Marie Stopes International Leeds Centre

Quality Report

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

Overall summary

Leeds Centre is operated by Marie Stopes International. The service provides a surgical treatment room and eight day-case beds at its main centre location. Other locations, including early medical abortion units (EMU) and vasectomy units provide consultation rooms.

MSI Leeds provides medical and surgical termination of pregnancy services, pre and post termination counselling as well as contraception advice and screening for sexually transmitted diseases. The service provides early medical abortions (EMA) up to nine weeks and four days gestation and surgical termination of pregnancy up to 18 weeks and six days gestation. The service also undertakes non-scalpel vasectomies. The service treats NHS and private patients.

We inspected this service using our comprehensive inspection methodology and carried out the announced part of the inspection on 13 and 14 July 2017, along with an unannounced visit to the service on 28 July 2017.

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

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

Services we do not rate

We regulate termination of pregnancy services but we do not currently have a legal duty to rate them when they are provided as a single specialty service. We highlight good practice and issues that service providers need to improve and take regulatory action as necessary.

Since our last inspection in 2016, we have noted the following improvements at MSI Leeds Centre:

- A new system for incident reporting and the implementation and monitoring of surgical safety checklists
- The introduction of early warning scores for detecting deteriorating patients
- Improved clinical governance and monitoring of patient outcomes, risks and complaints.

Summary of findings

- Improved communication with locality managers and the MSI executive management team.

We found the following areas of good practice:

- Record keeping and risk assessments were of a consistently high standard.
- Staff we spoke with demonstrated they understood the principles of safeguarding adults and children and knew what actions they needed to take in cases of suspected abuse.
- World Health Organisation (WHO) and five steps to safer surgery checklists were completed for all patients undergoing surgical procedures.
- There were locally agreed and up to date policies and standards that referred to evidence based practice and against which performance was audited.
- Records indicated that pain was assessed and treated in accordance with national guidelines.
- Staff treated patients attending for consultation and procedures with compassion and respect, were non-directive and non-judgemental.
- We found the service to be responsive to meeting people's needs and requirements.
- Complaints and concerns were acted upon and changes had been made to the service following comments from patients.
- Staff spoke positively about the changes to the local, regional and national procedures introduced by the management team since our 2016 inspection.
- Staff felt supported and valued by their managers and the organisation.

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

- At the time of inspection, nursing staff providing patient consultation had not received up to date training regarding contraception.
- Monitoring of mandatory training compliance via the training matrix was not effective, as the matrix was not kept up to date.
- Termination of pregnancy early warning scores (TEWS) to monitor and act upon any clinical deterioration had been introduced but we found this was not yet fully embedded

Following this inspection, we told the provider that it must take action to improve:

- The provider must enable all staff to complete training that is necessary for them to fulfil their roles. This includes contraception competence training and updates.

We issued the provider with one requirement notice. In addition, we told the provider it should make other improvements, even though a regulation had not been breached, to help the service improve. Details are at the end of the report.

Ellen Armistead

Deputy Chief Inspector of Hospitals (North)

Summary of findings

Our judgements about each of the main services

Service	Rating	Summary of each main service
Termination of pregnancy		We regulate this service but we do not currently have a legal duty to rate when it is provided as an independent healthcare single speciality service. We highlight good practice and issues that service providers need to improve and take regulatory action as necessary.

Summary of findings

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Summary of this inspection

Background to Marie Stopes International Leeds Centre

Termination of Pregnancy (ToP) refers to the termination of pregnancy by surgical or medical methods. Marie Stopes International (MSI) Leeds is part of the provider group MSI UK and MSI International, a not for profit organisation that was founded in 1976 to provide a safe, legal abortion service following the Abortion Act 1967.

Leeds Centre is operated by Marie Stopes International. It is a private single specialty service in Leeds, West Yorkshire. The centre primarily serves the communities of Leeds, Bradford, Wakefield, North Yorkshire and York, Huddersfield, Calderdale and North Kirklees with an additional vasectomy service in Middlesbrough and Stockton, Cleveland. It also accepts patient referrals from outside these areas.

The centre has had a registered manager in post since May 2013.

The Marie Stopes, Leeds centre was last inspected, in May 2016. CQC undertook enforcement action, following an inspection of the governance systems at the MSI corporate (provider) level in late July and August 2016. There were some breaches in regulation that were relevant to this location, which we have followed up as part of this inspection.

The breaches were in respect of:

- Regulation 17 Systems or processes must be established and operated effectively to ensure compliance with the requirements in this Part. (Good governance)
- Regulation 20 of the Care Quality Commission (Registration) Regulations 2009.

CQC continued monitoring compliance with the above enforcement action in order to ensure that services were operated in a manner, which protected patients from abuse and avoidable harm.

At this inspection, we found the service had introduced; a new system for incident reporting, monitoring of surgical safety checklists and early warning scores for detecting deteriorating patients. It had improved clinical governance and monitoring of patient outcomes, risks and complaints, and improved communication between operational staff and locality managers and the MSI executive management team.

Our inspection team

The team that inspected the service comprised a CQC lead inspector,Jill Bullimore, other CQC inspectors, and a specialist advisor with expertise in nursing and gynaecology. The inspection team was overseen by Amanda Stanford, Head of Hospital Inspection.

Information about Marie Stopes International Leeds Centre

The service is registered as a single speciality service for termination of pregnancy and is registered for the following regulated activities:

- Diagnostic & Screening Procedures
- Family Planning Services
- Treatment of Disease, Disorder and/or Injury
- Termination of Pregnancy
- Surgical Procedures

The services provided under these activities were:

- Pregnancy Testing
- Unplanned Pregnancy Counselling/Consultation
- Medical Abortion

Summary of this inspection

- Surgical Abortion using local Anaesthetic and conscious Sedation
- Surgical Abortion using general anaesthetic.
- Abortion Aftercare
- Miscarriage Management
- Sexually Transmitted Infection Testing and Treatment
- Contraceptive Advice
- Contraception Supply
- Vasectomies

During the inspection, we visited the Barrack Road, Leeds Centre, an early medical abortion unit (EMU) in Bradford and a vasectomy unit in Wakefield. We spoke with 13 staff including; registered nurses, health care assistants, reception staff, medical staff, operating department practitioners, and senior managers. We spoke with eight patients and two relatives. During our inspection, we reviewed 15 sets of patient records.

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

In the reporting period 1 June 2016 to 31 May 2017, the centre carried out 1,490 surgical abortions and 488 medical abortions. The centre also carried out 114 vasectomies.

Of all patients the centre treated, 91% were NHS-funded and 9% were self-funded.

Two surgeons were directly employed by MSI. Two anaesthetists who also worked at NHS trusts and other MSI sites were employed on a sessional basis. MSI employed seven registered nurses, two doctors, and five administrators. The centre had used no bank or agency staff in the three months prior to the inspection.

The centre provided one treatment room, three consulting rooms and eight, day care reclining chairs at the main location in Leeds patients undergoing treatment for surgical abortions up to 18 weeks and nine days and early medical abortions (EMA) up to nine weeks and four days. Patients did not stay at the centre overnight.

There were nine satellite units in Wakefield, Bradford, Batley, Airedale, Leeds City Centre, Huddersfield, Stockton on Tees, North Ormesby and Hartlepool. Six of these sites provided early medical abortions and four provided vasectomies. Each had one consulting room that could also be used as a treatment room. The Wakefield unit provided both early medical abortion and vasectomies. The vasectomy units provided a reclining chair for patients to use following vasectomy procedures.

The centre reported no never events or serious incidents requiring investigation in the between 1 June 2016 and 31 May 2017.

The total number of clinical incidents reported during the same reporting period was 68, with 62 resulting in no harm, four resulting in low harm, and two reported as moderate harm. No incidents resulted in severe harm or death.

The service reported no healthcare acquired infections.

The centre had received six formal complaints within the same 12 month timeframe.

The centre held a current Department of Health licence to practice under the Abortion Act and displayed copies of the licence at each of its registered locations.

Services provided at the hospital under service level agreement:

- Clinical and or non-clinical waste removal
- Interpreting services
- Grounds Maintenance
- Laundry
- Maintenance of medical equipment
- Pathology and histology

Summary of this inspection

The five questions we ask about services and what we found

We always ask the following five questions of services.

Are services safe?

We found the following areas of good practice:

- The introduction of a revised incident policy and an electronic patient safety system had increased staff awareness and local reporting and monitoring of safety incidents and risks. There was evidence of shared learning in relation to patients' safety.
- Serious incidents were investigated by a trained panel at MSI UK in a timely manner.
- Staff understood their responsibilities to raise concerns and report incidents and near misses and learning was shared with staff through team meetings.
- The service had robust arrangements and systems, in place for equipment and building maintenance, this included fire safety checks and drills at the main site and six monthly health and safety audits, including fire safety at the satellite centres.
- Record keeping was of a consistently high standard.
- Staff we spoke with demonstrated they understood the principles of safeguarding adults and children and knew what actions they needed to take in cases of suspected abuse. All staff had received safeguarding training to an appropriate level, relevant to their role. It included information on female genital mutilation, child sexual exploitation and PREVENT.
- All patients underwent an initial risk assessment to determine their suitability for treatment at the unit. If a patient was unsuitable for treatment at the MSI Leeds centre, for example due to an existing health condition, they would be referred to another centre or provider.
- There were systems and processes to ensure that standards of cleanliness and hygiene were maintained.
- All patients received a private initial consultation without anyone else present to safeguard against possible coercion or abuse and to give them the opportunity to disclose such information in a safe environment.
- World Health Organisation (WHO) five steps to safer surgery checklists were completed for all patients undergoing surgical procedures including ToP and vasectomy.

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

- Termination of pregnancy early warning score (TEWS) to monitor and act upon any clinical deterioration had been

Summary of this inspection

introduced but we found not all had been completed or documented correctly. This process was new to staff and required attention to detail in order to improve completion of forms and accurate recording of information.

Are services effective?

We found the following areas of good practice:

- There were locally agreed and up to date policies and standards that referred to evidence based practice and against which performance was audited. National and local policies had been reviewed, updated and shared with staff.
- Patient assessments were thorough and staff followed pathway guidance.
- Records indicated that pain was assessed and treated in accordance with national guidelines. Surgical patients received appropriate pain relieving medications and pain-relieving medications were routinely prescribed for patients to take at home following their procedures or initiation of medical treatment.
- Staff always made sure patients gave their consent in writing and adhered to Fraser guidelines in respect of children and young people.

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

- At the time of inspection, nursing staff had not received up to date training regarding contraception despite giving contraceptive advice and administration of contraceptives being a routine part of the patient pathway.

Are services caring?

We found the following areas of good practice:

- Staff treated patients attending for consultation and procedures with compassion and respect. Staff were seen by patients to be non-directive and non-judgemental.
- Patients told us how they had been listened to, that they felt safe and were treated with kindness.
- Staff focused on the needs of each patient and responded quickly to their preferences including options for termination and where and when to have the procedure. If patients needed time to make a decision, staff supported this.
- Staff established and respected each person's preference for sharing information with their partner or family members, and reviewed this throughout their care.

Summary of this inspection

- Staff explained the treatment and post-operative care for vasectomy patients.
- The service provided telephone counselling for patients of all ages considering termination of pregnancy and post-termination and support to partners and those people close to patients. Face to face counselling was mandatory for all patients under 16.
- At our last inspection in 2016, we observed not all areas provided patients with full access to privacy and dignity. At this inspection, we saw patients were given privacy and treated with dignity when being cared for in the treatment room and the recovery area following surgical procedures.
- At our last inspection in 2016, we reported staff had not informed patients of the requirement to submit abortion data to the DH. At this inspection we saw staff informed patients of this requirement and were prompted to include this in patient consultations through treatment pathway paperwork.

Are services responsive?

We found the following areas of good practice:

- We found the service to be responsive to meeting people's needs and requirements.
- Waiting times were consistently within the guidelines set by the Department of Health and patients were offered appointments to suit them. Services were tailored to meet individual needs and were delivered in a way to ensure flexibility and choice.
- The service was accessible via a telephone advice line for the booking of appointments and for advice and support 24 hours a day, seven days a week.
- Interpreting and counselling services were offered to all patients and the Leeds centre was accessible for those with reduced mobility. However, the satellite unit at Huddersfield was not accessible to people with reduced mobility.
- There were appropriate processes in place for disposal of pregnancy remains following the guidelines as set out by the Human Tissue Authority Code of Practice and to accommodate patient wishes.
- Complaints and concerns were acted upon and changes had been made to the service because of some comments made.
- Staff were involved in the learning from complaints.
- There was written information available to make a complaint with posters displayed in some sites we visited. There was a range of leaflets provided for patients to take away with them.

Summary of this inspection

- Since our previous inspection in 2016, we found patients did not wait for long periods to be seen or for prescriptions to be provided via the remote electronic system.

Are services well-led?

We found the following areas of good practice:

- There was a committee and meeting structure, throughout the organisation, to facilitate governance and oversee risk and quality management and there was a structured approach for escalation of issues and information sharing.
- Local manager and staff representation or attendance was evident at relevant local and regional meetings.
- Staff spoke positively about the changes to the local, regional and national procedures introduced by the management team since our 2016 inspection.
- The organisation vision of a world in which every birth is wanted and "children by choice, not chance" was well known and supported by staff at all levels.
- Local managers had a clear vision and strategy for their service and were keen to support services for patients. Managers were approachable, available, and generally supported staff within the service.
- All staff recognised it was their responsibility to ensure good quality of care and patient experience.
- At our previous inspection, it had not been clear how achievement of some indicators represented quality of service for patients. However, staff told us at this inspection, that they were able to use benchmarking information to improve their service to patients.
- At our previous inspection, we were not assured that all HSA4 forms were submitted and authorised within the Department of Health required time of 14 days following abortion. However, at this inspection staff were able to explain the process for submission of all HSA4 forms.
- Staff felt supported by their managers and were confident they could raise concerns and have them dealt with appropriately.
- There was a local risk register in place, which gave risks and mitigations, and we saw evidence that this was reviewed annually

Termination of pregnancy

Safe	
Effective	
Caring	
Responsive	
Well-led	

Are termination of pregnancy services safe?

Incidents and safety monitoring

- Marie Stopes International (MSI) had introduced a new electronic incident reporting system. Staff and managers had received training and information on how to use the system and had access to the incident reporting policy.
- Staff we spoke with were positive about improvements the new reporting system had made and perceived it had led to increased reporting.
- Managers told us staff had an increased awareness about reporting of incidents and we saw from regional team meeting minutes the number of reports made was continually increasing.
- There had been no 'Never Events' at the service in the 12 months before our inspection. Never events are serious incidents that are entirely preventable as guidance, or safety recommendations providing strong systemic protective barriers, are available at a national level, and should have been implemented by all healthcare providers.
- There were no serious incidents reported during the reporting period in the 12 months before our inspection.
- From June 2016 to May 2017 there were 117 clinical incidents reported by staff at the Leeds centre, 38 of these were safeguarding disclosures or referrals. Two incidents were graded as moderate harm and involved the omission of anti-D immunoglobulin injections. One incident reported completion of a prescription before the second part of the HSA1 form was documented. Action plans showed this was reported immediately, investigated, and lessons learned were shared with the team. We saw there had been five incidents reported prior to February 2017 where HSA4 forms had not been submitted to DH within 14 days. All had been investigated, staff involved were informed and the process was completed. A flowchart and new pathway documentation had been implemented and no further incidents had occurred.
- All the remaining incidents were low or no harm. There were no particular themes or trends noted. Verbal and written complaints were also recorded on the incident reporting system.
- Managers and staff investigated serious incidents (SIs) using Root Cause Analysis (RCA). Two people had been identified to receive RCA training and one had received this at the time of our inspection. Managers told us and action plans showed that transfers to hospital were also investigated to identify clinical management and quality improvement opportunities but would not necessarily be classified as SIs.
- Since the last inspection, the organisation had introduced incidents as standing agenda items at team meetings to ensure that learning was shared and action identified from incidents was progressed and improvements made.
- Staff described how learning from incidents was shared formally through staff meetings, emails and face-to-face discussion with colleagues. Records we looked at, including minutes from staff meetings, confirmed this. Staff told us they received information and feedback from incidents at local team meetings.
- Senior staff told us the new system now enabled analysis at corporate level and review of incidents at the weekly Complaints, Litigation, Incident and Patient Feedback (CLIP) meetings enabled them to identify any incidents that may meet SI criteria or the duty of candour threshold.
- Under the Health and Social Care Act (Regulated Activities Regulations 2014), the duty of candour is a regulatory duty that relates to openness and

transparency and requires providers of health and social care services to notify patients (or other relevant persons) of "certain notifiable safety incidents" and provide reasonable support to that person.
- Staff we spoke with were aware of the importance of reporting incidents and near misses and understood the principles of 'being open' and 'duty of candour'.

Mandatory training

- All staff received mandatory training as part of their induction and at regular updates. Mandatory training included; manual handling, infection prevention and control, children and adult safeguarding, information governance, display screen equipment, informed consent, equality and diversity, medical gases, control of substances hazardous to health (COSHH), fire safety and essentials of health and safety, anaesthetic and recovery training, ultrasound training and lone working was also required for relevant staff.At the time of inspection data for mandatory training indicated a poor compliance with basic and immediate life support (relevant to staff role) recorded at 20% and 14% respectively. Following the inspection, updated information demonstrated 100% compliance with the majority of modules (including basic and immediate life support). However, there remained some areas of poor compliance such as information governance at 50%. We were not assured that monitoring of mandatory training compliance via the training matrix was effective, as the matrix was not kept up to date.
- Staff were required to complete a local induction the first time they worked at a satellite centre to familiarise themselves with the workings and the local health and safety policies and procedures at the centre.

Safeguarding

- Processes were in place to safeguard vulnerable adults and young people. Staff we spoke with were all aware of their responsibilities and had access to safeguarding policies for adults and children.
- The organisation had policies and procedures for staff to follow if cases of female genital mutilation or sexual exploitation were discovered and staff were clear what actions they needed to take in this situation.
- All clinical staff were trained to level three in children's and adults safeguarding and reception staff were trained to level two, in line with the 'Intercollegiate Document' (Royal College of Paediatrics and Child Health 2014). There were level four and five safeguarding leads within the organisation and staff knew who they were and how to contact them for advice and support.
- Compliance with all aspects of safeguarding training including, child sexual exploitation, female genital mutilation (FGM) and protecting children from radicalisation (PREVENT) was 100%.
- Staff we spoke with felt the recent training had been of a good standard and they felt better equipped to deal with any safeguarding concerns they came across.
- We saw from records and staff told us that they carried out safeguarding risk assessments for all patients, to enable identification of vulnerable adults and any safeguarding concerns for adults or children. Staff told us, and we saw, they made safeguarding referrals to the local authority following discussion with the local safeguarding lead.
- Organisational policy was that if a girl under the age of 13 years used the service then staff would automatically make a safeguarding referral in line with the 'Sexual Offences Act 2003.' No children under 13 years attended the service from June 2016 to May 2017. If a girl under the age of 13 years did attend the service they would not be treated but referred to an NHS provider. However, young patients between the age of 13 and 15 years did use the service.
- Where young people had a social worker, MSI staff would contact them if the young person consented to this.
- For those patients aged 13 to 18 years, staff completed a safeguarding risk assessment and a decision made on the outcome of the assessment.
- Staff told us and we saw that all patients received a private initial consultation without anyone else present to safeguard against possible coercion or abuse and to give them the opportunity to disclose information in a safe environment.
- The centre and satellite units held a file of local contact numbers to enable staff to quickly access adult and children safeguarding teams.
- Senior staff told us that the new incident reporting system enabled them to collect information regarding referrals made to social services so best practice and areas for improvement could be identified.

Cleanliness, infection control and hygiene

Termination of pregnancy

- The consulting rooms, waiting areas and other clinical rooms were visibly clean and tidy.
- Some cleaning duties were the responsibility of nursing staff and schedules and checklists for cleaning were completed.
- We observed a good standard of cleanliness in the treatment room and records indicated that nursing staff undertook a schedule of daily cleaning of the environment and equipment. Equipment that was in contact with the patient, such as couches and blood pressure cuffs were cleaned with disinfectant wipes in-between patients.
- Facilities for hand hygiene were provided in all clinical areas and soap dispensers were in good working order.
- We observed staff washing hands and using cleansing gel appropriately in all clinical areas. Personal protective clothing was available in all areas we visited.
- Surgeons in the treatment room wore plastic aprons and gloves. They decontaminated their hands prior to putting their gloves on between each procedure and they changed aprons between patients.
- Disposable curtains were in use in the clinical areas and were marked with the date of last change.
- MSI Leeds centre had a link practitioner for infection prevention and control (IPC) who undertook environmental and hand hygiene audits. Hand hygiene audits were carried out twice a year and an IPC audit of the centre was carried out once a year. Latest audit results for the observational hand hygiene facilities audit in October 2016 showed 100% compliance. We noted that the audit had included a practical session and the use of a light box to demonstrate effectiveness of hand washing practice.
- The IPC audit, which looked at a range of criteria such as environment, equipment, cleaning, management of sharps and personal protective equipment, in November 2016 showed 97% compliance. The auditor had reminded staff regarding the completion of cleaning schedules.
- There was a policy in place regarding safe disposal of clinical waste and a service level agreement was in place with a waste contractor for removal.
- We saw that staff segregated and disposed of waste appropriately. They used sharps bins correctly and had access to spillage kits if needed. There was appropriate segregation and storage of pregnancy remains to enable sensitive disposal.

Environment and equipment

- The premises and rooms used to provide this service were suited to their purpose.
- Treatment rooms in early medical units were well equipped to provide the service.
- There was a dedicated procedure room with recovery areas at the Leeds, Barrack Road centre. Ventilation in these rooms was appropriate to their use.
- The second stage recovery area was light and airy with privacy screens over the windows. The recovery area had semi reclining chairs where patients stayed until they were ready for discharge. Each chair had lighting and call bells.
- There was a comprehensive planned maintenance programme in place, which covered; heating and ventilation, fire systems, generator testing, emergency lighting and other elements of maintaining centre premises. We saw evidence of recent servicing of ventilation.
- We saw evidence that fire safety checks and drills were carried out at the main site as part of six monthly health and safety audits. We also saw audit reports for six-monthly health and safety checks, including fire safety at the satellite centres. All satellite centres had last been audited in April 2017 and were 100% compliant with the checks carried out. The latest audit at the Barrack road site was July 2017 and the centre was 100% compliant.
- With regard to emergency situations including fire drills or evacuation at satellite centres, Managers told us that MSI staff were expected to complete a local induction the first time they worked at a satellite centre to familiarise themselves with the workings of the centre. MSI staff were expected to work to the local health and safety policies and procedures at each satellite centre. We found this expectation was stated clearly in premises licence agreements.
- Evidence of stock rotation was in place and all stock we checked was in date and stored in an appropriate manner.
- Resuscitation equipment and medications were checked regularly and resuscitation trolleys were tamper proof. Trolleys and emergency rucksacks were checked daily when clinics were running and sealed draws and packs were opened and checked weekly. Other emergency equipment such as defibrillators were checked daily.

- A designated member of staff made a complete check of anaesthetic machinery daily and the anaesthetist made a second check before use. We reviewed records of checks and maintenance and they were up to date.
- An external contractor carried out sterilisation of instrument trays. The health care assistant (HCA) in the treatment room packed up used instruments into secure transport boxes, which were collected and returned clean. The HCA informed us that this system ran smoothly and there were no issues with supply or decontamination.
- Records indicated that staff at the early medical units undertook equipment checks for safety and maintenance daily.

Medicine Management

- Medicines were stored safely and securely in the clinics, we visited. Records indicated that nurses checked medicines regularly and rotated stock monthly. Medicines taken to satellite units were transported safely and securely by a registered nurse with a logging out and in process at each end of the journey.
- For medicines, requiring refrigeration there is a requirement to maintain the recommended fridge temperatures to ensure the safety and efficacy of these medicines and minimum and maximum temperatures should be read and recorded daily. Records indicated that daily checks of minimum and maximum temperatures were made and that temperatures had been within the recommended range from April 2017 to June 2017.
- Opiate analgesia (Oramorph) and anaesthetic medications were stored appropriately and two staff always signed the register for the administration of these medications. Staff checked the stock was correct at each use and the whole stock level was checked on a weekly basis. We checked the controlled drug book and found this was completed correctly.
- Medication cupboard keys were kept by the nurse in charge and locked away when the centre was closed.
- The centre dispensed prescriptions for analgesia, antibiotics and contraceptives.
- Nursing staff checked that patients had received contraceptive advice and that prescriptions had been written up. We observed contraceptive implants and injections were given to patients in accordance with good medicine administration guidance.
- A doctor prescribed all abortifacient medicines. Medication that induced abortion was only prescribed for patients undergoing medical abortion following completion of a face-to-face consultation with a member of the nursing team, written consent and completion of the HSA1 (grounds for carrying out an abortion) form signed by two doctors. There had been one incident in the previous 12 months where a patient had been administered the first dose of an abortifacient medicine after the HSA1 form had been signed but before the prescription had been completed. The error was identified immediately and reported, investigated and action taken appropriately. The prescription was written and in place before the second dose was due.
- Nurses were able to administer pain-controlling medication, treatment for sexually transmitted infections (STI) and prophylactic antibiotics to prevent post procedure infection as prescribed.
- The discharging nurse or midwife provided antibiotics and contraceptive medications and checked that patients understood what the medications were for and the importance of taking them as prescribed.
- Staff were supported by an outreach pharmacist who was contactable for any medicine concerns or queries.
- There was a local audit plan that demonstrated medicines management was audited on a quarterly basis and the most recent audit results from 2017 showed consistent 98%- 100% compliance.

Records

- Patient records were largely electronic, however, paper copies of HSA1 forms, venous thromboembolism (VTE) assessments, consent forms and safer surgery checklists, were also in use as physical signatures were required. Paper records were scanned and stored with the electronic record and paper copies were stored safely and securely in lockable cabinets in line with the Data Protection Act.
- MSI policies stated that all records, which included patient-identifiable information, must be stored securely and kept strictly confidential within the establishment. We saw this to be the case.
- All paper held records that were transferred to other MSI locations were transported by courier to ensure their safe and secure delivery.
- The electronic patient record included speciality pathways and risk assessments for VTE, sexual health and safeguarding for patients under 18 years of age.

Termination of pregnancy

- We looked at 15 sets of records across various pathways and found them to be up-to-date and complete. Records indicated risk assessments were completed and any medical concerns or issues identified were clear. Counselling records were separate from the medical record and marked as confidential.
- Staff we spoke with told us that prior to the termination of pregnancy all patients had an ultrasound scan to confirm the gestational date, which is the term used to describe how many weeks pregnant the woman is. In all of the patient records we looked at, we saw a record of the ultrasound scan and the reported gestational date; in addition, a print out of the scan as well as an electronic copy was correctly stored and maintained.
- Bi-monthly record keeping and documentation audits were carried out and compliance was consistently high at 97%-100% throughout 2016.

Assessing and responding to patient risk

- There was an admission policy for patients using the ToP service to determine their suitability for treatment at the centre. This was based on Royal College of Obstetricians and Gynaecologists (RCOG) guidelines. The policy set out the patient pathway from admission to after discharge and included how to provide written information for patients about potential risks and what to be aware of after the procedure. The MSI One Call centre was given as a contact number (24 hours a day 7 days a week) for reporting any concerns after discharge.
- At their initial consultation, patients were asked about their medical history to assess their suitability for treatment; this included assessment of potential risk factors. If a patient was unsuitable for treatment at MSI Leeds, for example due to an existing health condition, they would be referred to another centre or provider.
- The MSI 'Pre-existing Conditions Guideline' clearly documented which medical conditions would exclude patients from accessing treatment, and those medical conditions, which require a risk assessment by a doctor. If more information was required or a patient was not suitable for treatment, staff liaised with the patient's GP. For patients who were not suitable for treatment at MSI Leeds on medical grounds, MSI had a 'Do Not Proceed' team, which sourced appointments for the patient within the NHS.
- Before treatment, all patients were initially assessed by a telephone consultation with One Call. On arrival at the clinic, the patient received an assessment by a nurse or healthcare assistant for their general fitness to proceed. This assessment included obtaining a medical and obstetric history and measurement of vital signs, including blood pressure, pulse and temperature.
- Blood tests were performed on all patients to establish those patients who had rhesus negative blood group. These patients received treatment with an injection of anti-D to protect against complications should the patient have future pregnancies. Other relevant laboratory testing was undertaken as appropriate and as agreed with the patient. These tests could include haemoglobin level, chlamydia and HIV testing if this was commissioned by their clinical commissioning group (CCG). Staff offered all patients the screening tests for chlamydia. If patients lived in an area that commissioned HIV testing, they would also be offered this test. For patients whose CCG did not commission HIV testing staff offered the patients the opportunity to self-fund this test or referred them to local sexual health services for free testing.
- Risk assessments, medical follow up, interventions and preoperative reviews were evident in our observation of patient journeys and in the records, we reviewed.
- All patients who underwent surgical abortion were risk assessed for venous thromboembolism (VTE). Data we reviewed indicated that 100% of surgical patients had received this risk assessment from June 2016 to May 2017.
- The patient pathway involved nurses performing an ultrasound scan to confirm dating, viability, multiple gestations and the location of implantation. Staff told us that if they were concerned about a scan or wanted a second opinion, they could ask for another member of staff to repeat the scan. If there was no second member of staff available the patient would be re-booked to come back or directed to an early pregnancy unit if the need was urgent.
- We observed that staff made positive identity checks before commencing a consultation or treatment and when entering the treatment room.
- MSI had developed its own Surgical Safety Checklist (SSCL), modelled on the World Health Organisation (WHO) five steps to safer surgery checklist. We observed good compliance with use of the SSCL during the inspection. Use of the checklist was audited as part of medical records audit and the last two audits had shown 100% compliance.

Termination of pregnancy

- We found that registered medical practitioners reviewed anaesthetic and surgical risk during their review of the patient record / medical history, before prescribing abortifacient treatment or initiating surgical treatment.
- We observed the anaesthetist reviewing patients' medical history prior to them coming in to the treatment room.
- We saw that during and after surgical treatment, each patient's vital signs, blood loss and pain level were monitored. Patients were scanned during surgical abortion to check whether any products had been retained.
- The MSI Leeds centre and satellites had formal transfer agreements in place with local NHS hospitals, should a patient's condition require an emergency transfer. Under these agreements, the service was also able to refer patients with suspected retained products of conception and patients who were suspected of having an ectopic pregnancy.
- Recovery staff took over patient care immediately post operatively. A member of staff remained with the patient when in the first stage recovery area. Staff in the recovery areas monitored blood loss and recorded patient observations every five minutes until they were awake.
- Nurses assessed the patient's vital signs including temperature, pulse, respiratory rate, blood pressure, oxygen saturation and blood loss. They used this as part of an adapted national early warning score (NEWS) referred to as the termination of pregnancy early warning score (TEWS) to monitor and act upon any clinical deterioration. In a small number of records we looked at, we saw gaps where scores had not been calculated or actions not noted. We did note that staff carried out all observations appropriately. This suggested the new system had not yet become fully embedded in practice and still required some attention to detail before it would be completely reliable. Managers and the senior nurse were aware that the system still needed fully embedding and told us they were reminding staff of the need to complete the scores fully and that they were monitoring the situation.
- There was a member of staff in each of the recovery areas at all times during our inspection.
- Patients in the second stage area all had nurse call bells if they required assistance and nursing staff were out of sight.
- Staff told us they took part in unannounced emergency scenario exercises to ensure they knew what to do in case of medical emergencies.
- Patients were given written and verbal information regarding what to expect following treatment, the warning signs they needed to be aware of and when to contact the service or attend emergency services. Nurses used a 'Criteria-Based Discharge Checklist' to help them assess patients were fit for discharge before they left the unit.
- Nursing staff told us that a member of medical staff stayed at the centre until 30 minutes after the last patient had left the treatment room and they had assessed them as fit for nurse-led discharge.

Staffing

- Required standard operating procedure (RSOP) 18: Staffing and emergency medical cover requires that providers of a ToP service should ensure there is a sufficient number of staff with the right competencies, knowledge, qualifications, skills and experience to safeguard the health, safety and welfare of all who use the service and meet their routine and non-routine needs.
- There were sufficient qualified and support staff to run the service there were seven (4.8 whole time equivalent (WTE)) registered nurses (RNs) working at MSI Leeds. At the time of the inspection, there was one (0.7 WTE) vacancy.
- There were five (2.7 WTE) healthcare assistants (HCAs) and administrative staff also working out of the Leeds centre. There was a 0.4 WTE vacancy in this staff group.
- Short-term sickness, absence cover was usually provided by staff at the Leeds and Manchester centres working flexibly across the region and on additional hours, when necessary.
- Managers told us that staffing levels were based on the environment and predicted caseload for the coming year and budgets were adjusted accordingly with the business plan for the centre.
- Due to the need for a specialised skill set, it was not possible to use agency staff for consultations and treatments. However, there was occasional use of agency nurses or operating department practitioners (OPD) in the treatment room. All were known to the service and had completed local inductions.

Termination of pregnancy

- Data provided by the service indicated there had been no agency staff working in the three months prior to our inspection; however, an agency OPD was working in the treatment room on the day of inspection.
- A RN working alone usually staffed outlying EMUs. There was lone worker policy in place and generic lone worker risk assessments were in place for clinics in commercial buildings and GP practices. Staff had all completed training regarding lone working.
- Not all staff felt that staffing levels were always adequate in all areas. They told us that on occasions there were only two members of nursing staff available for the procedure room. This did not meet the planned level of three staff in this area; however, the senior nurse told us if the area was struggling then staff would be moved from the consultation area to ensure safety was maintained. Managers told us staffing was altered to reflect capacity when surgical bookings are low and to reflect the type of sedation or general anaesthetic procedures booked.
- There were plans for the clinical team leader to be supernumerary within the unit. However, we were told that this happened only rarely at the time of inspection.
- There were two surgeons (0.4 WTE) working at MSI Leeds. MSI employed these doctors on a full time and 0.8 WTE contract to work across the Leeds and Manchester centres and to carry out remote services, including clinical assessment, signing of HSA1 forms and prescribing for EMA. Anaesthetists were employed on a sessional basis.
- There were no vacancies for medical staff and surgeons working at other MSI centres provided cover if necessary. There had been no locum / agency use in the three months prior to the inspection.
- MSI corporately employed other doctors to work remotely to undertake clinical assessment of patients' case notes and medical histories prior to signing HSA1 forms and prescribing of medical treatments.
- Nursing and midwifery staff told us that if they needed any clinical advice regarding a patient they were always able to contact a remote doctor on duty.

Major Incident awareness and training

- There were national and local contingency plans in place, such as fire or loss of utilities. Fire plans were visible in clinical areas.
- Records showed that all staff had received training in fire safety and took part in fire drills every six months, the latest one being July 2017. Two members of staff had been trained to act as fire wardens.
- The main risk was IT failure that could prevent remote clinical assessments, prescribing and signing of HSA1 forms. Staff were aware of the need to escalate this immediately to ensure an alternative solution was put in place quickly.

Are termination of pregnancy services effective?

Evidence-based treatment

- All places holding a valid termination of pregnancy (ToP) licence issued by the Department of Health are required to follow required standard operating procedures (RSOPs). The Department of Health RSOP 10: professional guidelines states that providers should have regard to authoritative clinical and professional guidance and professional opinion such as that provided by relevant Royal Colleges. Guidelines published by the Royal College of Obstetricians and Gynaecologists (RCOG), Royal College of Nursing, and National Institute of Health and Clinical Excellence (NICE) are key resources to aid good clinical practice in ToP, based on published evidence. We saw that reference was made to these documents in staff guidelines and local standard operating procedures. We saw from minutes of regional and local meetings these were monitored and adhered to.
- RSOP 16 Performance standards and audit recommends that all providers should have clear locally agreed standards against which performance can be audited – and that are guided by appropriate national standards. At our previous inspection in 2016, we saw some out of date policies that required updating.
- Staff showed us policies and guidelines were easily accessible via the staff intranet, these were up to date and had been reviewed by relevant clinical staff.
- Staff told us that updates of policy changes and reviews were communicated via the interim chief nurse newsletters and we saw evidence that this happened.
- Patients were offered a choice of procedure within appropriate timeframes, processes were in place to support patients with options for future contraception

and screening for sexually transmitted disease was available. This was in line with National Institute for Health and Care Excellence (NICE) and Royal College guidelines.

- Medical abortion medicines must currently be administered in a service or centre that is registered to provide abortions. Therefore, patients must attend a centre for both stages of the treatment and were not able to take the medicines at home. In all of the records we looked at, there was evidence that this happened, and we saw this to be the case with all of the patients who attended on the days of our inspection.
- The service worked within the requirements of RSOP 13 'contraception and sexually transmitted infection (STI) screening', which states that providers should be able to supply all reversible methods of contraception, including long acting reversible methods (LARC) which are the most effective. All patients should be offered testing for chlamydia, offered a risk assessment for other STIs (e.g. HIV, Syphilis etc.), and tested as appropriate. The service offered all patients attending MSI Leeds a chlamydia screening test. Patients were also offered testing for other STIs but this was dependent on the contract agreement with each clinical commissioning group.
- Patients were offered a choice of medical termination or surgical termination, using vacuum aspiration, under conscious sedation if they did not want to receive a general anaesthetic. Early medical terminations were offered up to nine weeks and four days gestation and surgical termination of pregnancy was offered up to 18 weeks and six days gestation.
- In terms of medical abortions, the provider offered a number of treatment options. Medication could be administered at the centre in two stages with six hours, 24 hours, 48 hours and 72 hours in between each stage. At the time of our inspection, the service was not carrying out simultaneous administration.
- Staff told us that new policies or guidelines were cascaded to them via email and we saw that updates were outlined in the corporate bulletin. Clinical policies regarding TOP were in line with Royal College of Obstetricians and Gynaecology (RCOG) guidance.
- All patients undergoing medical abortion were asked to ensure that a pregnancy test was completed three weeks after their treatment to ensure it had been successful. Patients were asked to contact the MSI aftercare line and were invited back to the treatment centre if they had a positive pregnancy test.
- The RCOG recommends that patients have access to a 24 hour post procedure counselling service following termination of pregnancy. Patients were asked to contact the One Call centre where counselling services were provided by trained counsellors who held a Level 4 Diploma in counselling, and were members of the British Association for Counselling and Psychotherapy. MSI counsellors were required to have knowledge and experience of various cultures and religious beliefs.

Nutrition and hydration

- Water was available for patients in the waiting areas.
- Patients were given information when necessary about when to stop eating and drinking prior to surgery and understood the reasons for this.
- Staff gave patients tea and biscuits or cold drinks in the recovery area following their surgical procedure.

Pain relief

- Pain relief was administered in the centre and recorded on the medicines administration records.
- All discussion about pain and the effect of pain relief was documented in the patient's notes.
- We saw that nurses gave patients good information and advice regarding what to expect post treatment and how to alleviate pain. This included advice regarding suitable medications that patients could purchase.
- Analgesia was given prophylactically (to prevent or minimise pain) pre-operatively to patients of more than 15 weeks gestation. These patients were also given medication to soften the cervix in line with policy prior to their procedure.
- Patients who underwent surgical abortion were routinely prescribed co-codamol and oramorph if needed for the immediate post-operative period.
- We observed nursing staff asking patients about pain in the second stage recovery area.
- We observed nurses administering pain relieving medicines and giving warming packs to patients to help relieve abdominal cramps.
- We saw that local anaesthetic was given to patients prior to contraceptive implants being fitted.

Termination of pregnancy

- The service was rated as third best MSI centre in England for pain scores during vasectomy procedures and 89% of patients had recorded their pain level as low.

Patient outcomes

- The RCOG recommend information about the outcomes of patients' care and treatment is routinely collected and monitored. RSOP 16 Performance standards and audit recommends that all providers should have clear, locally agreed standards against which performance can be audited, with specific focus on outcomes and processes. We saw these were in place and that information showed that the intended outcomes for patients were being achieved.
- We asked for evidence of any benchmarking against Department of Health (DH) statistics or reports regarding waiting times for treatment, RCOG recommended audits include pathways of care, information provision, pre-abortion assessment, abortion procedures and care after the abortion.
- Results were collected centrally for benchmarking; managers told us units were benchmarked across MSIUK and against DH statistics.
- The provider monitored and audited outcomes, which were presented through the quarterly quality assurance meetings. Senior staff shared with us the standard agenda template, which included sharing of learning and effectiveness of the service. Regional management meetings included centre updates, which included audits, incidents and lessons learned.
- The service routinely monitored and reported on the outcomes of; evacuation of retained products following medical termination , evacuation of retained products following surgical termination, haemorrhage, uterine perforation , continued pregnancy following medical termination and continued pregnancy following surgical termination . Staff told us that they monitored outcomes and entered all clinical complications as incidents through the incident reporting system.
- The service had specification agreements and performance standards in place with the clinical commissioning groups (CCGs). There were targets for waiting times, STI testing and the uptake of long acting reversible contraceptives (LARC). The service also reported any instances of ectopic pregnancy to the commissioners.
- Long Acting Reversible Contraception (LARC) data was collected on a monthly basis and was provided to the commissioners on a quarterly basis to demonstrate uptake of implants, Long Acting Reversible Contraception (LARC) methods included implants and intrauterine devices or system (IUD/S)). Uptake was poor and did not exceed 38% from March 2017 – June 2017. For March and May the service performed better than the MSI national average but worse than the national average for April, June and July 2017, with performance dropping to 19% in July 2017 against the service target of 50%.
- We observed nurses discussing contraception options with patients at their initial assessments and encouraging patients to make a plan for contraception after their abortion. Staff recorded this plan in the patient's consultation notes and doctors prescribed the correct medication after checking the patient's medical history. Therefore, we observed patients were provided with the contraception of their choice before leaving the centre or choosing to make their own arrangements.
- Choices of contraception included long acting reversible contraceptives (LARCs) such as injections and implants or Intrauterine devices or systems (IUD/IUS). Nurses at the satellite units told us they would administer a depot injection (a contraceptive injection, lasting twelve weeks) prescribed by the doctor, if a patient wanted this following the second stage of treatment for a medical abortion. Those wanting other LARCs could make an appointment at the Leeds centre or use their usual contraceptive service.
- The service performed a monthly audit of sexually transmitted infection screening, MSI Leeds screened between 74% and 98% from March 2017 to June 2017; this was above the provider's target of 70%. April and May 2017 performance was worse than the MSI national average but March, June and July 2017 performance was better than the average performance.
- There were six unplanned returns to the treatment room from June 2016 to May 2017, which were all due to retained clots or haematoma. All of these issues were reported as incidents and resolved at the centre.
- From June 2016 to May 2017, there were nine incidents of retained products of conception and eight incidents of ongoing pregnancy/ failed procedure.

- The treatment centre kept a record of all patients that were referred to NHS hospitals with suspected ectopic pregnancy. Staff actively followed up the outcomes for these patients by direct communication with the early pregnancy assessment unit (EPAU) or with the patient.
- There were three emergency transfers from MSI Leeds in the 12 months before the inspection. There were no particular themes or trends.
- MSI Leeds took part in local audits which managers told us were used to identify best practice and areas of improvement. The annual audit programme identified planned audits and actions with time frames.

Competent staff

- RSOP 18: Staffing and Emergency Medical Cover: states that providers should ensure there is a sufficient number of staff with the right competencies, knowledge, qualifications, skills and experience to safeguard the health, safety and welfare of all who use the service and meet their routine and non-routine needs.
- Data submitted showed 100% of nurses had current registration with the Nursing and Midwifery Council (NMC) and 100% of doctors had current registration with the General Medical Council.
- We saw in patient records and from observations during our inspection, that assessments and treatments in relation to ToP were carried out by medical staff or nursing staff who had successfully completed most of their required training and assessment and who had appraisal and supervision.
- However, nursing staff told us they had not all completed training updates in contraception.
- Ultrasound scanning was undertaken by staff who had received initial training in scanning. Due to previous concerns, the ultrasound internal training programme had been changed to being provided by a qualified external sonographer delivered in line with the requirements of MSI policy specifically to only date pregnancy.
- There was an internal ultrasound competency framework in place. This was co-ordinated by the lead scanning trainer for MSI, supported by a regional scanning mentor. Staff were required to perform a certain amount of scans before they were competent and had a scanning mentor assigned throughout their training
- The ultrasound policy stated that staff must attend a minimum of two days continuous professional development every three years. Information provided showed that seven members of staff at MSI Leeds had completed the ultrasound training. Managers stated that ongoing competency was assessed monthly with assurance via a monthly audit to evidence that 30 images had been successfully completed, Should staff not complete these requirements, they would be subject to further assessment of competence by the scan mentor before resuming unsupervised practice.
- RSOP 13 states that providers contraception and sexually transmitted infection screening RCOG guidelines 'Care of women requesting induced abortion guideline 6 recommends a regular audit of the number of staff competent to provide methods of contraception and the availability of staff.
- Although we had raised concerns at the last inspection that contraception training was not included as part of required training on the training matrix this was still classified as optional training. Advice and discussion of contraception methods, including oral contraception, was a fundamental part of every patient consultation and staff had previously told us they felt they had not had sufficient training regarding contraception. The skills matrix indicated that none of the staff had received any contraception training in the last five years. However, following the inspection all consultation staff attended a contraceptive update delivered by the contraception and sexual health (CASH) lead nurse on 2 October 2017.
- Information provided following inspection was that since July 2016 MSUKhas moved away from an'in house' certification to train and accredit staff to fit contraceptive implants. The organisation now supports nurses to undertake the training for the Letters of Competence in subdermal implants (LoC SDI). There is no statutory requirement for staff to have the LoCs but it is considered best practice and many commissioners are requiring this in their contracts. Marie Stopes UK had a team of Faculty registered Trainers (FRTs) who hold the qualification to allow them to deliver this training.
- There were national competency frameworks in place for RNs and HCAs and all staff told us they were assessed against these before being able to carry out unsupervised practice. Competency based frameworks were used for a wide range of procedures, such as taking and recording of observations, patient consultation, scanning, point of care testing and taking consent.

- For new staff, an induction and training programme was in place where competencies were assessed with mentor support and supervision. We were told, all new staff worked as supernumerary until assessed as competent in their role.
- We observed a number of consultations and treatments, by both HCAs and RNs, and saw that staff were competent and knowledgeable about the care they provided. Staff discussed treatment options, provided information about risks and complications and described what to expect.
- Staff told us they received clinical supervision and the clinical team leader confirmed they had received training to support this.
- Data from June 2016 to May 2017 showed that at the Leeds centre 100% of medical staff, 100% of nursing staff and 100% of administrative staff had received an appraisal.
- Staff were encouraged to access training when they identified a skills gap through supervision or the appraisal process. At our last inspection, some staff had said they found it difficult to complete training due to staff vacancies as this made finding cover for training difficult. At this inspection, we found this had improved. Not all vacancies had been filled but staff told us they could make time to attend training.
- Managers told us that incident, complaint and complication data was used to inform medical appraisal and revalidation. Medical staff we spoke with told us they had an annual appraisal as part of the GMC revalidation process. Appraisal and continued personal development rates were published monthly and monitored by the central management team at provider level (MSI UK). Evidence submitted during the provider inspection at MSI in February 2017 demonstrated 100% compliance.
- There were link nurses in the centre who could give advice regarding contraception, safeguarding, risk assessments and infection prevention and control.
- Training information showed that 100% of nursing staff working in the treatment room had undergone anaesthetic & recovery training that was refreshed every three years. The anaesthetist we spoke with told us they were advanced life support trained and that this was up to date.
- Staff working in the treatment room environment told us all registered nurses working there were trained in immediate life support.
- The agency ODP told us they had anaesthetic training and treatment room experience. They told us they worked at MSI regularly, had completed an induction, and were familiar with and able to fulfil the requirements of their role.

Multidisciplinary working

- Medical staff, nursing and midwifery staff and other non-clinical staff worked well together as a team and respect for each other's roles was evident in the observations we made. We saw that there were clear lines of accountability for doctors, nurses and HCAs.
- Doctors told us that clinical meetings now included sessional doctors and anaesthetists and that this was a welcomed improvement aiding sharing of good practice and improving networks and support.
- Communication with the patient's GP only happened with the patient's consent.
- Staff told us they could seek medical support and advice when needed. If doctors were not on site, staff could go to the electronic record system where they could have an online discussion with a doctor regarding suitability for EMA. Nurses and doctors could also contact each other by telephone if they needed to discuss a patient in detail. Staff told us that the medical staff were easy to contact through these systems and responded to requests for advice quickly.
- Managers and specialists were available at the end of the phone if staff needed help or support with other issues such as safeguarding or infection prevention and control. Staff told us they found it easy to access any help needed and specialists and managers were responsive and supportive.
- Staff told us that they knew how to contact and refer patients to other agencies and services such as the local safeguarding team. Staff gave examples of having made referrals to children's safeguarding services and to the women's refuge.
- Staff told us there were good relationships with the early pregnancy centres in the area.
- Counselling was available through a 24-hour helpline.

Access to information

- Patient notes were mainly electronic and staff could access them from any MSI registered premises. This

ensured patients had a single contemporaneous record and facilitated effective management of care and treatment as well as making it easier to track any safeguarding issues.
- Staff were able to access diagnostic tests/blood results in a timely manner.
- RSOP 3 states that, on discharge, women should be given a letter that includes sufficient information about the ToP procedure to allow another practitioner to deal with any complications and ongoing care. Discharge letters were generated and printed for patients to take with them to share with their GP if they wished, or emergency services should this be required. In the records we reviewed, we saw copies of discharge letters were stored and that sufficient information was included.
- Minutes of meetings, newsletters and other corporate information was accessible through the staff intranet.

Consent, Mental Capacity Act and Deprivation of Liberty

- All staff, we spoke with or observed, were familiar with the importance of consenting patients before any treatment. Staff we observed and a review of records confirmed that staff adhered to RSOP 14 and RCOG Guidelines 'Care of Women Requesting Induced Abortion (2011). These guidelines highlight that: "all women attending an abortion service will require a discussion to determine the degree of certainty of their decision and their understanding of its implications as part of the process of gaining consent. Careful and sensitive enquiry as to the reasons for requesting an abortion should be made, with the opportunity for further discussion, especially where women express any doubts or suggestion of pressure or coercion".
- All staff had received training regarding informed consent and capacity within the last 12 months.
- We observed that staff took verbal consent before scanning and point of care testing and took written consent for medical and surgical treatments.
- Consent forms were pathway specific and listed all possible complications for the treatment the patient had agreed to. The forms acted as a prompt sheet for staff, ensuring they discussed all complications and risks.
- Staff we spoke with were aware of the requirements of consent and information sharing to safeguard young people and vulnerable adults. They knew what to do if a patient lacked capacity.
- We saw that staff discussed risks and complications and gave patients the opportunity to ask questions before they asked the patient to sign their consent.
- We saw nurses carrying out medical treatments and staff in the treatment room re-checked consent prior to any treatment, procedure or anaesthetic starting.
- We saw that the anaesthetist and surgeon checked the patient's records and consent form as the patient entered the treatment room. Staff in the treatment room checked the consent form and signature with the patient and the surgeon verbally confirmed the procedure with the patient.
- We observed the anaesthetist taking verbal consent for the use of rectal analgesia.
- Staff we spoke with said that if females under the age of 16 years attended, they were encouraged to involve a parent or guardian, and that staff applied the Fraser guidelines for checking rationale and understanding when obtaining consent from girls under the age of 16. Fraser guidelines are used specifically to decide if a child can consent to contraceptive or sexual health advice and treatment.
- Information was available in folders in the waiting areas for young people regarding Gillick competence; this guideline is used by staff to help assess whether a child has the maturity to make their own decisions and to understand the implications of those decisions.
- There was access to guidance and policies for staff to refer to concerning Mental Capacity Act (MCA) and 100% of staff had received training.
- All care records we reviewed contained signed consent from patients. Possible side effects and complications were recorded and the records showed that these had been fully explained.

Are termination of pregnancy services caring?

Compassionate care

- We saw that doctors and nurses in the treatment room introduced themselves to patients and were kind and compassionate. They gave full explanations of what was to happen and gave reassurance regarding the

procedure and post-operative recovery and pain relief. We observed staff interactions with patients undergoing medical termination or vasectomy, and those close to them at satellite sites.

- We saw how staff involved and treated patients with compassion, kindness, and respect, maintaining dignity at all times and how they communicated at patient level to minimise the risk of conversations being overheard.
- At our previous inspection in May 2016, we were concerned that surgical patients did not have full access to privacy and dignity when being cared for in the treatment room and recovery areas and observed a number of occasions when dignity was not maintained. At this inspection, we saw that surgical patients' privacy and dignity were maintained when being cared for in the treatment room and recovery areas.
- At our previous inspection in 2016 we had observed patients having surgical procedures were placed in the lithotomy position (their legs were raised and placed in stirrups) prior to sedation or anaesthesia being given. Patients had complained about this process but, at the time, no action had been taken to change it. However, at this inspection, we observed staff ensured dignity was maintained at all times by providing a suitable sheet to cover exposed areas and by explaining to the patients what would happen. The centre had received no further complaints relating to privacy or dignity.
- We observed staff using privacy screens for a patient who felt nauseous and requesting that the anaesthetist review the patient with a view to giving an antiemetic (anti-sickness medication).
- The service staff routinely asked patients to complete feedback questionnaires and managers told us they regularly achieved a good response rate. Figures provided by the service showed that the response rate for Quarter 3 in 2016 was only 34%. However, this improved to 75% for Quarter 4 of 2016 and 67% for Quarter 1 in 2017.
- The service set a target of 95% for client experience rates and overall care. External reports showed for overall care the service achieved 97% in Quarter 3 of 2016, 96% in Quarter 4 of 2016 and 95% in Quarter 1 of 2017. However, in Quarter 1 of 2017 the responses around the way patients felt they were treated by staff for their consultation dropped from a satisfaction rate of 92% to 74% and satisfaction about their treatment dropped from 90% to 70%. Other responses remained static, or had improved which ensured the overall satisfaction rate remained at target.
- The centre had access to the same information for vasectomy patients, which showed that overall 100% of patients were satisfied with the service they received and 100% would recommend the service to others.
- Staff told us that patients' preferences for sharing information with their partner or family members were established, respected and reviewed throughout their care.
- The vasectomy treatments were held on a separate day to the termination of pregnancy treatments, this ensured that males and females did not meet during their treatments.
- We observed staff in the recovery areas asking patients about their comfort and needs.
- Patients and relatives we spoke with were impressed with access to the service and the support given by all staff.

Understanding and involvement of patients and those close to them

- Staff told us, and we observed during the initial assessment with a patient, staff explained all the available methods for termination of pregnancy that were appropriate and safe, to patients. The nurse or HCA considered gestational age and other patient needs whilst suggesting these options. Staff gave information booklets to all patients, including vasectomy patients. They explained side effects and complications of treatments and patients were given the time to ask questions if required. Staff reminded all patients they could use the 24-hour helpline.
- Staff told us patients could attend for counselling only and that they may change their minds or use another service if they wanted a different procedure for example if a patient preferred a surgical termination or if they needed a later termination.
- We observed six consultations for termination of pregnancy and saw that staff informed patients that details of their termination procedure would be provided to the Department of Health. Staff told us that patients were all made aware of the statutory requirements of the HSA4 forms and were informed that the data sent to the Department of Health for statistical purposes was anonymised.

- We observed staff giving patients undergoing vasectomy information before, during and after their procedure. Staff explained what was happening at all times and what to expect in terms of pain and how to alleviate or prevent as much pain and bruising as possible during their recovery in the centre and at home. They stressed the importance of rest and personal hygiene to prevent any complications including infection.
- Staff provided termination and vasectomy patients' partners, and those supporting them, with non-confidential information should they require it. Staff spoke to people face to face or signposted them to on line information. Staff explained to us that their priority was always the decision of the patient.
- Staff told us, and we observed, younger patients were encouraged to involve their parents or family members and their wishes were respected.

Emotional support

- We observed staff following procedures to provide a caring, confidential and non-judgemental service.
- A patient told us staff were supportive and gave explanations at every step of the pathway, which was very reassuring.
- All patients were offered a telephone consultation and assessment prior to their treatment through the Marie Stopes telephone appointment line "One call". Some patients opted to have a face to face consultation, which was organised before any treatment was undertaken. A telephone counselling service was available pre and post-procedure and a patient information leaflet stated that MSI could arrange counselling or suggested, if they preferred, a patient's GP could recommend a counsellor.
- We observed nurses encouraging patients to call if they had any concerns or questions before or after their treatment. They gave patients the service telephone number at the satellite unit with details of when the Leeds centre was open to take a call, as well as the main Marie Stopes information line for calls at other times of day or night.
- We saw records for a patient who had undergone a vasectomy and had returned to the unit two weeks after their treatment due to concerns and pain. Notes made by both the nurse and the doctor showed the patient had been listened to, examined and reassured. The doctor had prescribed antibiotics and encouraged the patient to telephone the advice line should they have any further concerns.
- Counselling was offered to all patients pre- and post-treatment, but patients aged less than 16 years of age were required to have a counselling appointment on a day prior to their treatment.
- Nurses told us that all patients under 18 years old received telephone counselling when they attended for their consultation and in the presence of the nurse. Managers told us this was in line with MSI policy and the under 18 patient pathway.
- Staff told us that if they felt a patient was unsure about their decision, they would encourage them to use the counselling service and re-booked appointments to ensure the patient had time to come to a firm decision before they went ahead with any treatment.
- All patients were offered a private consultation to establish whether they felt safe at home and to identify any pressure put upon them by a partner, friend or parent.
- All patients under the age of 18 years were encouraged to bring a companion for first treatment and were told that they must bring an escort for second stage to ensure they got home safely. Staff told us that they also encouraged all patients to bring an escort for the second part of their treatment.
- The records we reviewed recorded the post discharge support offered to patients and those close to them. We observed staff gave vasectomy patients written information about accessing help from the staff at the unit during service opening hours and the 24-hour telephone service following their procedure.

Are termination of pregnancy services responsive?

Meeting the needs of local people and individuals

- In accordance with Department of Health guidance, service planning was managed by a business development team in discussion with clinical commissioning groups (CCGs). Treatment was carried out under NHS contracts with Leeds, Bradford, Wakefield, North Yorkshire and York, Huddersfield, Calderdale and North Kirklees, and CCGs to provide a termination of pregnancy and vasectomy service for the patients of West Yorkshire and surrounding areas. Self-funding patients were able to self-refer.

Termination of pregnancy

- Since our last inspection in 2016, the centre had won an additional contract to provide a vasectomy unit in Middlesbrough and Stockton and had ceased providing one satellite early medical abortion unit (EMU) service in South Shields.
- Staff told us some referrals to the centre were made because of local NHS services waiting times being too long, for example, where a patient's estimated gestation was over 12 weeks. This was to ensure women could be treated before their gestation exceeded the limits for treatments available through Marie Stopes centres and the legal limits for abortion.
- MSI Leeds centre appointments were offered to women seeking abortion on Mondays and Thursdays each week and to men for vasectomy on Fridays. The satellite clinics were each open one or two days a week. Nursing staff and surgeons rotated between the Leeds centre and the satellite clinics.
- We observed no long waiting times in clinics and some staff told us they had fewer concerns about patient waiting times. New appointment time calculations ensured patients under the age of 18 and those requiring interpreters were allocated 45 minute appointments rather than the standard 15 minutes. Staff told us they did not feel as rushed as previously but would always want to be able to spend more time with patients.
- Satellite clinics were located in single rooms or suites, mostly within primary care centres. Accessible toilets were provided at the sites we inspected.
- At our previous inspection in 2016, we visited the satellite unit at Huddersfield, which was located on the second floor of an old building. At that time, we raised concerns then that there was no information provided to patients or booking staff that this location had no lift and was not easily accessible for patients with poor mobility, or for mothers with babies and buggies. We saw that this information was now published on the website and patients were informed of access difficulties.
- Patients were able to choose their preferred treatment option and location, subject to their gestation and medical assessment. If patients needed to use services on days when the main centre was closed, they could use alternative MSI satellite clinics in Yorkshire or further afield. Patients who wanted or needed weekend services could use the Marie Stopes centre at Manchester. If treatments were in two parts, staff worked to provide appointments at other satellite clinics or regional centres to provide patients with more flexibility.
- If Marie Stopes Leeds centre could not offer the treatment the patient had chosen, staff helped them to decide where, when and how they could access the treatment they required. We observed nurses making appointments for patients at other Marie Stopes clinics and providing directions to them. We also saw examples where staff had made referrals to other independent abortion services and to the NHS to support the individual needs of patients, especially those with later gestation.
- There was a female doctor available at the Leeds service, if patients directly expressed a wish to see a female doctor, they could be booked for the appropriate list.
- Service level agreements were in place with local laboratories for screening and blood testing if needed. Staff carried out point of care blood testing for haemoglobin (iron levels) and rhesus status during consultations.
- Staff told us that very occasionally patients with complex needs or particularly vulnerable groups such as very young patients had used the service. When this happened, a friend or relative could accompany the patient to help ensure the patient fully understood the treatment. Depending on the wishes of the patient, the friend or advocate could stay with the patient throughout treatment and examinations, following their private consultation.
- A professional telephone interpreting service was available to enable staff to communicate with patients for whom English was not their first language. However, during our treatment room observation we noted a patient who did not speak English and the staff had great difficulty in completing the surgical check list and checking the consent. The patient had previously completed a consent form in their own language during their consultation, using the telephone service.
- Staff told us that patients were signposted to information to access online during their telephone consultation and we observed nurses in the clinics giving information leaflets to patients about different options available for termination of pregnancy. This information included what to expect when undergoing a surgical or medical termination, details of potential

risks, counselling services and sensitive disposal of pregnancy remains. Information in different languages was available on the MSI website through a translation application and staff said they would inform any patient who did not read English about the site.

- Staff undertaking pre-surgical and medical abortion assessments had a range of information to give to patients. There was also a range of leaflets and posters displaying information, easily accessible within waiting areas and consultation rooms. This included advice on contraception, sexually transmitted infections and services to support patients who were victims of rape or domestic abuse.
- Staff provided men undergoing vasectomy with comprehensive information leaflets regarding what to expect, the procedure and aftercare. All patients undergoing vasectomy, who completed the MSI questionnaire, evaluated the information given as either very good or excellent.
- There was a patient information file in the waiting area at each location we inspected. These files contained a range of information about local patient services including drop in services, counselling, and other support services about abuse, relationships and bullying.
- The centre provided vasectomies once a month on Fridays at the Leeds centre or one of the satellite units. There were no other clinics held on those days so men and women would receive their treatment separately.
- Men could attend the Leeds Centre, the Wakefield unit or satellite units in Middlesbrough and Stockton for vasectomy and to follow up concerns if they could not be alleviated by the call centre.
- We spoke with patients undergoing vasectomy who told us they had received useful and clear information online, from staff and in booklets given to them.
- Leaflets included information on what to expect following procedures and the advice line number that patients could telephone to seek any advice if they were worried.
- MSI staff told us, if requested by patients whose STI results were positive, they would make anonymous contact calls to their previous partners to encourage them to be tested.
- The disposal of pregnancy remains followed the Human Tissue Authority Code of Practice and the Management of Foetal Tissue Policy described the standard.
- An external company undertook the disposal of pregnancy remains following surgical terminations of pregnancy according to the Code of Practice, unless a patient expressed a personal wish for any other method of disposal.
- MSI stored the pregnancy remains in a sealed receptacle in the clinical specimen freezer until the clinical waste contractor collected the pregnancy remains. When the service needed to keep pregnancy remains, for example for DNA testing or criminal investigation, the policy stated that staff must use new equipment and a separate storage container. The contents needed to state the patients name, MSI number, date of birth and date of procedure. Any non-standard disposal option had to be documented in the patient's record and on a freezer log sheet indicating the reason for keeping and date for either collection or disposal. Where products were not collected, the patient would be contacted to ask for further instruction or a decision made to dispose of their pregnancy remains after three months.
- Staff told us that no patients to date had requested a change to wording used in summary disposal of pregnancy remains.
- Posters were displayed in the centre about domestic violence and counselling.

Access and flow

- Patients aged 13 years and over could refer themselves or be referred into this service through traditional referral routes such as their GP or a sexual health clinic.
- Staff at the telephone booking service carried out an initial consultation and offered patients a choice of dates, times and locations. This ensured patients were able to attend the most suitable appointment for their needs, subject to their gestation and clinical assessment.
- When a decision to proceed was made, One-call made an appointment for the patient at one of the clinics for further consultation, assessment and treatment. This was often on a separate day but MSI Leeds could offer treatment later in the same day subject to a full medical assessment and legal procedures being carried out.
- If a patient's gestation was later than 18 weeks with no other concerns, they would be booked into the MSUK Manchester centre that has facilities to treat patients up to the legal limit. If the consulting nurse had any

concerns about a patient's medical condition or history, or if there was a suspicion of an ectopic pregnancy, they referred the patient to a local NHS acute hospital for further assessment and treatment.

- Department of Health Required Standard Operating Procedures state that patients should be offered an appointment within five working days of referral and the abortion procedure should be carried out within five working days of the decision to proceed. The service monitored its performance against the waiting time guidelines set by the Department of Health and the total time from access to procedure never exceeded 10 working days in the 12 months from June 2016 to May 2017, which met national guidance.
- Audits relating to the MSI Leeds centre showed 100% were within the time limits of five days from initial referral to consultation and a further five days from consultation to treatment. The MSI Quality Accounts for 2016 to 2017 showed a target of five days and staff told us if patients were treated outside of the guidelines this would be due to patient choice such as patients who were undecided on whether to proceed.
- When demand peaked and waiting times were likely to exceed recommendations, the service could provide additional appointments at the Leeds centre or by providing a service on a Saturday.
- When attending the MSI clinics for medical or surgical treatment, following the initial telephone consultation, patients had a 15-minute appointment. Patients under the age of 18 years were given a 45-minute appointment to allow additional time for safeguarding checks.
- Appointments involved confirmation of pregnancy gestation by ultrasound scan, observations and point of care testing for rhesus status, sexually transmitted infection screening (if required), discussion of treatment and consent, booking an appointment for treatment, administration of medication and discussion and, or administration of contraception.
- Staff told us they felt that although they had additional time to see some patients, they would always benefit from further flexibility and time to spend with individuals. However, they did accept there would have to be limits set so that all patients could be seen on time.
- We observed that staff always gave patients time according to their individual needs and that appointments were not rushed.
- At our previous inspection, we noted there could be delays and long waits for patients following their initial consultation with a nurse or HCA, for a medical opinion or prescription from one of the doctors working remotely. Staff told us at this inspection the on line system flagged patients waiting and doctors were able to complete checks or prescriptions quickly and staff working together reduced delays.
- Staff told us they referred patients to the do not proceed (DNP) team if staff were unable to detect an intrauterine pregnancy, the pregnancy exceeded the 9 weeks and 4 days early medical abortion (EMA) limit, or if the patient was uncertain about their decision.. The DNP team was a central team that would arrange further appointments, counselling or treatment for the patient concerned. This included arranging follow up appointments, or appointments or treatment at other MSI clinics or NHS services where necessary.
- The MSI target for DNP was 15% or lower and figures for the MSI Leeds centre collected between March and July 2017 ranged between 14% and 26%. Staff told us the decision to proceed with a termination was entirely the choice of the patient but could sometimes be due to a later gestation confirmed by ultrasound scan.
- If nurses found that patients appeared to be uncertain about their decision, they were advised to take time to consider their options before rearranging an appointment.
- Patients had access to a 24-hour aftercare telephone line serviced by registered nurses trained to assess clients over the phone and provide advice. Clients could be booked back into the centres for further assessment if required or signposted to emergency services if necessary.
- Patients we spoke with told us the service was very easy to access.

Learning from concerns and complaints

- There was a complaints policy with clear responsibilities for all staff and managers. The operations manager recorded and investigated all complaints arising from patients at their centre and complaints were discussed at Central Governance Committee meetings. Managers forwarded written complaints to the Head of Quality and customer services, who acknowledged them all. Staff monitored progress through the complaints action plans on a monthly basis.

Termination of pregnancy

- We observed there was information on how to complain or raise concerns in a patient information folder in each clinic. New posters displayed this information on information boards or walls in the Marie Stopes satellite clinics we visited.
- The Marie Stopes website gave information on how to provide feedback or make a complaint.
- A record of informal and formal complaints was maintained as part of the electronic patient safety system. Complaints were investigated locally and escalated to the MSI UK executive management team if local resolution was not achieved.
- The local Leeds centre complaints action plan showed discussion of complaints at local governance meetings and managers told us that lessons were learned and shared across all centres.
- The service had received six formal complaints in the 12 months prior to our inspection. We reviewed all six complaints and found they had been investigated appropriately and actions had been taken where necessary. All actions met timescales laid down in the complaints policy. Only one complaint was upheld and this resulted in an action plan regarding anti D immunoglobulin being given.
- The service told us and staff confirmed the regional clinical operations manager shared lessons learnt with staff.
- A verbal concerns log showed six informal complaints had been raised between April and June 2017. Five out of six informal complaints had been resolved and the MSI Leeds team had given the most recent caller advice on making a formal complaint. There were no particular trends or patterns identified.
- Patients were encouraged to raise issues with staff and through patient feedback questionnaires. If a patient indicated less than a 'very good' response or documented a particular issue, a record of this was sent to the centre management team. Managers communicated positive and negative feedback to staff through team meetings and shared the feedback reports with the team on publication.

Are termination of pregnancy services well-led?

Leadership and culture

- The Marie Stopes, Leeds centre was last inspected, in May 2016 and CQC undertook enforcement action, following an inspection of the governance systems at the MSI corporate (provider) level in late July and August 2016. There were some breaches in regulation that were relevant to this location, which we have followed up as part of this inspection. The breaches were in respect of:
  - Regulation 17 Systems or processes must be established and operated effectively to ensure compliance with the requirements in this Part. (Good governance)
  - Regulation 20 of the Care Quality Commission (Registration) Regulations 2009.
- Staff told us the findings of the last inspection had been taken on board throughout the organisation and many improvements had been made. They told us the pace of change had been very fast but the changes were welcome. Staff were aware that not all of the required national improvements had been fully actioned yet and that changes were ongoing and were being rolled out.
- At this inspection, we could see the positive effect of high level management changes and new policies having been put into practice. Staff and managers at the Leeds centre told us they felt previous MSI policies and procedures had not supported staff to meet patient needs and follow clinical best practice. They told us that new MSI policies reflected good practice and they felt better supported corporately.
- The leadership team at the MSI Leeds centre consisted of a regional director, a newly appointed senior service delivery manager and a regional clinical operations manager.
- All managers worked across sites between the Leeds and Manchester centres but were present at Leeds on the days the main centre was providing treatments. However, as noted at our previous inspection, nursing and medical staff from this centre worked from Monday to Friday and some Saturdays. We found that staff who worked at satellite units could only access managers face to face when they visited or worked at the Leeds Centre premises.
- The medical director was based at MSI UK central office in Conway Street, London.
- The Leeds centre was set up as a hub and spoke model with nine satellite clinics. The regional manager was the registered manager for the Leeds and Manchester centres.

- The Leeds centre had a full-time nursing team lead that provided day-to-day supervision and support.
- Staff reported that teamwork was good and senior staff were approachable. They told us they received regular communication through team meetings and email communications.
- Staff we spoke with felt there was an open and supportive culture.
- All staff we spoke with felt the local leadership team were visible and accessible when they needed to contact them for advice or support.
- At our previous inspection, some members of staff had felt that shortages of staff and increased workloads had led to low morale. At this inspection, staff told us they felt morale was better because recruitment had improved. Staff still had to travel long distances at short notice to outlying clinics to cover short-term sickness or absence but told us they understood there were good reasons for this, especially the aim to provide the best care for patients.
- The regional manager held a local team meeting once a month at the Leeds centre to meet with staff, discuss operational issues such as patient feedback and to share information and planned developments. Although the diary was blocked out between 8am and 9am, staff told us, they were not always able to attend these meetings.
- Doctors and nursing staff told us they felt able to raise concerns or ideas, felt listened to and discussed ideas for improvements with their regional managers and professional lead.
- Staff we spoke with told us that communication and training had improved as a result of the recent management changes. For example, monthly staff meetings with a structured agenda had been introduced and face-to-face and email communication had improved.
- Staff spoke positively about the high quality care and services they provided for patients and were proud to work for MSI Leeds. They described MSI Leeds as a good place to work.
- Managers were proud of the service and staff. They told us staff were very passionate about delivering high quality care in way that was accessible to patients.
- Staff told us they were comfortable reporting incidents and raising concerns. They told us they were encouraged to learn from incidents. Staff we spoke with told us they could openly approach managers if they needed to seek advice and support.
- Nursing staff and managers told us they liked working for MSI and felt the organisation was patient focussed and generally supportive of staff.
- At our previous inspection, staff told us that the 15% 'do not proceed' (DNP) key performance indicator felt punitive at times when they received an email telling them they had exceeded this. At this inspection, staff told us they felt managers better understood this, as every referral to the DNP team was justified and made in line with MSI guidance regarding exclusion criteria, gestational dates or ambivalence.

Vision and strategy for service

- Since the appointment of an interim managing director, MSI UK had identified six objectives with deadlines to achieve defined goals by the end of 2017. These goals aimed to ensure MSI create a culture that values everyone's contribution in establishing a confident multi professional workforce to deliver patient centred quality services and financial success.
- Managers we spoke with understood the vision and strategy for the service entitled 'Fit for Future' which was introduced in April 2017. The vision and strategy had been shared with staff.
- Local managers had a clear vision for their service and operational staff also knew what developments were planned. Staff told us they were kept informed of business and operational developments.

Governance, risk, management and quality measures for this core service

- At our inspection in 2016, we found there was insufficient national managerial oversight of the service and its delivery. There was limited evidence to support the governance of clinical practice or staff involvement in policy development.
- In March 2017, a new post of regional clinical quality and governance lead had enabled improved oversight of performance. Staff said they felt it had enabled them to have formal communication about risk and governance between local, regional and national level within the MSI UK organisation.

Termination of pregnancy

- Since our inspection in 2016, a clinical forum for doctors had been established. Regional meetings were held on a quarterly basis, chaired by the MSI UK Medical director. Doctors we spoke with were positive about the forum and its direction. They said they felt better supported clinically and this had not been the case previously.
- The service kept a register of people who had undergone ToP, which was up-to-date and kept for three years. All centres, including the six EMUs held a licence from the Department of Health (DH) to undertake termination of pregnancy services in accordance with the Abortion Act 1967. The EMUs were nurse led and staffed by the centre's nursing team. MSI Leeds displayed the Department of Health certificate of approval in the waiting area of each clinic.
- We found previously that at a national level that there were poor governance arrangements. Staff and managers told us there had been a restructure of governance arrangements and this now provided clear reporting, risk management and quality improvement mechanisms. Staff and managers felt that this had led to improvements in patient safety and clinical quality.
- There was a clear governance framework which included a local integrated governance committee that fed into the corporate meetings. There was a clear committee and meeting structure, throughout the organisation, to facilitate governance and oversee risk and quality management. It was apparent from minutes of meetings that various manager, governance and team meetings occurred locally and at different levels throughout the organisation with clear escalation and information sharing processes.
- It was evident from minutes that the team aimed to ensure local manager or staff representation at all relevant meetings. Clinical governance meeting minutes followed a standard agenda to ensure all key elements of governance and risk were addressed at each meeting.
- The corporate reporting structure enabled oversight of the whole organisation in relation to key performance indicators and allowed for performance benchmarking between units.
- Managers told us that on a quarterly basis, the MSI UK governance support team produced national clinical governance reports that were shared through the central governance committee.
- The service monitored its performance against key performance indicators, which were benchmarked, using a dashboard, across all MSI centres. Local audits, assessments, activity and performance data were reported nationally. The dashboard enabled local managers to monitor their centre's performance and identify areas where performance was above or below targets. The KPI dashboard included, did not attend appointment, DNP, regional opening, start time, patient flow, LARC, STI, case mix and occupancy. The Leeds centre was usually exceeding targets relating to STI screening and start time and performing below target regarding LARC, patient flow and DNP. Staff we spoke with were aware of the centre's performance against the KPIs but felt that patient flow and DNP were targets largely outside of their control as longer appointments and referrals to the DNP team were integral to patient safety and experience.
- MSI Leeds had risk assessments in place and held a local risk register identifying current risks and mitigations in place to reduce those risks. Managers and staff at the Leeds centre knew what the top risks were for business continuity and patient safety and knew how to raise any problems that arose. Equipment and IT failure, nursing turnover and the incident reporting system were identified as the top risks, both locally and for the organisation as a whole. There were actions in place to improve recruitment and retention of staff and for business continuity if IT or other equipment failed.
- We saw from minutes that staff discussed updated actions relating to risks at local and regional governance meetings.
- The assessment process for termination of pregnancy legally requires that two doctors agree that at least the same legal grounds for termination of pregnancy are met and sign a form to indicate their agreement (HSA1 Form). Medical practitioners (including remote doctors) had access to all patient information to enable them to make an informed decision in good faith. We looked at 15 termination patient records and found that all forms included two signatures and the reason for the termination.
- We observed the process for medical abortions; two doctors working remotely in a MSI registered location reviewed the completed documentation on the electronic system following the initial consultation by One-call and the assessment by the nurse or health care assistant. If they agreed that the same legal ground for an abortion had been met, they signed the HSA1 form and one of them prescribed the treatment needed.

Termination of pregnancy

- For surgical abortions, we observed that the anaesthetist and surgeon both accessed records to clinically assess, check grounds for termination and prescribe for patients, individually, before they came into the room. HSA1 and consent forms were checked as part of the process when the patients entered the procedure room.
- The doctors at the MSI Leeds centre checked the reason for requesting an abortion carefully and told us they would reject an application if the information was incomplete or if they disagreed with the first doctor's decision. Nursing staff and doctors stated that it was rare they returned a form because of insufficient information.
- We observed that nurses checked correct completion of HSA1 forms before any aspect of treatment was initiated.
- Marie Stopes' centres completed monthly HSA1 audits to ensure and evidence compliance with DH practice. Marie Stopes Leeds centre's audits consistently showed 100% compliance with HSA1 forms.
- The Department of Health (DH) requires every provider undertaking termination of pregnancy to submit data within 14 days following every termination of pregnancy performed (HSA4 form). We saw that the anaesthetist and surgeon completed records during and at the end of each procedure. The surgeon completed the HSA4 and uploaded to DH as part of their completion of each patient's record. Staff were able to show us the process they used to assure themselves of HSA4 submission within 14 days for patients undergoing medical terminations.
- At our previous inspection, we had not been assured of HSA4 submission within 14 days for patients undergoing medical terminations. However, at this inspection records we looked at showed this process had been followed. The doctors authorised the HSA4 forms online at the DH, through a secure individual log in, and told us they submitted them within 14 days of the abortion. MSI had produced a flowchart that all staff accessed and records showed that the new system had flagged one record where a submission could have previously been missed.
- We saw risk assessments regarding lone working for clinics in commercial buildings and GP surgeries. These had not previously been individualised to specific clinics or staff where risks were greater. Staff working at the EMUs told us they had received lone worker training.

Public and staff engagement

- Patients attending the centre were able to provide feedback by completing comments cards or by commenting online on the NHS choices websites. Patients were able to visit the MSI UK website and give feedback by accessing the feedback page. This included location-specific feedback where the patients wished to comment on a specific centre.
- The centre staff told us they routinely asked patients to complete feedback questionnaires and managers told us they regularly achieved a good response rate. The target score for patient feedback was 95% and the unit met or exceeded this score for the three feedback reports between June 2016 and May 2017.
- The Quarter 2 (April to June 2017) report, shared at the Quality Assurance meeting, showed Leeds had received 12 red alerts; six relating to staff attitude, four due to delays within the centre and patients feeling they were not informed and one relating to confidentiality in the reception area. Staff told us these were shared with the whole team.
- We looked at feedback from patients who had undergone a vasectomy and we observed staff asking men to complete questionnaires following their procedures. Staff told us all patients had completed feedback forms. We saw in the last quarter 100 % of respondents said they were satisfied with the overall service and 100% of respondents also said they would recommend the service.
- The registered manager told us they monitored feedback for the centres and took action where needed.
- The service did not display information regarding service improvements or changes made because of patient feedback although staff told us they used a "You said: We did" model.
- Staff told us the service was working closely with local and national charities and working with these organisations had increased their awareness around domestic violence.
- At our previous inspection in 2016, staff told us MSI carried out an annual staff survey to establish the satisfaction of their staff. However, staff had been told centre level results were not available as staff would be identifiable. The information provided did not include a response rate for the staff survey.

- The provider informed us that a staff satisfaction survey had recently been undertaken but as this closed on the 14 July 2017results were not available at the time of our inspection.
- Staff told us although they were not directly involved in the development of policies and practice or service improvement; however, they were fully informed about any changes planned.
- Nurses, doctors and managers felt that they had a voice within the organisation.
- The regional clinical operations manager told us they felt empowered and supported to make changes where necessary.

Innovation, improvement and sustainability

- The Leeds centre had seen continued success in uptake of STI testing in comparison with other MSI Centres. Improved testing rates were achieved through a system to label patients' notes for those who were eligible for tests. This flag notified the clinician as the patient arrived. STI testing results continued to exceed commissioning and organisational targets.
- The organisation provided assisted travel and accommodation for staff that were required to cover clinics away from their usual base.
- The Leeds centre was expanding its services by offering vasectomy for men from a range of local areas. Uptake was still low but men who used the service gave 100% recommendations.

Outstanding practice and areas for improvement

Areas for improvement

Action the provider MUST take to improve

- The provider must enable all staff to complete training that is necessary for them to fulfil their roles. All relevant staff must complete timely competency-based training and updates regarding contraception.

Action the provider SHOULD take to improve

- The provider should carry out and act upon investigation and analysis of staff satisfaction.
- The provider should ensure patient feedback is consistently obtained and used to improve the service.
- The provider should continue to embed the use of termination of pregnancy early warning scores (TEWS) and regularly monitor the full and correct completion of TEWS documentation and whether patients are escalated appropriately when scores meet the threshold for escalation.
- The provider should ensure that there is a system locally for confirmation that all staff have completed mandatory training in appropriate time frames.

This section is primarily information for the provider

Requirement notices

Action we have told the provider to take

The table below shows the legal requirements that were not being met. The provider must send CQC a report that says what action they are going to take to meet these requirements.

Regulated activity	Regulation
Termination of pregnancies	Regulation 12 HSCA (RA) Regulations 2014 Safe care and treatment Health and Social Care Act 2008 (Regulated Activities) Regulations 2014: Regulation 12 Safe Care and Treatment 12.1, 2 (c) 1. Care and treatment must be provided in a safe way for service users. 2. Without limiting paragraph (1), the things which a registered person must do to comply with that paragraph include – c) ensuring that persons providing care or treatment to service users have the qualifications, competence, skills and experience to do so safely. How the regulation was not being met · Relevant staff had not received timely training regarding contraception. · Mandatory training updates were not always undertaken within the appropriate timeframe and monitoring of this was not effective