide enough to render loss of consciousness unlikely'.
- The clinic did not provide high dependency, intensive or overnight care. In an emergency situation or if a patient deteriorated, the standard 999 system was used to facilitate the transfer of the patient to an NHS hospital. Staff would be alerted to a patient deteriorating if the patient's vital signs such as blood pressure, respiratory rate, heart rate and temperature showed signs of decline.
- The clinic used a modified early warning score (EWS) to assess and monitor their patients. EWS is a guide used by hospital services to quickly determine the degree of illness in a patient. Pain scores, blood pressure, pulse, respiration rate and levels of consciousness were recorded as part of this. In the four patient records we viewed, we saw staff monitored patients at regular intervals findings were recorded.
- We were told there had been no unplanned transfers to other hospitals or unplanned returned to theatre in the past year.
- Before treatment, the anaesthetist and consultant assessed patients for their general fitness to proceed. This assessment included obtaining a medical and obstetric history and measurements of vital signs, including blood pressure, pulse, and temperature.
- After treatment, staff confirmed that patients were alert and orientated, had something to eat and drink, had passed urine and had a friend or family member to escort them home. Anaesthetists remained at the clinic until they could confidently confirm the patient was safe to be discharged home.
- The clinic provided patients with an information leaflet on the hysteroscopy service, prior to the procedure. This gave patients clear instructions on any symptoms to look out for during their recovery which may suggest a complication of surgery, for example, a high temperature.

Nursing and support staffing

- **The service had enough nursing and support staff with the right qualifications, skills, training and experience to keep patients safe from avoidable harm and to provide the right care and treatment. Managers regularly reviewed and adjusted staffing levels and skill mix, and gave bank and agency staff a full induction.**
- The clinic employed three full time equivalent nurses and two healthcare assistants. Since our last inspection, the service had also employed one and a half full time equivalent pharmacists.
- There were no staff vacancies at the time of our inspection.
- In the event of sickness, or short-notice absence, the clinic could seek support from agency staff or from within the staffing establishment, by asking staff if they were able to cover shifts.
- Managers reviewed nursing and support staffing arrangements and planned in advance to ensure there were enough staff to care for patients. We observed a clinical staff team meeting and saw that leaders arranged rotas in advance to ensure there was sufficient staffing for holiday periods.
- There was a comprehensive induction policy for new starters or bank and agency staff. This outlined each stage in the induction process, and who was responsible for the individual's progress at each stage. In the case of agency, bank and locum staff, the process was amended to take account of the time they would be spending with the organisation but ensured they had received training and completed induction checklists.

Medical staffing

- **The service had enough medical staff with the right qualifications, skills, training and experience to keep patients safe from avoidable harm and to provide the right care and treatment. Managers regularly reviewed and adjusted staffing levels and skill mix and gave locum staff a full induction.**
- The registered manager led the service. There were two gynaecology consultants working on the hysteroscopy service and there was a bank of eight anaesthetists, who had practising privileges to work at the clinic. Practising privileges is a term used when doctors have been granted the right to practise in an independent hospital, having satisfactorily provided evidence of the fitness to practice, along with other essential information.
- The registered manager had a system in place whereby fitness to practise was regularly monitored. For example, if a consultant surgeon or anaesthetist appraisal was due, the registered manager would flag this up with the consultant and remind them to provide evidence. On our previous inspection, we viewed personnel files for medical staff which contained evidence of fitness to practise, appraisals, safety training undertaken at their substantive NHS hospital, General Medical Council registration, and professional indemnity cover. We did not view personnel files on this inspection, but we did view records which showed all consultant surgeons and anaesthetists working on the hysteroscopy service at the clinic had their registration validated.
- The surgeons and anaesthetists provided availability by telephone during evenings and weekends, in cases of emergency.
- The induction policy outlined above under nursing and support staffing also applied to bank, locum or agency medical staff.

Records

- **Staff kept detailed records of patients' care and treatment. Records were clear, up-to-date, stored securely and easily available to all staff providing care.**
- We looked at four sets of patient notes relating to patients receiving hysteroscopy at 134 Harley Street. The notes were legible, signed and dated, and fully complete.
- The care plans for the four records we looked at were complete and included risk assessments such as venous thromboembolism (VTE), allergies, and patient vital signs after procedures, medication prescribed and given and discharge information.
- Paper files were stored securely in locked cupboards in the staff office, which meant they could not be accessed by unauthorised persons.

Medicines

- **The service had mostly reliable systems and processes to safely prescribe, administer and store medicines, although we found one instance where controlled drugs were not recorded correctly.**
- Medication was prescribed by consultants. Records of patient's allergies and drugs prescribed were contained within the patient's care pathway documentation.
- The service had a medicines management policy which outlined all aspects of medicines management within the clinic, such as storage, responsibilities of key staff, prescribing and administration. The policy was based upon national guidance and best practice, referencing standards from national bodies such as the Royal Pharmaceutical Society of Great Britain.
- Since our last inspection, the clinic had employed one and a half whole time equivalent pharmacists. The pharmacists were responsible for rotating stock and ensuring all medicines that had reached their expiry date were disposed of safely. The pharmacist recorded weekly any drugs that were due to expire and the batch number and noted when the medicines were disposed of. Pharmacists conducted a monthly full stock check, including medicines in theatres. This meant staff could be assured that medicines were in date and optimum for patient treatment.
- Pharmacists conducted medicines audits. Controlled drugs audits were submitted to the Local Intelligence Network, an NHS England initiative to share information and intelligence about the misuse and unsafe use of controlled drugs.
- Medication, including controlled drugs, was stored securely in locked cupboards and the keys were held by the nurse in charge.
- However, upon viewing the controlled drugs register in theatre, we found one instance where staff had not dated a controlled drugs entry, and the 'discarded' box had not been signed by the anaesthetist, although it

had been signed by a witness. This meant staff could not be assured that the controlled drug had been disposed of safely in line with controlled drugs regulations.

Incidents

- **The service managed patient safety incidents well. Staff were trained to recognise and report incidents and near misses. Managers investigated incidents and shared lessons learned with the whole team and the wider service.**
- The clinic had an up to date adverse incident policy which described how staff should report incidents, and how incidents should be investigated and followed up.
- From July 2018 to June 2019 the service had not reported any never events. Never events are serious patient safety incidents that should not happen if healthcare providers follow national guidance on how to prevent them. During the same period there had been no clinical incidents relating to surgery in the clinic.
- Staff were able to describe how they would report an incident and confirmed they could seek support from senior staff if necessary.
- Although there had been no incidents relating to the hysteroscopy service at the time of our inspection, we saw through clinic meeting minutes, that managers investigated incidents and shared learning with all staff. We saw the general manager conducted an audit of incidents every six months, identifying corrective and preventative action for any incidents that occurred.

Safety Thermometer (or equivalent)

- The clinic, unlike NHS trusts, was not required to use the national safety thermometer to monitor areas such as venous thromboembolism (VTE).
- However, we saw evidence in patient's records we reviewed, which demonstrated 100% compliance with monitoring and reporting of VTE assessments. The assessment of patients for the risk of VTE was in line with venous thromboembolism: reducing the risk in hospital National Institute for Health and Care Excellence (NICE) guidelines QS3. The clinic audited the care pathway documentation quarterly, which included surgery checklist, VTE assessment, and early warning scores. The audits included actions plans for improved completion to areas that had not been completed.

Are surgery services effective?

Not sufficient evidence to rate

Our rating of effective stayed the same. There was insufficient evidence to rate effective, due to the size of the service.

Evidence-based care and treatment

- **The service provided care and treatment based on national guidance and evidence-based practice. Managers checked to make sure staff followed guidance.**
- Patient care and treatment reflected current legislation and nationally recognised evidence-based guidance. Guidelines were developed in line with the Royal College of Obstetricians and Gynaecologists (RCOG) and NICE guidelines. The clinic's protocols were based on national guidance that was used to deliver care to patients receiving surgery. For example, Patients assessed to be at risk of VTE are offered VTE prophylaxis in accordance (NICE QS3 statement 5).
- Staff were knowledgeable about the best practice guidance they used in their everyday work, for example from the National Institute for Health and Care Excellence (NICE). Staff also had access to study days, conferences and forums from national professional bodies, such as the Royal College of Nursing Fertility Nursing Forum. Staff rotated which members of the team attended such events, and those who attended would be required to feed back to the rest of the team.
- Clinic leaders attended external conferences from national professional bodies to try to keep up to date with the latest evidence-based care and treatment, relevant to the service they provided.

Nutrition and hydration

- **Staff assessed patients' food and drink requirements to meet their needs during their time at the clinic for a day case procedure. The service made adjustments for patients' religious, cultural and other needs.**
- The clinic provided water, tea and coffee to all patients and could provide a choice of sandwiches (outsourced) to surgical patients. Cultural and religious food choices could be sourced externally if a patient requested it.

- The service did not offer general anaesthesia, so patients did not have to fast before a procedure.
- Staff ensured that patients had something to eat and drink before they left the clinic after having a hysteroscopy, and this was recorded in the patient's care pathway.

Pain relief

- **Staff assessed and monitored patients regularly to see if they were in pain and gave pain relief in a timely way.**
- Pre and post procedural pain relief was prescribed by the registered consultant and recorded on the patients records.
- Prescribed local and conscious sedation medication was administered for effective pain relief during the procedure. If required, patients were given pain relief medication to take home post procedure
- We saw patient's pain scores were monitored on a regular basis whilst in recovery, and this was recorded in the patients records. The anaesthetist reviewed patients pain prior to the patient being discharged, to ensure the patient was comfortable.
- Patients we spoke to who had undergone a hysteroscopy, told us staff controlled their pain well before, during and after the procedure.

Patient outcomes

- **Staff monitored the effectiveness of care and treatment. They used the findings to make improvements and achieved good outcomes for patients.**
- The clinic had completed 38 hysteroscopy surgical procedures between July 2018 and June 2019. Information provided showed there were no returns to theatre and no re-admissions during that time.
- Staff gave patients clear instructions about what to expect post-surgery and any follow up appointments that were required.
- Leaders monitored clinic performance against key performance indicators based on current evidence-based practice. These were measured through clinic program of audits undertaken, which included audits of consent forms and the care pathway. The audits included actions plans for improvement.
- At the time of our inspection the clinic had not engaged with the Private Healthcare Information Network (PHIN) in accordance with the Private Healthcare Market Investigation Order 2014 regulated by the Competition Markets Authority (CMA). PHIN is an independent, not-for-profit organisation working with the private healthcare industry on behalf of patients formalised by the Competition and Markets Authority. It aims to publish independent, trustworthy information to help patients make informed treatment decisions, and providers to improve standards. It was not unexpected that the clinic had not engaged with PHIN due to the small size of the service.

Competent staff

- **The service made sure staff were competent for their roles. Managers appraised staff's work performance and held supervision meetings with them to provide support and development.**
- Staff and leaders had the right skills, knowledge and experience to carry out their roles and meet the needs of patients.
- All staff were required to complete competencies to demonstrate their fitness for the role. The competency framework was specific to the work of the clinic (fertility treatment) and was for clinical staff in addition to mandatory training. At the time of our inspection, the clinic was in the process of revising its competency framework and assessments for staff, led by the lead nurse.
- We viewed the log which tracked competency completion amongst staff, which showed all relevant staff were up to date with competencies key to the hysteroscopy service.
- The clinic provided us with information which showed 100% staff had received an appraisal in the current appraisal year. The appraisal year ran from January to December.
- Staff told us they had good access to development opportunities and were able to meet with leaders outside of their appraisal to discuss this should they wish to.

Multidisciplinary working

- **Nurses and other healthcare professionals worked together as a team to benefit patients. They supported each other to provide good care.**
- There was no hysteroscopy list running during our inspection, therefore we were not able to observe

interactions between staff in the theatre. However, nursing and other staff we spoke to commented that they knew the consultants well and there was a positive team work ethic during surgical procedures.
- We observed a clinical meeting between nursing, health care assistant, the general manager and pharmacy staff and saw staff worked well together, and all disciplines were respected. Staff told us they worked well with consultants to plan and provide patient care.

Seven-day services

- **Key services were available six days a week, with extended hours, to support timely patient care.**
- The clinic was open and able to offer appointments six days a week, between 8am to 8pm on Monday, Wednesday and Friday, between 8am to 7pm on Tuesdays and Thursdays, and between 10am and 4pm on Saturdays.
- Hysteroscopy procedures were arranged at a mutually agreeable time between patients and the clinic.
- The clinic offered hysteroscopy list on a Saturday, approximately twice per year, to provide flexibility for patients.
- There was a telephone line available to patients 24 hours a day, seven days a week, which patients could use if they had any concerns or medical issues. This phone was carried by a senior member of staff, which was escalated to the consultant on call if necessary.

Health promotion

- **Staff gave patients practical support and advice to enhance their health and wellbeing, before, during and after surgical procedures.**
- Patients were given an information leaflet about hysteroscopy, which encouraged patients to stop smoking as smoking increased their risk of chest infections.
- The clinic's website had resources that patients could access to inform themselves about fertility treatment and how to best support their health and wellbeing whilst undergoing treatment.

Consent, Mental Capacity Act and Deprivation of Liberty Safeguards

- **Staff supported patients to make informed decisions about their care and treatment. They followed national guidance to gain patients' consent.**
- We did not observe consent being taken as there was no hysteroscopy list on the day of our inspection.
- Staff we spoke with were able to tell us about the procedure used for gaining consent from patients.
- Patients were given a consent form to sign and this was placed into the patient's records. In the four patient records we reviewed all consent forms had been fully completed, signed and dated by both the patient and consultant. The consent form contained detailed information about the procedure, intended benefits, possible complications, and risks. Consultants were required to sign to confirm they had explained these to the patient. This meant patients could make an informed decision about consenting to the procedure.
- Patients told us staff had informed them about the risks and benefits associated with the procedure, and felt staff gave them adequate time to consider their decision to consent to surgery.
- The consultant surgeon took consent from patients during the consultation stage, and patients were asked to confirm their consent on the day of the procedure.
- Mental Capacity Act and Deprivation of Liberty Safeguards training was part of the annual mandatory training bundle, which all staff were compliant with. Staff could escalate any concerns to the lead nurse or general manager.

Are surgery services caring?

Not sufficient evidence to rate

Our rating of caring stayed the same. There was insufficient evidence to rate caring, due to the size of the service.

Compassionate care

- **Staff treated patients with compassion and kindness, respected their privacy and dignity, and took account of their individual needs.**
- We spoke with three patients in total. They described their experience of the care they had received as 'great', 'second to none', and 'very positive' and that staff had 'pulled out all the stops' to meet their needs. Patients told us staff were 'helpful', 'professional' and 'friendly'.
- We saw many cards in the director's office from patients thanking the clinic and staff for caring for them.

- The clinic had a chaperone policy and staff ensured a chaperone was always available to support patients, particularly during intimate examinations.

Emotional support

- **Staff provided emotional support to patients, families and carers to minimise their distress. They understood patients' personal, cultural and religious needs**.
- Counselling was available for all patients accessing the service. There were two onsite counsellors, who offered two types of counselling.
- Patients we spoke with told us staff were always available via the telephone to provide them with reassurance if they were anxious or had questions. Patients told us they felt staff had built trust and rapport with them over time, and staff were reliable in getting back to them on any requests for information.

Understanding and involvement of patients and those close to them

- **Staff supported and involved patients, families and carers to understand their condition and make decisions about their care and treatment.**
- Patients we spoke with told us staff explained their care and treatment in a way they could understand, without jargon, and allowed them plenty of time to ask questions.

Are surgery services responsive?

Good

Our rating of responsive stayed the same.We rated it as **good.**

Service delivery to meet the needs of local people

- **The service planned and provided care in a way that met the needs of local people and the communities served.**
- The clinic was focused on providing continuity of care for patients. Staff arranged clinics so that patients could be seen by the same nursing staff and consultants from the beginning of their treatment.
- The clinic had a lift, which was suitable for people who used wheelchairs. There was also a ramp that could be used on the front steps of the clinic to assist entry for patients in wheelchairs.
- The clinic was located close by to public transport links and was accessible to the population of London and the surrounding areas, and those further afield, including people living overseas.
- The clinic offered monthly open evenings where patients could meet staff, and receive information about the clinic, facilities and treatment, before deciding to book a consultation.

Meeting people's individual needs

- **The service was inclusive and took account of patients' individual needs and preferences. Staff made reasonable adjustments to help patients access services.**
- The clinic offered holistic services such as acupuncture, reflexology and counselling on site, if patients felt this would be beneficial to them as part of their treatment pathway.
- The clinic could source face to face interpreters for consultations, prior to treatment, and after procedures, if patients did not speak English.
- The clinic's website could be viewed in English and Arabic. The clinic had taken this step as around 15% of their patients were international patients, and the main language spoken was Arabic.

Access and flow

- **People could access the service when they needed it and received the right care promptly.**
- Patients were able to book appointments by telephone and online.
- Staffed planned admissions in advance at a time to suit the patient. The patients we spoke with told us they had not experienced any delays in agreeing a consultation appointment or setting operation dates, and they were often able to choose a date that was convenient to their schedule.
- The clinic offered a hysteroscopy list on a Saturday approximately twice per year, to offer more flexibility and choice for patients.

- Where relevant, the clinic also offered a 'one stop' hysteroscopy where patients could have a polyp removed and undergo egg collection within one procedure. This meant patients did not have to return to the clinic for separate appointments.

Learning from complaints and concerns

- **It was easy for people to give feedback and raise concerns about care received. The service treated concerns and complaints seriously, investigated them and shared lessons learned with all staff. The service included patients in the investigation of their complaint.**
- Staff told us if a patient was unhappy with the service, they would speak with them to try to diffuse the situation and resolve the issue at the time it arose. The clinic had a complaints policy which set out the procedure for how patients could make a complaint, how it would be investigated, how patients would be involved, and how learning and action plans would be shared.
- During the reporting period, the service had received 13 complaints, a rise from 10 in the period August 2017 to July 2018. We asked the General Manager whether there was an explanation for this increase. The General Manager explained that the number of complaints had increased in line with the expansion of the fertility service, so this was not unexpected. The General Manager showed us the complaints log, and we noted the main themes of the complaints centred around administration and communication. We saw that none of these complaints directly related to the hysteroscopy service.
- The service reviewed complaints received on a quarterly basis, to identify and share learning with all staff. The general manager could give examples of how clinic processes had been changed and improved in response to feedback. For example, as a result of comments from a patient, all staff informed patients at the time of their consultation that the consultant surgeon would be male, but they could request a female surgeon should they wish.
- Patients told us staff listened to their feedback, and could give examples of where staff had made changes to the service as a result.

Are surgery services well-led?

Good

Our rating of well-led stayed the same.We rated it as **good.**

Leadership

- **Leaders had the integrity, skills and abilities to run the service. They understood and managed the priorities and issues the service faced. They were visible and approachable in the service for patients and staff.**
- Leaders demonstrated awareness of the experiences of frontline staff and held meetings with them to understand what was working well and any areas for improvement.
- Leaders had access to external leadership development, through internationally recognised schemes.
- All staff we spoke to told us leaders were visible and accessible, and they would be happy to approach them with any concerns.

Vision and strategy

- **The service had a vision for what it wanted to achieve and a strategy to turn it into action.**
- The clinic provided us with information which stated the vision and strategy for the service was to be the most caring fertility clinic in the country. Leaders expressed a commitment for the clinic to lead the field in fertility treatment and had a vision to provide a more comprehensive service. For example, told us they were working towards bringing pathology services in house, to reduce the time patients would have to wait for pregnancy blood test results.
- There were no specific plans for development of the hysteroscopy service itself, aside from keeping up to date with the latest guidance. This was not unexpected due to the size of the service.

Culture

- **Staff felt respected, supported and valued. They were focused on the needs of patients receiving care.**
- Staff described the culture of the service as a 'family atmosphere'. Staff told us there was a non-hierarchical

ethos where the newest member of staff could approach the director. Staff also mentioned they felt valued for the experience they brought to the service and there was a healthy respect amongst colleagues.
- The service had an open culture where patients, their families and staff could raise concerns without fear. This was reflected in the clinic's incident policy, where leaders had outlined an approach focused on learning rather than blame.
- Staff expressed a commitment to providing the best possible care to patients and their families.
- Patients told us of a culture of integrity in the service, including staff having an open and transparent approach to fees for treatment and NHS referrals if relevant.

Governance

- **Leaders operated mostly effective governance processes, throughout the service and with partner organisations. Staff at all levels were clear about their roles and accountabilities and had opportunities to meet, discuss and learn from the performance of the service, although formalised governance meetings were infrequent.**
- We viewed the organisational structure for the clinic which showed that all functions of the clinic, including nursing, administration were accountable to the general manager, who then reported to the director (who was the registered manager).
- The registered manager, lead consultant and lead nurse held an annual governance meeting. We viewed the minutes from the last meeting and saw the discussion was divided in to sections focusing on regulatory matters, clinical reviews, clinical staff and any adverse incidents or near misses. The minutes also had a list of actions and who would be responsible for following them up. However, as the governance meeting was only held annually this meant there was a risk that leaders did not always take timely action to address areas for improvement. We found examples of this on our inspection, including the safeguarding policy had not been updated to reflect the most recent national best practice guidance, and leaders had not completed the action plan from the most recent infection prevention and control audit.
- The registered manager and lead consultant also held quarterly calls throughout the year to discuss the running of the service and any issues. However, these calls were not minuted. This meant there was a lack of audit trail of these conversations for the service to refer to. The registered manager told us they would consider recording minutes of their regular calls in the future.

Managing risks, issues and performance

- **Leaders and teams used systems to manage performance effectively. They identified and escalated relevant risks and issues and identified actions to reduce their impact. They had plans to cope with unexpected events. Staff contributed to decision-making.**
- Since our last inspection, the service had implemented a risk register. The risk register was divided in to environmental, operational, leadership, information and clinical risks. Each risk was score for likelihood and severity out of ten, and a factored risk score out of 100. The risk register also contained a continuous improvement log, which showed actions taken to reduce the impact of risks or eliminate them completely.
- The clinic had a risk policy which described in more detail how risk assessments were carried out and the process for including a risk on the risk register. All staff were able to raise new and emerging risks with leaders, for inclusion on the risk register, and make suggestions for how they were dealt with.
- Leaders were able to tell us what was on the risk register without referring to it, which meant they were knowledgeable about the issues and challenges the service faced.

Managing information

- **The service collected reliable data and analysed it. Staff could find the data they needed, in easily accessible formats, to understand performance, make decisions and improvements. The information systems were integrated and secure. Data or notifications were consistently submitted to external organisations as required.**
- The clinic had an electronic quality management system, which monitored the performance of the service through data collection on all aspects of the service including complaints, mandatory training and risks. This information was stored on computers at the clinic and could only be accessed by staff through secure logins. Staff reviewed and commented on information from the quality management system during quarterly meetings.

- The clinic submitted all fertility data to the Human Fertilisation and Embryology Authority.

Engagement

- **Leaders and staff actively and openly engaged with patients and staff to plan and manage services.**
- We saw staff had an opportunity to contribute to the running of the service. For example, during the nursing team meeting we observed, the lead nurse gave staff the opportunity to comment and make suggestions before decisions were made.
- Staff actively sought patient feedback either on paper-based forms which patients which they could send back through a freepost address, or through an electronic tablet whilst present in the clinic.
- Leaders commented that they had good relationships with external service providers, such as the nearby hospital that provided equipment sterilisation services for the clinic.

Learning, continuous improvement and innovation

- **All staff were committed to continually learning and improving services. Leaders encouraged innovation.**
- Staff told us they could access opportunities for development, including participating in national programmes. We saw leaders sought the views and input of staff on how to make improvements.

Outstanding practice and areas for improvement

Areas for improvement

Action the provider SHOULD take to improve

Action the provider SHOULD take to improve

- Ensure all staff are bare below the elbow.
- Ensure action taken as a result of infection control audits is clearly recorded.
- Review the safeguarding policy to ensure it reflects the most up to date national guidance.
- Ensure the supply, administration and disposal of controlled drugs is consistently recorded correctly.
- Consider increasing the frequency of formalised governance meetings and discussions.