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

Ratings

Overall rating for this location

Are services safe?	
Are services effective?	
Are services caring?	
Are services responsive?	
Are services well-led?	

Summary of findings

Letter from the Chief Inspector of Hospitals

Marie Stopes International (MSI) Leeds is part of Marie Stopes International UK founded in 1976 to make family planning services available to women and men around the world. Marie Stopes is a specialist reproductive healthcare organisation and registered charity. The Leeds Centre opened in 2006.

MSI Leeds provided 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 was providing medical abortions up to nine weeks and four days gestation and surgical termination of pregnancy until 18 weeks and six days gestation. The service also carried out non-scalpel vasectomies. The service treated NHS and private patients.

We made an announced inspected of the service on 16-18 May 2016 and an unannounced inspection on 26 May 2016 as part of our independent healthcare inspection programme.

We have not rated this service because we do not currently have a legal duty to rate this type of service or the regulated activities, which it provides.

Whilst this inspection identified a number of positive factors it also identified someconcerns linked to the provider's governance arrangements[WT1].[OL2][OL3]

Due to the number of concerns arising from the inspection of this and other MSI locations, we inspected the governance systems at the MSI corporate (provider) level in late July and August 2016. We identified serious concerns and MSI undertook the immediate voluntary suspension of the following services as of 19 August 2016 across its locations, where applicable:

- Suspension of the termination of pregnancy for children and young people aged under 18 and those aged 18 and over who are vulnerable, to include those with a learning disability
- Suspension of all terminations using general anaesthesia or conscious sedation
- Suspension of all surgical terminations at the Norwich Centre

MSI responded to the most serious patient safety concerns we raised and was able to lift the restrictions on the provision of its termination of pregnancy services at this location on 7 October 2016.

CQC has also undertaken enforcement action for breaches of the following regulations, which are relevant to this location.

Regulation 12 Care and treatment must be provided in a safe way for service users.

Regulation 13 Service users must be protected from abuse and improper treatment in accordance with this regulation.

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 is actively monitoring compliance with the above enforcement action taken in order to ensure that services are operated in a manner, which protects patients from abuse and avoidable harm.

Are services safe at this service?

Staff understood their responsibilities to raise concerns and report incidents and near misses. Record keeping was of a consistently high standard and records were stored safely and securely. 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. We saw that all patients received a private initial consultation without anyone else present to safeguard against possible coercion or abuse and to give patients the opportunity to disclose such information in a safe environment.

However, we did not see evidence that local staff received regular information and learning messages from elsewhere in the organisation. Staff were trained to safeguarding adults and children level two, which was not in line with the 'Intercollegiate Document' (Royal College of Paediatrics and Child Health 2014) which recommends level three training for staff working in this type of service. At a national level we found that the in-house training provided was not tailored for the specific needs of patients seeking termination of pregnancy, or to educate and enable staff to meet safeguarding requirements of their patient group. Staff did not always follow procedures in line with medicines management policies.

Are services effective at this service?

Policies and pathways were in line with national best practice guidelines. We saw that patient assessments were thorough and staff followed pathway guidance. Records indicated that 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. We observed in consultations and records that staff always made sure patients gave their consent in writing and adhered to Fraser guidelines in respect of children and young people.

However, not all consultation staff had received training on giving oral contraception advice and dispensing. There were a number of policies requiring review and updating.

Are services caring at this service?

We observed that patients were treated with respect and compassion while they received care and treatment. Patients told us how they had been listened to, that they felt safe and were treated with kindness.

We were concerned that staff did not provide patients with full access to privacy and dignity when being cared for in the recovery area following surgical procedures. Staff did not inform patients of the requirement to submit abortion data to the DH.

Are services responsive at this service?

We found the service to be responsive to meeting people's needs and requirements. Patients did not wait longer than three days for consultations although national guidance stipulated five days, not more than 10 days in total for treatment, and were offered appointments to suit them. Options were given, if requested, on the disposal of foetal remains following the guidelines as set out by the Human Tissue Authority. 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 but there were no posters displayed or leaflets available for patients to take away with them.

Appointments frequently overran due to shortage of time for staff to carry out all procedures with each patient and to ensure that the patients were sure about their decision. Patients sometimes had to wait for long periods to be seen and for prescriptions to be provided via the remote electronic system.

Are services well led at this service?

Although there was a committee and meeting structure, throughout the organisation, to facilitate governance and oversee risk and quality management there was not a structured approach for escalation of issues or information sharing. Local manager or staff representation or attendance was not evident at all relevant meetings. The corporate

Summary of findings

reporting structure enabled oversight of the whole organisation in relation to key performance indicators and allowed for performance benchmarking between units. However, it was not clear how achievement of some indicators represented quality of service for patients. We were not assured that all HSA4 forms were submitted and authorised within the Department of Health required time of 14 days following abortion.

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. Quality of care and patient experience was seen as the responsibility of all staff. Most 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.

Our key findings were as follows:

- There were some staff vacancies and recruitment procedures were underway to increase the size of the team.
- Record keeping was good.
- Staff generally followed MSI policies and procedures.
- There was enough equipment to allow staff to carry out their duties. The service had processes in place for checking and maintaining equipment.
- Staff understood their responsibilities to raise concerns and report incidents and near misses but we were not assured that learning was shared across the organisation.
- Location staff and managers were able to verbalise what the duty of candour meant.
- Staff had not received children's safeguarding training to an appropriate level and the training offered to staff did not meet the requirements for the patient groups they treated.
- Staff were competent in their roles, received an annual appraisal and support for revalidation.
- The service had a rolling programme of local clinical audits. Managers monitored and benchmarked performance of all units across the organisation using a performance dashboard.
- The governance structure did not provide clear processes for escalation of issues or shared learning.
- A number of policies were not in line with national guidance and required review.
- Managers were supportive and the culture encouraged candour, openness, and honesty.

We saw several areas of good practice including:

- Staff were described and observed as being non-judgemental.
- Staff were responsive to the individual needs of patients.
- Staff ensured that all patients received a private initial consultation without anyone else present to protect patients against possible coercion or abuse and to give them the opportunity to disclose such information in a safe environment.
- Staff had access to a 'Do Not Proceed' (DNP) team who would arrange referral to appropriate providers for patients with complex or additional medical needs, who did not meet usual acceptance criteria.
- Although we found that staff training did not meet the requirements of patient groups, staff we spoke with knew their own role and remits for safeguarding children and vulnerable adults and had a heightened awareness of the needs and vulnerabilities of children and young people using their service.
- Completion of records was consistently of a high standard

Summary of findings

However, there were also areas of practice where the provider must make improvements. The provider must:

- Ensure that staff always follow procedures in line with medicines management policies with regard to refrigerated drugs and administration of controlled drugs.
- Review the children safeguarding training requirements for all staff to ensure the standard and level of training is in line with intercollegiate guidance 2014
- Ensure that all HSA4 forms are submitted to the DH within 14 days of abortion.
- Ensure women are informed of the requirement to submit abortion data to the DH and explain how this information is anonymised

Professor Sir Mike Richards
Chief Inspector of Hospitals

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 it. We highlight good practice and issues that service providers need to improve and take regulatory action as necessary

Summary of findings

Contents

Summary of this inspection

Page

Background to Marie Stopes International Leeds Centre 9

Our inspection team 9

How we carried out this inspection 9

Information about Marie Stopes International Leeds Centre 10

Detailed findings from this inspection

Outstanding practice 40

Areas for improvement 40

Action we have told the provider to take 41

Marie Stopes International Leeds Centre

Services we looked at
Termination of pregnancy

Summary of this inspection

Background to Marie Stopes International Leeds Centre

Marie Stopes International was founded in 1976 to provide family planning services to patients around the world. Marie Stopes Leeds Centre opened in 2006 and was part of the provider group Marie Stopes International; a specialist reproductive healthcare organisation and registered charity.

Leeds, Bradford, Wakefield, North Yorkshire and York, Huddersfield, Calderdale and North Kirklees, and South Tyneside CCGs contracted Marie Stopes Leeds to provide a termination of pregnancy service for the patients of Leeds, North and West Yorkshire and surrounding areas. The service was set up on a hub and spoke model with the Leeds centre and eight satellite clinics at Wakefield, Huddersfield, Bradford, Leeds central, Scunthorpe, Batley, Airedale and South Shields. The service also treats a small number of private patients.

The service was registered as a single speciality service for termination of pregnancy and was 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
- Surgical Abortion Local Anaesthetic/conscious Sedation
- Surgical Abortion using general anaesthetic.
- Abortion Aftercare
- Miscarriage Management
- Sexually Transmitted Infection Testing and Treatment
- Contraceptive Advice
- Contraception Supply

Our inspection team

Our inspection team was led by:

Inspection Lead: Karen Knapton, Inspection Manager, Care Quality Commission.

The team included CQC inspectors trained to carry out the inspection of termination of pregnancy services.

How we carried out this inspection

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

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

We carried out an announced onsite inspection on 16 – 18 May 2016 where we observed practice, spoke with doctors, nurses, healthcare assistants (HCAs), patients, visitors, the registered manager, clinical operations manager and the health systems director. We followed up with an unannounced visit to the Leeds Centre and South Shields clinic on 26 May 2016. We looked at the care records of 33 patients records and analysed information provided by Marie Stopes International and a range of other information.

Summary of this inspection

We inspected the main Leeds centre and five out of eight satellite clinics: Leeds Central, Wakefield, Batley, Huddersfield and South Shields. We visited the satellite centres that were open on the days of our inspection and we visited South Shields at our unannounced inspection.

Information about Marie Stopes International Leeds Centre

Marie Stopes International, Leeds centre provided termination of pregnancy and family planning services including vasectomies to private and NHS patients. The service provided termination of pregnancy services to children under sixteen and could provide counselling and treatment for girls as young as twelve. It had one operating theatre with a stage one and two recovery area at the Leeds centre where day case procedures were undertaken. There were three consultation rooms at the Leeds centre and one consultation room at each of the satellite clinics where early medical abortions (EMA) were provided. In addition, vasectomies were carried at the Leeds centre and the clinic in Wakefield. No overnight accommodation was provided and no schedule 2 controlled drugs were prescribed or administered on any of the premises.

The Leeds centre provided early medical termination of pregnancy up to nine weeks and four days and surgical termination of pregnancy until 18 weeks and six days of gestation. The centre also provided counselling and contraceptive services, long acting reversible contraception and non-scalpel vasectomy procedures. The centre and one satellite clinic provided vasectomies and all eight satellite clinics provided early medical termination of pregnancy up to nine weeks and four days. The Leeds centre and its satellite clinics provided services for clinical commissioning groups in North and West Yorkshire.

From January to December 2015, the service carried out 508 medical terminations, 1,931 surgical termination procedures and 206 vasectomies.

The service employed seven (4.8 whole time equivalent (wte)) registered nurses (RNs), three (1.8 wte) healthcare assistants (HCAs) and two (1 wte) receptionists. There were 1.2 wte RN vacancies at the time of the inspection. Medical cover was provided by two surgeons (1.8 wte) who were employed by MSI and worked across the Leeds and Manchester centres. Anaesthetic services were provided by anaesthetists working under practice privileges.

The regional manager was the registered manager for the Leeds and Manchester centres and was based at the Manchester Centre with the regional clinical operations manager for the North. The registered manager and the regional clinical operations manager travelled once or twice a week to Leeds to manage and support staff and the service. There was a full-time nurse team leader based within the Leeds centre.

The registered manager had been registered with the Care Quality Commission since May 2013.

Termination of pregnancy

Safe	
Effective	
Caring	
Responsive	
Well-led	

Information about the service

Marie Stopes Leeds is part of Marie Stopes International (MSI). Marie Stopes Leeds opened as a termination of pregnancy service in 2006. Marie Stopes Leeds provided early medical termination of pregnancy up to nine weeks and four days of pregnancy, surgical termination of pregnancy treatments up to 18 weeks and six days of pregnancy. The service also provided counselling, screening for sexually transmitted diseases, contraceptive services, including long acting reversible contraception (LARC) and non-scalpel vasectomy procedures. The Leeds centre was supported by eight satellite clinics at Airedale hospital (Keighley), Batley, Bradford, Huddersfield, another service in Leeds City Centre, Scunthorpe, South Shields, and Wakefield. Early medical terminations were carried out at all the sites. In addition, the Leeds centre at Barrack Road offered surgical termination of pregnancy and vasectomies. The Wakefield clinic also offered vasectomies. Services were provided to both NHS and private patients, around 98% of patients were for NHS funded treatments. The Leeds centre worked with four clinical commissioning groups throughout the North Yorkshire and Leeds area.

The Barrack Road, Leeds centre had three consulting rooms, one operating theatre and eight day care beds. Across the Leeds centre and satellites, in the previous 12 months, 508 patients underwent medical termination and 1,931 had a surgical termination procedure. In the previous 12 months, 206 vasectomies were carried out. Counselling services were offered to all patients prior to and post treatment.

The service treated patients of all ages, including those aged less than 18 years and could treat young people and children as young as 12. Staff caring for patients less than 18 years of age followed strict safeguarding and management processes.

We inspected the service on 17-18 May 2016 and made an unannounced inspection on 26 May 2016.

We inspected this service as part of our independent healthcare inspection programme.

We have not rated this service because we do not currently have a legal duty to rate this type of service or the regulated activities, which it provides.

Termination of pregnancy

Summary of findings

Staff understood their responsibilities to raise concerns and report incidents and near misses. Records we reviewed were of a consistently high standard and we saw that records were stored safely and securely. Although the staff training programme did not meet the requirements of all patient groups, 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 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.

However, we did not see evidence that local staff received regular information and learning messages from elsewhere in the organisation. Staff were trained with an in-house programme to safeguarding adults and children level two, which was not in line with the 'Intercollegiate Document' (Royal College of Paediatrics and Child Health 2014) which recommends level three training for staff working in this type of service. Staff did not always follow procedures in line with medicines management policies.

We saw that patient assessments were thorough and staff followed pathway guidance. Records indicated that 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. We observed in consultations and records that staff always made sure patients gave their consent in writing and adhered to Fraser guidelines in respect of children and young people.

However, not all consultation staff had received training on giving oral contraception advice and dispensing. There were a number of policies requiring review and updating.

Senior managers and staff involved and treated patients with compassion, kindness, and respect. Patients were respected and valued as individuals. Staff treated patients attending for consultation and procedures with compassion and respect. However, we were concerned that patients did not have full access to privacy and dignity when being cared for in the recovery area following surgical termination of pregnancy.

Patients told us how they had been listened to; they felt safe and were treated with kindness.

Staff were non-directive and non-judgemental. Staff focused on the needs of each patient and responded quickly to their needs. Patients gave very positive feedback in the patient feedback questionnaires. The service provided counselling for all patients considering termination of pregnancy and post-termination counselling and support to partners and those people close to patients.

At corporate level, 'service planning' monitored activity and staff scheduled sufficient clinics to meet demand although staff felt rushed with a 15 minute appointment slot for most patients. Staff made sure they had enough information to treat and support patients and could get further advice when necessary. Pre-assessment appointments were carried out with the patient by telephone before a procedure date and time was agreed. The service met waiting time guidelines and patients could choose a date or alternative venue for their procedure. The service shared learning from complaints and staff gave examples of this during the inspection.

Although there was a governance committee and meeting structure throughout the organisation, to facilitate governance and oversee risk and quality management there was not a structured approach for escalation of issues or information sharing. There was oversight of the whole organisation in relation to key performance indicators and this allowed for benchmarking between units. However, it was not clear how achievement of some indicators represented quality of service for patients. We were not assured that all HSA4 forms were submitted and authorised within the Department of Health required time of 14 days following abortion.

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. Senior managers had a clear vision and strategy for their

service and were keen to support services for patients. Quality of care and patient experience was seen as the responsibility of all staff. Most staff felt supported by their managers and were confident they could raise concerns and have them dealt with appropriately.

Are termination of pregnancy services safe?

By safe, we mean people are protected from abuse and avoidable harm.

- Staff understood their responsibilities to raise concerns and report incidents and near misses.
- The service had processes for checking and maintaining equipment.
- 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 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.

However;

- We did not see evidence that local staff received regular information and learning messages from elsewhere in the organisation.
- Staff were trained, following an in-house programme, to safeguarding adults and children level two. This was not in line with the 'Intercollegiate Document' (Royal College of Paediatrics and Child Health 2014) which recommends level three training for staff working in this type of service.
- We found that the national staff training programme for safeguarding vulnerable adults and children did not meet the requirements of all patient groups.
- There was a lack of clarity regarding training requirements for infection prevention and control.
- The dress code policy was not in line with current practice guidance regarding theatre dress.
- Staff did not always follow procedures in line with medicines management policies.

Incidents

- There were no serious incidents or never events at the Leeds centre in the 12 months before the inspection.
- Managers told us they were aware of serious incidents elsewhere in the country and received communications

from the corporate office regarding these. They told us that the director of communications was due to visit the centre to share the investigation and findings from a recent case.

- Policies were clear regarding grading of incidents, reporting and escalation of incidents causing harm. The 'Management of serious incidents' policy stated, "the lead investigator will be appointed by the Director of Quality and Assurance. Lead Investigator will have previously received MSI Investigation and root cause analysis (RCA) training"
- The regional clinical operations manager told us they had been trained in root cause analysis and could be appointed as an investigating officer.
- Between April 2015 and March 2016, the Leeds centre reported 29 incidents. Of these 20 were clinical complications, the other nine included three medication errors (two none or not full dose of antibiotics in box). There were no particular themes or trends noted in the incidents reported.
- Staff we spoke told us they would report incidents in line with MSI policy and were able to give examples of incidents that had happened locally. They were aware of the recent medication incidents and the need to check that medication boxes held correct doses before giving to the patient.
- Staff we spoke with were aware of the principles of 'being open' and 'duty of candour'. 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) ofcertain 'notifiable safety incidents'andprovide reasonable support to that person.
- We saw from the 'nominated individual self-assessment' that staff had received information relating to duty of candour, however, we saw that the incident reporting policy and management of serious incident policy did not include guidance relating to duty of candour but being open was covered. Managers told us that a policy was in development regarding duty of candour and this was provided to us following the inspection.
- Doctors told us they received information from serious incident investigations, elsewhere in the organisation, through their professional meeting and via email. We saw from doctors meeting minutes that learning from serious incident case studies was an agenda item at one of three meetings between September 2015 and March 2016.
- We did not see evidence in team or local integrated governance minutes that learning from incidents elsewhere in the country was shared with nursing staff and HCAs, however, they did record discussions regarding possible under-reporting and that managers encouraged staff to report incidents.
- Staff told us that following an emergency transfer, there was a reflective session, held with the surgeon and staff on duty to establish the cause of the incident and to identify any learning points. The root cause was identified as an undisclosed pre-existing condition that meant the patient would have been initially referred to the NHS for treatment had the MSI staff been made aware of this.

Cleanliness, infection control and hygiene

- The consulting rooms, waiting areas and other clinical rooms were visibly clean and tidy.
- There was a contract in place with an external cleaning company to keep the premises clean. We saw that issues with cleaning had been picked up through a nominated individual inspection and the action plan indicated these were discussed with the nursing team and cleaning company as necessary.
- We saw that some cleaning duties were the responsibility of clinic staff and schedules and checklists for cleaning were in place. There were a number of actions for staff from the latest inspection by the nominated individual, which had been actioned.
- We observed a good standard of cleanliness in the theatre room and records indicated that nursing staff undertook a schedule of daily cleaning of the environment and equipment. We saw that equipment that was in contact with the patient, such as couches and blood pressure cuffs were cleaned in-between patients.
- Facilities for hand hygiene were provided in all clinical areas and soap dispensers were in generally in good working order.
- We observed that one hand wash sink in a patient toilet and the staff sink in the second stage recovery area were out of order. The towel dispenser in the patient toilet was also broken. Staff informed us that the taps on both

of these sinks needed new sensors. These had been ordered but not received yet. They told us that there was a local maintenance man who would fit these as soon as they came.

- We observed one of the hand gel dispensers in the second stage recovery area was not working. When we pointed this out to the lead nurse, she said it was likely the batteries needed changing and she would ensure this was done. This meant that staff and patients needed to use the one working sink inside of a patient toilet to wash their hands in this area. There were also hand gel dispensers available for staff use in this area.
- We observed staff washing hands and using gel appropriately in all clinical areas.
- We saw that surgeons in theatre wore plastic aprons and gloves. They decontaminated their hands prior to donning gloves between each procedure and they changed aprons between patients.
- Theatre staff involved in the termination procedure wore theatre dress and theatre clogs but these were not changed or covered when staff moved out of the theatre suite. Staff who are involved in the operative procedures should cover theatre dress if they leave the theatre environment to work in other areas or for breaks.
- Policy indicated that individual staff were responsible for cleaning their own theatre clogs daily however, spare theatre clogs looked grubby.
- There were policies in place for the flushing of little used water outlets and water temperature checking to prevent legionella. There was a programme of planned maintenance in place, which included water testing, and temperature control checks. We looked at records that indicated an external contractor carried these out monthly.
- Specialised ventilation is a statutory requirement in operating departments and a clinical requirement to reduce surgical site infections. We saw records that demonstrated ventilation systems were serviced and maintained in line with national guidance.
- Disposable curtains were in use in the clinical areas and were marked with the date of last change.
- Personal protective clothing was available in all areas we visited.
- The 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 March 2016 showed 100% compliance. Observational hand hygiene audit showed compliance of 90%, this was due to a question on the audit which asked if staff had received training in the last 12 months and the response from staff was no. However, the mandatory training requirement for IPC training was three yearly and all staff were compliant with this.
- The IPC audit, which looked at a range of criteria such as environment, equipment, cleaning, management of sharps and personal protective equipment, in April 2016 showed 100% compliance.
- 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.
- All staff had received infection control training in line with the three yearly mandatory training requirements. However, some policies such as disposal of waste indicated an annual training requirement. Training data provided did not indicate any staff at Leeds had received annual updates regarding waste disposal.

Environment and equipment

- The premises and rooms in use to provide this service were suited to their purpose. All clinics except Huddersfield were situated within GP surgeries or other busy healthcare premises. The Huddersfield clinic was housed within a shared building but independent of other shops and organisations using it. There was a security lock with an intercom and a member of staff on reception in addition to the nurse on duty.
- There was lone worker policy in place and generic lone worker risk assessments were in place for clinics in commercial buildings and GP practices. We did not see individual risk assessments for the more isolated members of staff or those in less accessible premises such as South Shields and Huddersfield. Training information provided by MSI indicated that staff did not receive any training regarding lone-working.
- We saw that clinic rooms in early medical units were well equipped with everything staff needed to provide the service.

- Staff told us they had requested a new scanner for the Wakefield clinic, as images were less clear on this machine than those in the other clinics.
- There was a dedicated theatre suite with first and second stage 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. We saw that each chair had lighting and call bells
- We saw a comprehensive planned maintenance programme was in place, which covered; heating and ventilation, fire systems, generator testing, emergency lighting and other elements of maintaining clinic premises. We saw evidence of recent servicing of ventilation.
- Evidence of stock rotation was in place and all stock we checked was in date and stored in an appropriate manner.
- We saw records that indicated resuscitation equipment and drugs were checked regularly and observed that trolley drawers were locked. Trolleys and emergency rucksacks were checked daily when the clinics were running and sealed draws and packs were opened and checked weekly.
- Other emergency equipment such as defibrillators were checked daily.
- The anaesthetic nurse 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 saw that they were up to date.
- An external contractor carried out sterilisation of theatre trays. The HCA in theatre 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.
- The service was using single use surgical trays and equipment for first trimester procedures and was introducing single use trays for all procedures to coincide with the end of the sterilising services contract.
- Non-scalpel vasectomies were carried out at the Wakefield satellite unit and nursing staff transported equipment needed each week. The surgeon used sterile, single use packs for the procedures and disposed of them on site.

Medicines

- There was a designated nurse for the ordering of drugs online with the centralised MSI purchasing department. The regional manager told us that budget holders needed to authorise orders before they were processed and the procurement officer would sense check orders before they were sent to external suppliers.
- A registered nurse, checked supplies on receipt against the orders made. We saw there were local records of drug ordering and receipt.
- We saw that medicines were stored safely and securely in the clinics we visited. Records indicated that nurses checked drugs regularly and rotated stock monthly.
- Fridge temperatures were recorded daily when clinics were open. Recommended fridge range is between 2 and 8 degrees centigrade to ensure safety and efficacy of refrigerated drugs and minimum and maximum temperatures should be read and recorded daily. However not all fridges had minimum and maximum temperatures recorded. Different recording sheets were in use in different clinics and those in Barrack Road did not have a column to record both minimum and maximum temperatures, therefore a single temperature was recorded. The daily recording for the last two weeks had been 4C but staff had not been checking or recording temperature range.
- Minimum and maximum temperatures taken at the time of inspection were 0.5C and 10.1C. As the range of temperature had not been checked regularly, staff did not know if this was a new or prolonged issue.
- Anti-D and Rhesus reagents were stored in the fridges and the staff we spoke with were aware that these items could be safely stored at room temperature for seven days if a temperature exceeded 8C. Medicines management policy stated Anti-D or reagent that has been stored at room temperature for seven days must be discarded. Anti-D must not be stored at temperatures at or below 0C. We were concerned because staff had no way of knowing how often or for what time period a fridge had been above 8C this meant that there was a risk the Anti-D had been above recommended storage temperature for more than seven days, or on multiple

occasions. Although the fridge temperature had not fallen to 0C at the time of inspection, we were not assured that staff would be aware if this occurred or that they knew to discard the Anti-D if this occurred.

- A member of staff told us they had previously reported issues to an engineer but had not sought pharmacy advice regarding the safety or efficacy of the fridge contents. Staff told us that the engineer had told them to reset the fridge thermometer when the reading was out of range. However, the member of staff we spoke with was unsure when it had last been reset. Thermometers should be reset after each recording has been made.
- Some fridges had an integral thermometer (with a display on the outside of the fridge) and a probe left inside the fridge. The staff we spoke with appeared uncertain which thermometer to use for recordings.
- We highlighted the fridge temperature recording issues to managers following the announced inspection but we observed that the single, daily temperature-recording sheet was still in use at Barrack Road during the unannounced visit the following week and minimum and maximum temperatures had not been recorded.
- We saw that controlled drugs and anaesthetics were stored appropriately and two staff always signed the register for administration of controlled drugs. Staff checked the stock was correct at each use and whole stock was checked on a weekly basis. We checked the controlled drug book and found this was completed correctly. However, we observed that the administering nurse did not take the register to the patient with the medication and she signed retrospectively to say the drug had been given. This was not in line with controlled drug policy, which stated "At the time of administration all fields in the CD register must be completed".
- The controlled drug policy did not cover the administration of oramorph by nurses to recovering patients and it appeared to have been written in relation to the administration of anaesthetics and controlled drugs by medical staff during surgical procedures only. Managers have since told us that this policy is being reviewed.
- Drug 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.
- Theatre staff checked that patients had received contraceptive advice and that prescriptions had been written up. We observed contraceptive implants and injections given in accordance with good medicine administration guidance.
- A doctor prescribed all abortifacient medicines. Drugs that induced abortion were 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 and abortion) form signed by two doctors.
- Nurses were able to administer pain-controlling medication, treatment of chlamydia and prophylactic antibiotics to prevent post procedure infection as prescribed.
- Nurses informed us that due to the electronic record system it was rarely necessary to administer drugs using PGDs, as prescriptions were easy to obtain, although these were available if needed.
- We observed 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.
- There was a medicine management policy in place, which stated staff had access to a pharmacist, employed by MSI on a consultancy basis, if needed. However, staff we spoke with had not tried to access this service.
- We saw from the local audit plan that medicines management was to be audited on a quarterly basis during 2016. The latest audit in February 2016 showed 100% compliance with medicines management. However, the audit results regarding fridge temperatures, recording sheet in use and staff knowledge did not match our findings and observations.

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.

Termination of pregnancy

- The electronic patient record included speciality pathways and risk assessments for VTE, sexual health and safeguarding for patients under 18 years of age.
- We looked at 33 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.
- If records needed to be transported to community clinics, they were transported by courier in sealed bags. Scanned records were sent between clinicians and nurses using secure email.
- The assessment process for termination of pregnancy legally requires that two doctors agree that at least one and the same legal ground for the termination of pregnancy is met and sign a form to indicate their agreement (HSA1 Form).
- We observed the practice of one of the doctors performing remote signing of HSA1 forms and prescribing. We saw that they had access to full and complete records including additional letters from GPs where patients had medical conditions or were undergoing treatment for a long-term condition. The doctor was able to ask for and view additional notes from assessing nurses or HCAs when required. We were assured that clinical records contained sufficient information for doctors to make a clinical assessment and be satisfied that at least one of the legal grounds for abortion had been met.
- We saw that the doctor reviewed the patient's completed electronic record which included the assessment carried out by the nurse or healthcare assistant, the reason for seeking abortion and any additional notes or attached medical information from general practitioners or consultants (where relevant). When the doctor had finished their assessment, they passed the information on electronically for their colleague's assessment and signature on the HSA1. Both doctors signed the HSA1 form if they agreed that at least one and the same legal grounds for abortion had been met and one of them prescribed the medications necessary to induce abortion. We saw that the two doctors communicated via the electronic system and by email regarding the patients they were assessing. They were able to discuss reasons for termination or consult with each other if they wanted a second opinion regarding a patient's suitability for treatment, when necessary.
- The doctor told us they would refuse a record with insufficient information to confidently prescribe or make a judgement regarding the legal grounds for abortion. Staff at the centre would need to take further information from the patient and resubmit the request for signature or treatment, with the additional information.
- Nurses and HCAs confirmed that this did happen on occasion and we observed in one of the clinics that a doctor requested additional information before prescribing antibiotics for a patient.
- Record keeping and documentation audits were carried out and compliance was consistently good. Audits carried out in January and March 2016 showed 100% compliance.
- We looked at 22 termination patient records and found that all forms included two doctor' signatures and the reason for the termination. Documentation of the reasons for seeking termination was clearly documented in the electronic record.
- Two doctors in theatre told us that they had always accessed a patient's full medical record and information prior to their giving any treatment, to assess anaesthetic and surgical risk and prior to their prescribing any medications. However, they told us that they had been signing HSA1 forms with access to only the patient stated reasons for requesting termination, where they were not the prescribing or treating doctor. The reasons for termination were printed from the patient's record onto the reverse side of the HSA1 form for the doctors to view before signing to agree that a ground for termination had been met. They informed us that this practice had stopped following a CQC inspection elsewhere in the organisation and they now only signed HSA1 forms when they had checked a patient's full record.
- We observed that the surgeon and anaesthetist each had a computer terminal in the theatre room and they accessed records to clinically assess and prescribe for patients, individually, before they came into the room.
- 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 his completion of each patient's record. We were not assured of HSA4 submission within 14 days for patients undergoing medical terminations.

Safeguarding

- We found that the national staff training programme for safeguarding vulnerable adults and children did not meet the requirements of all patient groups.
- The centre safeguarding lead nurse was trained to level three and the registered and operational managers were trained to level three/ four. The corporate safeguarding lead was trained to level five. However, other nursing staff were trained to safeguarding adults and children level two, and reception staff were trained to level one, which was not in line with the 'Intercollegiate Document' (Royal College of Paediatrics and Child Health 2014). The guidance recommends level three training for all staff working in this type of service that have patient contact.
- MSI policy indicated that safeguarding training should be completed during induction and refreshed every two years. Most of the staff at the Leeds centre were compliant with this requirement. Two members of staff were overdue but had a date booked in June 2016 to attend.
- 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. However, we saw that the 'Safeguarding Children, Young People and Adults at Risk' policy was not up to date with current best practice guidance.
- We saw from records and staff told us that they carried out safeguarding risk assessments for all patients under 18 years and when there was any suspicion of abuse of older adults. Staff told us 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 during January – December 2015, however young patients between 13 and 15 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, a safeguarding risk assessment was completed and a decision made on the outcome of the assessment.
- HCAs told us that if they had safeguarding concerns they would discuss with the safeguarding lead nurse or the nursing team lead for the centre.
- We spoke with a corporate director who told us that all doctors had to have disclosure and barring (DBS) checks prior to appointment and child protection training to level three was mandatory. However, training data for one of the employed surgeons was not submitted and the data for the other surgeon indicated training had been at level two not three.
- MSI policy was that DBS checks were renewed every three years. Data we were give indicated that one surgeon's DBS was due for renewal in February 2016 and this had been missed. As soon as this was highlighted, the DBS process was initiated for the individual concerned. All other staff were up to date.
- 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 such information in a safe environment.
- Staff we spoke with told us they would seek advice and support from the regional manager, regional clinical operations manager or national safeguarding lead if needed.
- Staff we spoke with were aware of the requirements of consent and information sharing to safeguard young people and vulnerable adults. However, at a national level, we found that the consent training programme was not adequate to equip staff with the knowledge they needed to take informed consent appropriately.
- 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. However, we found the national staff training programme did not provide sufficient information on these subjects.
- We saw that the centre and satellite clinics held a file of local contact numbers for Adult and Children safeguarding teams. The latest safeguarding audit in

March 2016 showed 92% compliance. However, staff did not receive lessons learned from safeguarding alerts and incidents. There was no corresponding action to improve this on the action plan provided.

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, informed consent, equality and diversity, customer care and complaints and various aspects of health and safety, Anaesthetic training and ultrasound training was also required for relevant staff. However, we found at a national level that safeguarding and consent training did not equip staff appropriately regarding the needs of all patient groups.
- The frequency of mandatory training was annually for life support and information governance. All other modules were three yearly.
- The corporate training requirement was that reception staff and health care assistants undertook basic life support, nursing staff undertook intermediate life support and anaesthetists advanced life support. The data provided showed that most staff had received life support training within the last 12 months. However, data was not provided for one of the employed surgeons and the anaesthetists working under practicing privileges. Training data did not indicate which staff had studied what level training. The nursing staff we spoke with told us they had received intermediate life support training and that staff took part in unannounced emergency scenario situations three or four times a year.
- The training data provided showed that most employed staff were up to date with their mandatory training requirements. One member of staff needed an update in basic life support and information governance. One employed surgeon was missed off the training sheet and data for staff working under practicing privileges was not provided.
- One member of staff at the centre was first aid trained.
- Training was provided through a combination of online courses and updates and face to training.
- A member of agency staff we spoke with had mandatory training through their employing agency but received an orientation/ induction at MSI Leeds.

Assessing and responding to patient risk

- The MSI 'Pre-existing Conditions Guideline' clearly laid out which medical conditions would exclude patients from accessing treatment, and those medical conditions which, require risk assessment by a doctor.
- 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 via a telephone consultation with Onecall. 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 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 VTE. Data we reviewed indicated that 100% of surgical patients had received this risk assessment during the period January – December 2015.
- The patient pathway involved, nurses or healthcare assistants performing an ultrasound scan to confirm dating, viability, multiple gestations and the location of implantation. Staff told us that one of the aims of this was to exclude the possibility of ectopic pregnancy and if they suspected this, they made an immediate referral to a local early pregnancy centre.
- 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 centre if the need was urgent.

- We observed that staff made positive identity checks before commencing a consultation or treatment and when entering theatre.
- MSI had developed its own Surgical Safety Checklist (SSCL), modelled on the world health organisation (WHO) five steps to safer surgery. 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.
- The 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.
- Any identified medical risks were addressed prior to the patient having their procedure, by requesting further information from the patient and GP or by redirecting the patient into NHS services where necessary.
- We observed the anaesthetist reviewing all patients' medical history prior to them coming in to theatre. We they cancelled a patient procedure and redirected to NHS services, due to disclosure of a condition that was an anaesthetic risk. We also saw the anaesthetist ask nursing staff to check a patient record prior to the patient coming in to theatre as the record had been marked that the patient was ambivalent about their decision. The anaesthetist told us the patient would be asked to undergo further counselling if this was the case or to re-book an appointment when sure of her decision. The outcome was that there had been a recording error, the patient was sure about her decision and the procedure went ahead. The anaesthetist told us a procedure would not go ahead if there was any doubt about a patient's decision.
- 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.
- We saw that 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 if necessary.
- There was one emergency transfer from MSI Leeds in the 12 months before the inspection, although this was unrelated to treatment for abortion. Staff had dialled 999 and the patient was transferred to the local accident and emergency department.
- There was one other non-emergency transfer to the local NHS hospital in April 2016, when the surgeon was unable to complete a procedure
- During the inspection, we observed one patient whose surgical procedure did not proceed because the placenta was difficult to locate. The consultant surgeon performed a second scan and located an anterior placed placenta. This meant the patient needed to have her procedure in an NHS setting due to a higher risk of haemorrhage.
- 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 were monitored blood loss and recorded patient observations every five minutes until they were awake.
- We observed four patients transferred from the stage one to stage two recovery area. Transfer from bed to wheelchair occurred while the patients were still very groggy and required the assistance of two members of staff. While the patients' safety was maintained, we felt that they were rushed into the next stage of recovery before they were properly awake. One of the patients was unable to transfer to the chair at the first attempt and a second patient became faint and unresponsive immediately after transfer to the wheelchair. Staff called into theatre for emergency assistance and the anaesthetist was able to give support. Staff managed the situation appropriately.
- While staff were dealing with this patient, we saw that there was the possibility of patients in the second stage recovery area being left unattended until an emergency was dealt with. The theatre sister told us that if recovery staff were dealing with an emergency then she could call a member of staff through from the consultation area to care for the patients in the second stage area.
- Patients in the second stage area all had nurse call bells if they required assistance and nursing staff were out of sight.

Termination of pregnancy

- When patients were advised to attend early pregnancy units or A&E, from consultation clinics, staff followed up on this to check patients had received the care they needed before closing down episodes of care.
- When patients indicated they were unsure about their decision, staff encouraged them to use the counselling service and re-booked appointments for several days later to ensure the patient had time to come to a firm decision before they went ahead with any treatment.
- All patients under 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, if they started to bleed soon after taking the medication. Staff told us that they also encouraged adult patients to bring an escort for the second the second part of their treatment.
- We observed that nurses and healthcare assistants checked that patients had an escort home, before they left the second stage recovery.
- Counselling was mandatory for patients under 16 years of age.
- Staff told us they took part in unannounced emergency scenario exercises to ensure they knew what to do in case of medical emergencies.
- Training information showed that nursing staff working in theatre had undergone anaesthetic training that was refreshed three yearly.
- The anaesthetist we spoke to told us he was advanced life support trained and that this was up to date. The nurse team lead told us that the anaesthetist would always be trained to this level.

Nursing staffing

- 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.
- There were seven (4.8 whole time equivalent (wte)) registered nurses (RNs) working at MSI Leeds, however at the time of the inspection there were two (1.2 wte) vacancies.
- There were three (1.8 wte) healthcare assistants (HCAs) also working out of the Leeds centre.
- Staff told us the vacant RN posts caused additional work and pressure, particularly to cover EMA clinics.
- 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 in theatre.
- 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.
- Staff told us that due to vacancies if anyone was off sick, this could mean managers asked them to cover a satellite clinic, some distance away, at short notice. They also told us that the impact of having less staff was that patients often waited longer to be seen in the clinics.
- In the Leeds centre at Barrack Road there were two members of staff working in each of the three areas; consultation, theatre and recovery. There was usually one RN and one HCA working in each area. Staff felt that while this was sufficient to maintain patient safety it was not enough to keep patient appointments moving and patients could experience long delays waiting for consultation if staff needed to move elsewhere or if patients ran over their 15 minutes allocated time.
- Staff did not feel that numbers of patients through the clinics had been reduced when staff vacancies had arisen and hoped that when the posts were recruited to this would mean there would be three staff in the consultation area and patient waiting times would be reduced.
- There was usually one member of staff working alone at the outlying EMA clinics. This was usually a RN as HCAs could only offer consultation appointments and they could not administer drugs. Staff told us that sometimes a HCA did work alone in a satellite clinic and only patients not requiring medication were booked on these occasions.
- Managers and staff told us that there had been some issues with staff turnover at the centre and believed this was due in part to unrealistic expectations regarding the nursing role and also due to difficulties in supporting new staff. Staff and managers told us action had been taken to ensure posts were advertised with clearer expectations regarding the job role and steps had been taken to ensure supervision and experienced registered nurses provided support for new nursing staff.
- As the centre was looking towards opening a new satellite centre, it had been agreed that the centre would recruit to an additional post along with the

current vacancies to ensure staff were given time and plenty of support to complete induction and training in the main clinic before being expected to cover satellite clinics.

Medical staffing

- There were two surgeons (0.4 wte) working at MSI Leeds. MSI employed these doctors on a fulltime 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.
- 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.
- Doctors we spoke with told us that doctors employed by MSI elsewhere in the country would be used to provide cover for short-term absence and they would provide cover in other centres if needed.
- Anaesthetists worked on a sessional basis under practising privileges.
- MSI corporately employed other doctors to work remotely to undertake clinical assessment of patients, signing of 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.
- 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?

By effective, we mean that people's care, treatment and support achieves good outcomes, promotes a good quality of life and is based on the best available evidence.

- Patient assessments were thorough and staff followed pathway guidance.
- 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.
- There were links with local safeguarding teams, the local NHS hospital and other agencies.

However;

- Not all consultation staff received training on giving oral contraception advice and dispensing.
- There were a number of policies that needed to be reviewed and brought into line with current best practice or national guidance.

Evidence-based care and treatment

- We saw that staff had access to policies and procedures through the MSI intranet.
- 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.
- There were a number of policies that were due a review or did not mirror current best practice guidance or were unclear and did not fit their full purpose, for example, the dress code policy, controlled drug policy and the medicines management policy.
- Doctors told us there was regular monitoring of complication rates at corporate level and that they received results and feedback through their quarterly meeting and by email. Doctors and nursing staff told us that if anything was identified that needed urgent action then all staff received a 'red alert'. We saw that this had happened when the organisation had stopped providing simultaneous treatments for early medical abortion.
- We saw that staff followed policies and referred to a treatment decision flow chart during consultation and

scanning. The flow chart clearly laid out the criteria to be met to proceed to treatment and gave clear instructions regarding next steps for patients who did not meet the criteria.

- Options for patients who did not meet the criteria to proceed immediately to treatment included; carrying out a transvaginal scan, rescan in one week at consultation centre, or refer to the local Early Pregnancy Unit or A&E if ectopic pregnancy or abnormality was suspected.
- Following the evaluation of the failure rate of simultaneous medical abortions, when both parts of the treatment are given together rather than 24-72 hours apart, MSI had opted not to offer this treatment as a sustainable treatment option.
- The centre offered patients early medical abortions with a 24 or 48-hour delay between the two treatments, which was in line with RCOG guidance. Staff arranged appointments at alternative clinics to suit the patient's needs if timing of the second part of the treatment did not coincide with opening hours at the clinic attended for first part of treatment.
- This sometimes caused problems when satellite centres were not open on consecutive days but staff arranged appointments at an alternative clinic to suit the patient's needs.
- All patients undergoing medical abortion were asked to ensure that a pregnancy test was completed three weeks after their treatment to ensure that 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 service offered sexually transmitted infection screening and contraceptive advice and provision including long-acting reversible contraceptives (LARC). If a positive result was returned, processes were in place to track partners and offer treatment.
- Surgical patients were low anaesthetic risk only and received a pre-operative assessment by a healthcare assistant or nurse in a private consultation room. The anaesthetist then reviewed the medical records and patients observation records prior to the patient entering the treatment room.

Pain relief

- Pain relief was administered in the centre and recorded on the medicines administration records.
- 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 cocodamol 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.

Nutrition and hydration

- Water was available for patients in the waiting areas.
- Staff gave patients tea and biscuits or cold drinks in the recovery area following their surgical procedure.

Patient outcomes

- 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.
- Staff told us that results were collated centrally for benchmarking and complications were reported back to doctors through their quarterly meeting and by email. Other staff we spoke with told us they received feedback regarding clinical outcomes, such as complications associated with simultaneous treatments from head office and regional managers through email and local briefings.
- During January – December 2015 the service reported five complications to commissioners, three were

retained products of conception (RPC) following medical abortion, one was RPC following surgical abortion and one was a patient who was discharged with a venflon insitu.

- We saw from the data January to May 2016 there were 10 occurrences of retained products of conception. Five of these were attributed to simultaneous treatment, which had since been stopped as a treatment option. There were three occurrences of ongoing pregnancy, also attributed to simultaneous treatment, in the same period.
- MSI Leeds had shown improvement in the numbers of patients receiving testing for STIs since 2014 and had exceeded its 70% target for 2015. In 2015, the centre achieved 84% of patients eligible for STI tests and year to date in 2016 Leeds had completed 97% of testing for eligible patients.
- In 2015, Leeds achieved 53% of patients receiving a long acting reversible contraception method and in 2016 year to date has achieved 60% against a target of 50%, which was above the average for the organisation.
- 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.
- Managers and doctors we spoke with told us that oversight of outcomes took place at corporate level and information was shared through the meeting structures and with individuals as appropriate. We saw from minutes of the central governance committee in April 2016 that complication rates were presented on this occasion; however, this did not seem to be reflected in previous meeting or the regional managers, doctors or clinical lead meetings where minutes had been provided. The data provided at this meeting was provided at regional level therefore making it difficult to attribute outcomes to specific centres or clinicians.
- The service did not monitor numbers of patients where abdominal scans were ineffective in locating and confirming gestation of pregnancy. Three out of 10 patient consultations we observed needed to proceed to transvaginal scan to locate and confirm gestation of pregnancy. This inevitably lengthened the time needed for consultation and resulted in a longer waiting time for subsequent patients.
- We did not see a clinical audit programme in place with specific regard to all of the elements of the DH RSOP 16. However, we saw from commissioning reports that MSI Leeds collected and reported data regarding; age of patients seeking treatment, uptake of sexually transmitted infection screening, patients who received contraception by type (including long acting reversible contraception), numbers of women who had a previous abortion and whether they had left the service with LARC and all complications.
- Numbers of patients and reasons for not proceeding to treatment was not reported to commissioners but this information was collected centrally by the organisation. Feedback to staff regarding this was in the form of a percentage of patients who DNP against a target but detailed information regarding reason for DNP was not given.
- We did not see audit or reported information regarding reasons why women did not proceed to a termination or to what degree the service was able to accommodate patients' wishes to have a female doctor. We did see that the staff and service accommodated patient wishes wherever possible and that 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.

Competent staff

- There were national competency frameworks in place for RNs and HCAs and all staff told us staff 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.
- We were told, all new staff worked as supernumerary until assessed as competent in their role.
- We saw documentary evidence that staff practice was observed until staff had performed the required number of procedures and had been assessed and signed off as being competent by an experienced practitioner.
- HCAs were trained to carry out consultations, observations, take consent, perform ultra sound scans and perform point of care testing. The training requirement for MSI stated that ultra sound and consent training be refreshed every three years.
- Registered nurses working in theatre had received anaesthetic training and the agency operating department practitioner told us they had anaesthetic

training and theatre experience. The member of agency staff told us they worked at MSI Leeds regularly and were familiar with and able to fulfil the requirements of 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.
- The staff at MSI Leeds had received their training for ultrasound scanning at Birmingham University. Staff told us that during their training they had needed to maintain a portfolio undertake 100 first trimester scans, 25 second trimester scans and 50 trans vaginal scans under supervision and before they were signed off as competent and able to scan independently. Staff were signed off by a colleague who had previously been through training and assessed as competent.
- We reviewed one set of staff personnel records; these were well organised, well recorded and had up to date training records and competency assessments.
- All nursing staff were aware of revalidation requirements and were being supported by the organisation to produce a portfolio. Staff told us that clinical supervision had been available on an adhoc basis; however, reflective sheets and more formal supervision had recently been introduced.
- MSI Leeds staff were expected to attend clinical forums twice a year when the service operated a shutdown, to facilitate staff attendance.
- Data from January – December 2015 showed that at the Leeds centre 100% of medical staff, 100% of nursing staff and 100% of administrative staff had received an appraisal.
- The nurses we spoke to were aware of the requirements of NMC revalidation but none had been through the process yet. The clinical operations manager was supporting staff to collect evidence for revalidation through clinical supervision and reflection.
- There was a defined set of behaviours expected of all staff working at MSI, which managers used to aid recruitment and inform appraisal discussions.
- MSI had a named responsible officer for overseeing medical competence and carrying out appraisals for employed doctors. There was also a surgical lead and anaesthetic lead employed within the organisation.
- Doctors we spoke with confirmed they had an appraisal within the last 12 months. Doctors working under practicing privileges had their appraisals at their main employing organisation.
- Policy indicated that the responsible officer visited new doctors to establish expectations of MSI regarding behaviour and practice. Doctors worked to schedules of practice, which outlined job requirements and roles. The policy also stated that the responsible officer also observed surgeons' practice to assess competence when first employed and then as part of a rolling review programme.
- There were link nurses in the centre who could give advice regarding contraception, safeguarding, risk assessments and infection prevention and control.
- We saw that some staff had received additional training with aspects of clinical practice such as medicines management and one member of staff had received training regarding contraception. Although advice and discussion of contraception methods, including oral contraception, was a fundamental part of every patient consultation contraception training was not included as part of required training on the training matrix. The skills matrix indicated that one member of staff was family planning trained and one had received a contraception update but no dates were given. The other members of consultation staff (RNs and HCAs) had not received any training regarding contraception. Four out of five nurses had received training regarding implant fitting but only one had received training regarding removal of implants. Some nursing staff told us they felt they had not had sufficient or recent training to administer all contraceptive options.
- Doctors employed by MSI told us they were able to undertake continuing professional development and the local faculty of sexual health medicine supported this.
- There was a quarterly meeting for doctors, which included all surgeons, anaesthetists, and sessional doctors where case studies were discussed, as well as trends and themes from incidents and complaints and topical issues such as nurse revalidation and female genital mutilation.

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.
- Staff told us that they could seek medical support and advice when needed. Staff could go to the electronic record system where they could have an online discussion with a doctor regarding suitability for EMA. Nurse 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.
- MSI Leeds had service level agreements with a neighbouring NHS Trust, which allowed them to transfer a patient to the hospital in case of medical or surgical emergency.
- Staff told us there were good relationships with the early pregnancy centres in the area.

Seven-day services

- The Leeds centre offered services from premises at; Leeds, Bradford, Wakefield, Huddersfield, Batley, Scunthorpe, Airedale and South Shields, using a hub and spoke model. The service provided EMAs from one or more of the satellite clinics Monday to Friday with occasional Saturday clinics held.
- The service provided surgical abortions at the Leeds Barrack Road premises on a Monday and Thursday each week.
- MSI Leeds provided services for non-scalpel vasectomies two Fridays each month, one from the Leeds Barrack Road premises and one from the Wakefield satellite centre.
- MSI provided 24 hours per day and seven days a week advice line, which specialised in post-abortion support and care. This was in line with Required Standard Operating Procedures set by the Department of Health. Callers to this service could speak to RNs or midwives who would give advice.

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.
- Legislation requires that for an abortion to be legal, two doctors must each independently reach an opinion in good faith as to whether one or more of the legal grounds for a termination is met. They must be in agreement that at least one and the same ground is met for the termination to be lawful. Medical practitioners (including remote doctors) had access to all patient information to enable them to make an informed decision in good faith.
- Staff had access to relevant guidelines, policies and procedures in relation to termination of pregnancy services.
- Staff were able to access diagnostic tests/blood results in a timely manner.
- Staff did not routinely give patients a discharge letter but did ask if they wanted this to take away with them. Staff also asked patients if they wanted their GP to receive a copy of this letter.
- Patients advised to attend A&E of an EPU were given a letter to take with them.
- Minutes of meetings, newsletters and other corporate information was accessible through the staff intranet.

Consent, Mental Capacity Act and Deprivation of Liberty Safeguards

- Registered nurses and HCAs had undergone competency-based assessment regarding taking of informed consent. However, we found that the MSI national training programme did not equip staff appropriately with enough knowledge to fulfil the needs of all patient groups. Competency for consent was assessed against a number of standards, which included knowledge of surgical and medical pathways, communication skills and record keeping.

Termination of pregnancy

- 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.
- 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 anaesthetic nurses 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 theatre. The anaesthetic nurse 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 were aware of Fraser guidelines to obtain consent from young people regarding contraception.
- Information was available in folders in the waiting areas for young people regarding Gillick competence.
- There was access to guidance and policies for staff to refer to concerning Mental Capacity Act (MCA).
- Staff had received training in the Mental Capacity Act 2005 (MCA) as part of their safeguarding 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.

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Are termination of pregnancy services caring?

By caring we mean that staff involved and treated people with compassion, kindness, dignity and respect.

- We observed that staff treated patients attending for consultation and procedures with compassion and respect. Patients told us how they had been listened to; they felt safe and were treated with kindness.
- Staff were non-directive and non-judgemental.
- Staff focused on the needs of each patient and responded quickly to their preferences including the type of termination they wanted and where and when to have the procedure.
- Staff established and respected each person's preference for sharing information with their partner or family members, and reviewed this throughout their care.
- Staff explained the different methods and options for abortion. If patients needed time to make a decision, staff supported this.
- The majority of patients gave very positive feedback in the patient feedback questionnaires. The service provided telephone counselling for patients of all ages considering termination of pregnancy and post-termination counselling and support to partners and those people close to patients. Patients under 18 years old received telephone counselling when they attended for their consultation and in the presence of the nurse.

However,

- We were concerned that surgical patients did not have full access to privacy and dignity when being cared for in theatre and recovery areas and observed a number of occasions when dignity was not maintained.
- Staff did not inform patients of the requirement to submit abortion data to the DH.

Compassionate care

- We saw that doctors and nurses in theatre 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 medical termination patients and those close to them at satellite sites throughout our inspection. 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.

- However, we were concerned that surgical patients did not have full access to privacy and dignity when being cared for in theatre and the recovery areas. We observed that patients having surgical procedures were placed in the lithotomy position prior to sedation or anaesthesia being given. While patients agreed to this and staff maintained dignity as far as possible we observed that, the patients looked very uncomfortable about this. There were two negative comments from patients regarding this in the client feedback report from October to December 2015. It was not evident in the report that MSI intended to take any action regarding reviewing this practice to reduce the discomfort and embarrassment for patients.
- We observed that staff attempted to keep the patients' legs covered during the procedure however, sheets were unsecured and kept slipping down.
- We saw one patient moved to the second stage recovery area and seated in a reclining chair near other patients without her clothes being fully re-arranged. Her legs were left uncovered until she was able to rearrange her clothes herself some time later.
- We observed staff reassure patients about future fertility.
- The clinic staff routinely asked patients to complete feedback questionnaires and managers told us they regularly achieved a good response rate. National figures showed that the response rate was 42%; however, we were unable to disaggregate a response rate for the Leeds centre.
- We saw a client feedback report for October to December 2015. There were 75 responses for the Leeds centre during this quarter and analysis of the responses received showed that patients felt very satisfied with the care and treatment they had received. All categories regarding treatment at the Leeds centre showed 96% to 100% positive results.
- Staff told us that patients' preferences for sharing information with their partner or family members were established, respected and reviewed throughout their care.
- Staff told us and we observed younger patients were encouraged to involve their parents or family members and their wishes were respected. However, every patient was seen alone for the first part of the consultation to ensure they felt at ease and were not under any pressure for any reason from a partner or the person attending with them.
- We saw examples where staff supported patients in difficult situations. We observed nurses providing care for patients who had previously suffered from anxiety and depression. Staff were sensitive and used terminology that was clear to explain that the hormonal process following an abortion could make the patient feel low in mood and to be prepared for that.
- The vasectomy service was held on a separate day to the termination of pregnancy services, this ensured that males and females did not meet during their treatments.
- We observed staff in the recovery area asking patients about their comfort and needs.
- However, we spoke with a patient who commented that they were cold and we asked a staff member to provide the patient with a blanket. We observed that blankets were not routinely given or offered.

Understanding and involvement of patients and those close to them

- Staff told us and we observed that 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. They explained side effects and complications of treatments and patients were given the time to ask questions if required. Staff reminded patients they could use the 24-hour helpline.
- We asked staff if there were occasions when patients changed their minds about a procedure. We were told that 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 10 consultations and no patients were informed that details of their termination procedure would be provided to the Department of Health. Staff told us that patients were not routinely made aware of the statutory requirements of the HSA4 forms and were not informed that the data sent to the Department of Health for statistical purposes was anonymised.
- Staff provided 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.

Emotional support

- All patients had a telephone consultation and assessment prior to their treatment through the Marie Stopes telephone appointment line "Onecall". A telephone counselling service was available pre and post-procedure and a patient information leaflet stated that MSI could arrange counselling or suggested 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 centre with details of when the 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 observed the nurse at the South Shields clinic informing patients that they could also access a local counselling service that offered face to face counselling for patients of all ages, based at a nearby health centre.
- 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.
- The records we reviewed recorded the post discharge support offered to patients and those close to them. Staff gave patients written information about accessing help from the staff at the clinic during service opening hours and the 24-hour telephone service following their procedure.
- We observed staff following procedures to provide a caring, confidential and non-judgemental service.
- 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. We saw an example when a patient was clearly emotionally upset and asked for her mother to be present throughout. The nurse granted this after a simple question of confirmation to the patient.

Are termination of pregnancy services responsive?

By responsive, we mean that services are organised so that they meet people's needs.

- 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.
- Staff directed patients to other clinics if they needed or preferred treatment on days the Leeds clinic or satellite sites were closed.
- 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.
- The service displayed the Department of Health certificate of approval in the waiting area of each clinic.
- The service had a robust complaints procedure and shared learning from complaints.
- Interpreting and counselling services were offered to all patients and the Leeds centre was accessible for those with disabilities. However, one satellite clinic did not have disabled access.
- There was an appropriate process should a patient wish for pregnancy remains to be disposed of sensitively.

However, we did observe long waiting times in clinics and some staff told us they had concerns about patient waiting times. Staff told us they felt rushed and were aware they kept patients waiting longer than they felt was appropriate.

Service planning and delivery to meet the needs of local people

- Treatment was carried out under NHS contracts with Leeds, Bradford, Wakefield, North Yorkshire and York, Huddersfield, Calderdale and North Kirklees, and South

Tyneside CCGs to provide a termination of pregnancy service for the patients of West Yorkshire and surrounding areas. Self-funding patients were able to self-refer.

- Referrals were also made as a result of other NHS services treatment times being too long, for example if a patient's estimated gestation was over 12 weeks. This was to ensure they could be treated before their gestation exceeded the limits for treatments available through Marie Stopes centres and the legal limits for abortion.
- Marie Stopes Leeds centre appointments were offered to women seeking abortion on Monday and Thursday each week and to men for vasectomy once a month on a Friday. The satellite clinics were each open one or two days a week and nursing staff rotated between the Leeds centre and the satellite clinics.
- The satellite clinic at Huddersfield was located on the second floor of an old building. There were no other businesses on that floor, steep stairs and no lift. There was an intercom and a receptionist greeted patients during our inspection. There was no information provided to patients or booking staff that this location was not easily accessible for patients with poor mobility, or for mothers with babies and buggies. Staff told us that they would request this information to be added to the website information for staff and patients.
- 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 other days, they could be signposted to alternative Marie Stopes satellite clinics in West Yorkshire, Lincolnshire and South Tyneside. Patients who wanted or needed weekend services could use the Marie Stopes centre at Manchester.
- Men could attend the Leeds Centre or the Wakefield clinic. Each provided vasectomies once a month on Fridays. There were no other clinics held on those days so men and women would receive their treatment separately.
- Patients were able to attend the most suitable appointment for their needs and as early as possible. If treatments were in two parts, the clinic staff worked with the other satellite clinics or regional centres to provide patients with more flexibility.
- 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.

Access and flow

- Patients aged 13 years and over could refer themselves or be referred into this service through traditional referral routes such as via their GP or a sexual health clinic.
- Staff told us they would see a patient under 13years for a face-to-face consultation if they turned up at the service but they did not provide treatment at Leeds sites for patients under 13 years of age.
- Patients could make appointments for Marie Stopes Leeds centre and satellite clinics via the Marie Stopes appointments line 'One-call', which was a 24 hours a day, seven days a week telephone booking and information service. Patients who walked in to any of the centres without an appointment were directed to One-call in the first instance.
- We were told that staff at the telephone booking service carried out an initial consultation and offered patients a choice of dates, times and locations. This ensured that 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 Marie Stopes Leeds could offer treatment later in the same day subject to a full medical assessment and legal procedures being carried out.
- At the Leeds clinics, patients were informed of abortion options available to them and depending on gestation; they were offered treatment at one of the local clinics or referred to another Marie Stopes centre to suit their needs. If their gestation was later than 18 weeks or if the consulting nurse or HCA had any concerns such as; there was suspicion of an ectopic pregnancy, the patient was referred 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. Marie Stopes managers told us Leeds centre records showed 100% were within the time limits of five days. The MSI Quality Accounts for 2015 to 16 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. Nurses told us that they understood the current MSI key performance indicator target was three working days.

- When demand peaked and waiting times were likely to exceed recommendations, the service had provided more appointments by adding additional appointments at the Leeds Centre or by providing a clinic on a Saturday.
- When attending the MSI clinics for medical or surgical treatment, following the initial telephone consultation, patients had a 15-minute appointment (or 30 minutes for patients under the age of 18 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.
- Results from the Leeds Client feedback report for 2015 showed that 14% of patients who completed feedback questionnaires felt dissatisfied with the length of time spent at the centre. The same report showed that only 50% of patients received an explanation for delays at the centre.
- It was clear from our observations, and from what staff told us that any deviation from the standard pathway meant that patients were likely to need more than the 15 minutes allocated time. We observed a number of occasions when patients' consultation was much longer than 15 minutes. Reasons for this included; the pregnancy could not be detected by abdominal scan and patients needed to have a transvaginal scan to confirm pregnancy, when patients needed more time to discuss contraception, or when they were upset about their decision, when patients needed anti-D injections and when patients needed referring to the 'Do Not Proceed' (DNP) team.
- Staff told us that they had raised concerns regarding the length of appointment slots and patient waiting times but no changes had been made. We discussed the standard appointment time with the regional manager who told us the time was set corporately and she felt this should be long enough for most patients and understood that this had been tested out. We were told that patients under 18 years were allocated 30 minute slots.
- Despite staff concerns, regarding waiting patients we observed that staff always gave patients time according to their individual needs and that appointments were not rushed. However, we saw that this did have an impact on patients waiting for later appointments.
- Nurses told us that patients attending the clinic for follow up due to retained products or ongoing pregnancy may have a second wait, following their initial consultation with a nurse or HCA, for a medical opinion or prescription from one of the doctors working remotely,. We observed one patient who had to wait two hours for a prescription. This was because the doctor had requested further information about the patient through the on line system but this did not alert the nurse that there was a query and, therefore, a delay occurred.
- Staff told us they referred patients to the 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 ambivalent. 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.
- If nurses found that patients appeared to be ambivalent about their decision, they were advised to take time to consider their options before rearranging an appointment.
- Patients could also contact Marie Stopes via telephone for post-abortion or vasectomy counselling. Counselling was a free service to all Marie Stopes patients. Patients could access the service at any time after their procedure, whether this was the same day or sometime later.
- Aftercare advice following abortion or vasectomy was available all day every day via a national helpline. All patients could access this telephone service or call the

clinics directly during opening hours. Staff gave the clinic information to patients to take away with them so they could contact the Leeds centre directly during opening hours, if they wished.
- A service user told us the service was very easy to access.
- Patients attending the South Shields satellite clinic could also access face to face counselling at a nearby health centre.

Meeting people's individual needs

- Satellite clinics were located in single rooms or suites, mostly within primary care centres. Disabled toilets and lifts were provided. However, the Huddersfield centre was situated remotely, on the second floor of an old building via a very steep and narrow staircase and was not accessible to wheelchair users or those with mobility limitations. There was no lift. We asked if patients identified as needing an accessible location (by Onecall) were given appointments at other locations. Staff could not confirm this and information available about the centre did not mention difficult access.
- 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 had happened, a friend had accompanied the patient and had helped 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. A patient, who spoke English as a second language, told us that during her telephone consultation the nurse had given her full and clear explanations and had been happy to repeat or rephrase information to ensure she had understood what was being said.
- Nurses in clinics told us they provided patients under 18 years of age with compulsory counselling as part of their treatment to ensure they were fully aware and informed of their decisions. All patients under 18 spoke to a counsellor by telephone as part of their consultation with the nurse. Managers told us this was in line with the MSI under 18 policy and care pathway.
- Staff told us that patients were signposted to information to be accessed online during their telephone consultation and we observed nurses in the clinics giving information 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.
- Leaflets included information on what to expect following procedures and the advice line number that patients could ring to seek any advice if they were worried. Staff gave patients the local clinic number to ring for advice and guidance and encouraged patients to use this during opening hours.
- 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 the waiting area. This included advice on contraception, sexually transmitted infections and services to support patients who were victims of rape or domestic abuse.
- There was a patient information file in the waiting area at each location we inspected. These files contained a range of information and signposting to local patients' services including drop in services, counselling, and other support services about abuse, relationships and bullying.
- Counselling was provided before and following procedures for patients having any method of termination and for men having vasectomy.
- We observed staff encouraging patients to ask questions about the options available to them.
- 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.
- Patients could request that Marie Stopes International staff made anonymous contact calls on their behalf if STI test results were positive.
- We observed nurses discussing contraception options with patients at the initial assessments and encouraging patients to make a plan for contraception after the abortion. This plan was recorded 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 they could make their own arrangements.

- Choices included long acting reversible contraceptives (LARCs) such as injections and implants or Intrauterine devices or systems (IUD/IUS). Nurses at satellite centres told us they would administer a depot injection 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 disposal of foetal 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 foetal remains following surgical terminations of pregnancy. Incineration of foetal waste is recognised as the appropriate method of disposal (when a patient does not express any personal wish for any other method of disposal). MSI stored the tissue in a sealed waste receptacle in the clinical specimen freezer until the clinical waste contractor collected the tissue for incineration. When the service needed to keep products 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 products after three months.
- Due to the very low gestational limits (up to nine weeks and four days) for early medical termination procedures at the satellite centres, staff explained that there should be little or no evidence of pregnancy remains delivered at home. Staff told us that no patients to date had requested a sensitive disposal.
- There were posters displayed in patient toilets about domestic violence and counselling.
- Men undergoing vasectomy were provided with a comprehensive information leaflet regarding what to expect, the procedure and aftercare. All vasectomy patients, who completed the MSI questionnaire, evaluated the information given as either very good or excellent.

Learning from complaints and concerns

- Although there was information on how to complain or raise concerns in a patient information folder in each clinic, this was not easily visible or displayed on information boards or walls in the Marie Stopes clinics we visited.
- The Marie Stopes website gave information on how to provide feedback or make a complaint.
- Verbal and written complaints were recorded on the incident reporting system.
- 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 and we saw an example recorded in the minutes. Managers forwarded written complaints to the Head of Quality and customer services, who acknowledged them all. They monitored progress via complaints action plans on a monthly basis. 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 three complaints in the six months prior to our inspection. We reviewed all three complaints and found that they had been investigated appropriately and actions had been taken where necessary. Two were ongoing complaints and one had been a verbal complaint where a patient had felt the staff had lacked empathy. Managers told us the team were treating it seriously and they had spoken with the patient and explained they could raise a formal complaint if they wished. Managers told us they expected the patient to write a formal letter in line with the complaints policy.
- Patients could raise issues via 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 via team meetings and shared the feedback reports with the team on publication. However, we found some qualitative data in the Marie Stopes Client Feedback Report for Quarter 4 (between

October and December) 2015 that showed patients had raised concerns about their legs being put into stirrups before sedation for surgical abortion and about feeling a lack of dignity because of this. Although these comments had been received the year before, we observed this practice carrying on during our inspection.

Are termination of pregnancy services well-led?

By well-led, we mean that the leadership, management and governance of the organisation assure the delivery of high-quality person-centred care, supports learning and innovation, and promotes an open and fair culture.

- At a national and corporate level we found that the service was not well led. CQC have issued a warning notice to the service regarding the need for immediate improvements to its leadership, governance, management of incidents and risks, compliance to RSOPs and the competence of its managers in local centres.
- Although there was a committee and meeting structure, throughout the organisation, to facilitate governance and oversee risk and quality management there was not a structured approach for escalation of issues or information sharing.
- Local manager or staff representation or attendance was not evident at all relevant meetings.
- The corporate reporting structure enabled oversight of the whole organisation in relation to key performance indicators and allowed for performance benchmarking between units. However, it was not clear how achievement of some indicators represented quality of service for patients.
- We did not see any information in patient areas regarding how services had been improved or practice had changed because of their feedback.
- We were not assured that all HSA4 forms were submitted and authorised within the Department of Health required time of 14 days following abortion.
- Not all staff felt supported by managers.

However;

- 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.
- Quality of care and patient experience was seen as the responsibility of all staff.

Vision and strategy for this core service

- Local managers had a clear vision for their service and how this was developing at both corporate and local level. Operational staff also knew what developments were planned and felt they were kept informed of business and operational developments.
- There were clear organisational aims, which affected staff at Leeds MSI such as improving recruitment and retention of staff, improving training and support for staff and improving incident reporting. All staff we spoke with were aware of and supportive of these aims.

Governance, risk management and quality measurement for this core service

- MSI Leeds had Department of Health (DH) certificates of approval displayed in the reception and patient waiting areas.
- The electronic patient record system had a reporting function that held a treatment register for surgical and medical TOPs. Patient details were automatically registered at the time of treatment.
- We found at a national level that there were poor governance arrangements. However, there was a governance framework comprising of a corporate central governance committee and local integrated governance committees. There were infection, prevention and control (IPC) and children and adult safeguarding committees at corporate level.
- Although there was a committee and meeting structure, throughout the organisation, to facilitate governance and oversee risk and quality management there was not a structured approach. It was apparent from minutes of meetings that various manager, governance and team meetings occurred locally and at different levels throughout the organisation; however, there did not appear to be clear escalation or information sharing processes.
- It was not evident from minutes that there was local manager or staff representation at all relevant meetings,

such as the IPC committee or the clinical leads group. Clinical governance meeting minutes did not show any set or 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. However, it was not clear how achievement of some indicators represented quality of service for patients. For example, staff did not understand the 'did not proceed' (DNP) target. They felt that achievement of this was largely out of their control as every referral to the DNP team was made on clinical grounds and in the best interest of the patient. This made communications from the corporate team regarding failing this target feel punitive.
- 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. We saw from April 2016 minutes of this meeting that the purpose of this meeting was to update on all serious incidents, complications, transfers and incidents within MSI, to provide an update on rates of reporting and the quality of information recorded, the impact of training and to provide a framework of discussion for all incidents, trends and lessons learned. This appeared to be a new format for these new meetings as previous minutes did not reflect the same topics.
- Data presented at the clinical governance committee was sometimes at regional or national level therefore it was difficult to highlight any areas where there may be a need for improvement or alternatively good practice. This made it drive improvements where needed and to share good practice.
- There was a programme of audit, which included hand hygiene, medicines management, infection control and record keeping audits. Regional managers and the nurse team leader were responsible for different elements of the audit programme. There had been a nominated individual self-assessment in March 2016 and there was an action plan in place to make improvements where identified.
- The service was monitored 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 exceeding targets relating to LARC, STI screening and start time and performing below target regarding 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. Leeds managers and staff knew what the top risks were for business continuity and patient safety and knew how to escalate 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 updated actions relating to risks were discussed at local 4-6 monthly, integrated governance meetings.
- The assessment process for termination of pregnancy legally requires that two doctors agree that at least one and the same legal grounds for termination of pregnancy are met and sign a form to indicate their agreement (HSA1 Form). We looked at 22 termination patient records and found that all forms included two signatures and the reason for the termination.
- We observed 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.
- For surgical abortions, we observed that the anaesthetist and surgeon both checked the patient's records before signing the HSA1 and then carrying out the procedure.
- The doctors at MSI Leeds told us that they checked the reason for requesting a termination carefully and would

reject an application if the information was incomplete or if they disagreed with the first doctor's decision. If the record was rejected then it showed as red on the system for nursing or other consultation staff to gain further information and resubmit the form with sufficient information for the doctor to be certain of their approval.

- Nurses and HCAs confirmed that this was the practice and they had experience of forms being returned for further information to be added to the record. Nursing staff and doctors stated that it was rare for a form to be returned because of insufficient information.
- We observed that nurses checked the HSA1 forms were completed correctly 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 carried out in 2014 and 2015 had consistently shown 100% compliance with HSA1 forms.
- The DH requires every provider undertaking termination of pregnancy to submit data following every termination of pregnancy procedure performed, within 14 days, using a HSA4 form. We observed doctors carrying out surgical terminations complete these forms electronically through the patient record and upload them to the DH immediately. We were not assured of HSA4 submission within 14 days for patients undergoing medical terminations.
- Doctors who prescribed medical treatments for termination also need to complete HSA4 forms; however, this cannot be done until the treatment has been administered. This meant there could be delays between medical abortion and DH reporting. Doctors would need to wait for confirmation that nurses in satellite centres had administered prescribed treatment before they could upload to DH. 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. Managers told us, if doctors did not authorise forms within 14 days, a reminder was sent. If forms were not electronically signed within 6 weeks of the date of termination they were removed from the doctor's account and sent on paper to be checked that the information provided is correct and for a written signature. This meant that MSI could not assure us that they were compliant with the legal requirement for DH submission of data within 14 days of each abortion.
- The Leeds regional manager had spoken with the health systems director following our inspection to explore how this assurance could be provided in future.
- 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 generic risk assessments regarding lone working for clinics in commercial buildings and GP surgeries, however these were not individualised to specific clinics or staff where risks were greater. We observed that although there were two members of staff at the Huddersfield clinic, it was particularly difficult to access and this had potentially higher risks for personal safety. We also observed that the South Shields clinic was quite a distance from other more populated areas of the building.
- The nurse at South Shields worked single handed, remote from peer or management supervision or support. This posed a different set of risks including potential risks to; patient safety, personal safety and the personal and professional well-being and development of the nurse. These potential issues were not covered by the generic risk assessments.
- Whether employed or working under practice privileges, policy stated that doctors had to provide evidence of current GMC registration, indemnity insurance, qualifications and evidence of annual appraisal / revalidation. Managers told us this process was monitored through the corporate human resource function. Evidence was provided regarding indemnity and current GMC registration and all doctors working at Leeds were up to date with these. However evidence of appraisal / revalidation and relevant training and qualifications, for anaesthetists working under practicing privileges such as being trained in advanced life support or to level 3 in child protection, was not made available to the inspection team.

Leadership

- The regional manager and clinical operations manager, who were both based in Manchester, visited the Leeds centre one or two days a week to provide managerial and clinical support and direction. However, staff from

this centre worked from Monday to Friday and some Saturdays. We found that staff who worked at satellite centres could only access managers face to face when they visited or worked at the Leeds Centre premises.

- The Leeds centre was set up as a hub and spoke model with 10 satellite clinics. The regional manager was the registered manager for the Leeds and Manchester centres.
- The regional clinical operations manager who covered the Leeds and Manchester centres was in the process of becoming a second registered manager for both centres.
- The Leeds centre had a full-time nursing team lead that provided day-to-day supervision and support.
- Almost all doctors and nursing staff we spoke with felt the leadership team were visible and accessible when they needed to contact them for advice or support. However not all staff felt they had the face-to-face support they required from managers or the support they needed. We saw that the nurse working from the South Shields clinic had very little contact with managers and other members of the team.
- Some members of staff felt that current shortages of staff were causing low morale for some staff due to pressure of increased workload and on occasions the need to travel long distances at short notice to outlying clinics to cover any additional short-term sickness/ absence. They felt that unrealistic expectations among new staff due to the information in job adverts and a lack of nursing supervision of new starters had led to increased turnover of staff. Staff shortages were also affecting staff being able to attend training and meetings.
- The nursing staff were aware that local and corporate managers knew of these concerns and had taken actions to address them. We saw that improvements had been made to advertising and job descriptions to ensure applicants had realistic expectations of their role and to improve the supervision and support of new RNs by RNs already in post.
- Staff valued having clinical leadership in the locality and felt this was improving nursing supervision and support.
- 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. Most but not all staff were able to attend these meetings.
- Doctors and nursing staff told us they felt able to raise concerns or ideas with their regional managers or professional lead. However, staff were not always given feedback regarding their concerns, for example appointment slots and DNP targets.

Culture within the service

- 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 and as having an open culture.
- 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 we spoke with liked working for MSI and felt the organisation was patient focussed and generally supportive of staff.
- 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. Staff felt that every referral to the DNP team was justified and made in line with MSI guidance regarding exclusion criteria, gestational dates or ambivalence. Staff did not know if the organisation was analysing DNP information, to understand the reasons for referral or to improve services to patients.
- We met with regional managers who appeared supportive of their staff and discussed systems and procedures in place throughout the organisation that encouraged an open and supportive culture.
- Staff were encouraged to access training when they identified a skills gap through supervision or the appraisal process. However, some staff said that they found it difficult to complete training due to staff vacancies as this made finding cover for training difficult.
- 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.

Public engagement

- Patients attending the clinic were able to provide feedback by completing comments cards or by commenting online on 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 clinic staff routinely asked patients to complete feedback questionnaires and managers told us they regularly achieved a good response rate; however, we could not disaggregate a response rate for the Leeds centre from the data provided. Overall MSI nationally had a response rate of 42%.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.
- Staff told us the service was working closely with local and national charities; staff told us that work with these organisations had increased their awareness around domestic violence.

Staff engagement

- MSI carried out an annual staff survey to establish the satisfaction of their staff. Results from the 2015 survey showed; an overall satisfaction score of 78%, 86% of staff in the survey indicated they were happy to go the extra mile when needed, 85% felt they were committed to the organisation's goals, 73% were proud to work at MSI UK and 68% would recommend the organisation as a place to work. Centre level results were not available as staff would be identifiable. The information provided did not include a response rate for the staff survey.
- MSI operated a staff awards scheme where staff nominated other staff in the organisation to be recognised nationally for their good work.
- We saw that MSI produced a staff magazine, which included topics such as; information from staff surveys, planned developments across the organisation, what was happening about recruitment and retention, training and staff awards.
- Staff told us that although they were not directly involved in development of policies and practice or service improvement, they were fully informed about any changes planned.
- Locally, staff at the centre had planned and costed a redecoration plan and sourced a local gardener to make the centre more welcoming for patients by planting window boxes and flowerpots. Funds to complete the improvements had been included in 2015 budget process.
- Staff told they received regular information and updates through meetings, emails, the MSI magazine and other publications.
- The MSI doctors told us that the service was able to accommodate their needs in treating patients to the RCOG standards.
- Doctors and managers felt that they had a voice within the organisation.
- The regional clinical operations manager felt empowered and supported to implement changes where necessary.

Innovation, improvement and sustainability

- The service had shown significant improvement from 30% of eligible patients tested for sexually transmitted disease in 2014 to 84% in 2015 and 97% in 2016, year to date. This was achieved through the introduction of a system to flag patients who were eligible for tests, which notified the clinician as the patient arrived. Results were exceeding commissioning and organisational targets.
- By introducing individual targets for staff and by sharing and recognising outstanding performance, the Leeds centre had seen similar success in improving the uptake of long acting reversible contraception (LARC).
- The service managers were looking at ways to increase the patient activity through the Leeds centre and working towards opening a further satellite clinic at Rotherham, to make services more accessible in that area.
- The organisation provided assisted travel and accommodation for staff that were required to cover clinics away from their usual base.
- Staff within the Leeds centre had implemented a sticker system for notes to assist them in identifying patients eligible for HIV testing. (This test was not commissioned by all clinical commissioning groups.)
- The Leeds centre was in the process of planning to expand its services by increasing opening days.

Outstanding practice and areas for improvement

Areas for improvement

Action the provider MUST take to improve

Action the clinic MUST take to improve

- Ensure that staff always follow procedures in line with medicines management policies with regard to refrigerated drugs and administration of controlled drugs. We have taken regulatory action and applied a Requirement notice against MSI Leeds centre for Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 (Part 3) Regulation 12(2) (g) the proper and safe management of medicines.
- Ensure that all HSA4 forms are submitted to the DH within 14 days of abortion.
- Review the children safeguarding policy and training requirements for all staff to ensure the standard and level of training is in line with intercollegiate guidance 2014.
- Inform patients of the requirement to submit abortion data to the DH and explain how this information is anonymised.

Action the provider SHOULD take to improve

Action the clinic SHOULD take to improve

- Review how issues are escalated and how learning from incidents across the organisation is shared with local staff.
- Review the training requirements of consultation staff with regard to; contraception advice and dispensing and review infection prevention and control policies with regard to clarifying training requirements for staff, ensuring staff receive training updates as required.
- Review how the dignity of patients is maintained in theatre and the recovery areas to include the positioning of patients while awake, in view of patient feedback and inspection observations.
- Review the dress code policy in relation to theatre garb, infection prevention and control and current recommended practice. Ensure staff are aware of and implement this policy correctly
- Monitor patient waiting times in clinic and keep patients informed of delays and expected length of time waiting.
- Ensure patients and visitors are easily able to identify how to raise a complaint or concern.
- Review the support arrangements and lone worker risk assessments and arrangements for staff working in isolation from the rest of the team.
- Clarify for staff the 'DNP' key performance indicator and share findings from any audit of this aspect of the service.
- Provide information to service users how services have been improved because of their feedback.

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 Staff did not always follow procedures in line with medicines management policies with regard to refrigerated drugs and administration of controlled drugs.

Regulated activity	Regulation
Termination of pregnancies	Regulation 9 HSCA (RA) Regulations 2014 Person-centred care Staff did not inform patients of the requirement to submit abortion data to the DH.

This section is primarily information for the provider

Enforcement actions

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.