Marie Stopes International Manchester 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

Summary of findings

Letter from the Chief Inspector of Hospitals

Marie Stopes International Manchester Centre (MSI Manchester) is part of the Marie Stopes International group and was acquired in November 2004. The service provides surgical termination of pregnancy procedures (SToP) up to 23 weeks and six days gestation and early medical termination of pregnancy (MToP) up to nine weeks and four days gestation. Treatments can be provided under no-anaesthesia, sedation anaesthesia and general anaesthesia. The service does not carry out manual vacuum aspiration procedures. The service also provides advice on contraceptive options, provides oral contraception, long acting reversible contraception (LARC) and male sterilisation (vasectomy).

In terms of medical abortions, the provider offers three treatment options. Medication can be administered at the clinic in two stages with six hours, 24 hours,48 hours or 72 hours in between each stage. The service had previously offered simultaneous medical abortions (whereby both stages of medication are administered without a gap between each stage) but had suspended this treatment at the time of our inspection until more outcome data has been collected.

The clinic is open Tuesday to Saturday and alternate Thursdays for vasectomy patients. In addition MSI Manchester has 10 satellite clinics across Greater Manchester and Lancashire where they carry out consultations and early medical abortions up to nine weeks and four days. Staff work on a rotational basis between the satellite clinics and MSI Manchester.

We carried out this inspection as part of our comprehensive inspection programme of termination of pregnancy services. As part of our inspection we reviewed medical and surgical termination of pregnancy services carried out at the MSI Manchester clinic only. At the time of inspection there were no vasectomy lists.

The announced inspection of MSI Manchester took place on 19 May 2016 and we visited all areas within the service including the theatre, recovery areas, consultation rooms and waiting areas. We also carried out an unannounced inspection on 16 June 2016 to see how patients were cared for during a busy surgery day.

We have not provided ratings for this service. 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.

Although we do not currently have the powers to rate these services, we report on whether they are safe, effective, caring, responsive to people's needs and well-led. We highlight areas of good practice and areas for improvement.

Our key findings across all the areas we inspected were as follows:

Are services safe at this service

- There was an electronic system in place to report incidents, with triggers to alert senior management. Staff we spoke with were aware of the process and understood their responsibilities. Serious incidents had been investigated at local level, with identified actions to prevent reoccurrence. It was clear from the reports and resulting action plans that the identified actions had been completed in a timely manner.
- Staff we spoke with understood the requirements of duty of candour. A duty of candour policy had been introduced in April 2016.
- The service had clear systems in place to identify and report any safeguarding concerns. However, records showed only 57% of staff had completed level two training in safeguarding children and adults. Staff were not routinely trained to level three in children's safeguarding. The regional manager informed us that a new head of safeguarding had been appointed in the last six months and was reviewing training requirements in line with intercollegiate guidelines.
- There was a clear transfer policy agreement in place with the local NHS trust. If a patient required an emergency transfer to the local NHS provider, patients would be transferred by a member of clinical personnel and the theatre list would be stopped until staff were available.

Summary of findings

- There was little reliance on agency staff to cover nursing shifts and two shifts had required agency cover in the last three months. Registration with the Nursing and Midwifery Council and General Medical Council was monitored by the central human resources team and quarterly reports were sent to the registered manager flagging any issues.
- Medical staffing was provided by doctors working both remotely and within the centre. The service employed one surgeon to work at the centre on a full time basis. There were no vacancies for medical staff and surgeons; staff working at other MSI centres provided cover if necessary.
- However, we were not assured that staffing in theatres met the recommended staffing standard identified by the Association for Perioperative Practice (AFPP).
- The provider's schedule of services for anaesthetists and surgeons states that they should "assess all remaining clients and liaise with the senior nurse before leaving the centre". This meant that they were able to leave the centre before all patients have been discharged and potentially leave the clinic with no staff trained in advanced life support should a patient deteriorate post-operatively.
- At the time of our inspection we observed syringes containing an induction agent (drug used to help patients relax before and during general anaesthesia) in a kidney dish on the anaesthetic machine in theatre. The tips of the syringes were not covered to protect them from the risk of cross infection. We asked the anaesthetist if this presented a risk of infection and they told us they usually placed the tip of the syringe back into the sterile wrapping. At the time of our inspection we observed additional syringes being prepared and the tips were covered in the sterile packaging until used.
- Cleaning schedule checklists for the theatre had not been completed consistently and there was no record of how often and when the fabric covers for chairs in the ward area had been cleaned or changed.
- Resuscitation equipment was not checked daily, which is identified as best practice by the Royal College of Anaesthetists (2012).

Are services effective at this service

- The provider had policies and guidelines in place in relation to: offering patients a choice of procedure, discussion and options for future contraception and screening for sexually transmitted disease.
- Policies were not always updated to reflect practice changes in a timely manner. Both the ultrasound policy and the medicines management policy we reviewed were out of date at the time of inspection. The ultrasound policy had been due for review in July 2015 and the medicines policy had been due for review in March 2016.
- The service had key performance indicators in place and these were reported each month via the governance and quality dashboard. The dashboard showed there had been no returns to theatre or transfers from January to March 2016.
- The service had locally agreed standards in place with commissioners. The service also reported any instances of ectopic pregnancy to the commissioners.
- Medical records audits included monitoring of pathways of care, information provision and pre-abortion assessment in line with Royal College of Obstetricians and Gynaecologists' (RCOG) guidelines. The pre-abortion assessment was performed in conjunction with the corporate pre-existing conditions guidelines. Details about the type of abortion procedures that were carried out were captured and monitored via centrally produced capacity reports.
- For new staff, an induction and training programme was in place where competencies were assessed with mentor support and supervision. Senior staff we spoke with stated that staff were assessed against these before being allowed to practice unsupervised. Records showed all of the medical and nursing staff had received an appraisal in 2015.
- Staff across the service were aware of appropriate procedures in obtaining consent. Healthcare assistants and nurses had been trained in line with the provider's own policy and would go through the consent process with patients during the consultation. However, none of the staff had received safeguarding training at level three, which meant we were not assured that staff taking consent had the appropriate knowledge, skills and competence to support patients who may be vulnerable or lack capacity to make a decision.

Summary of findings

Are services caring at this service

- Staff took time to interact with patients; they were attentive to their needs and spoke in a compassionate manner most of the time. Staff in theatre were supportive and tried to put the patient at ease.
- All patients were provided with a feedback questionnaire prior to discharge, to be completed in the clinic or later at home. They were anonymous, sealed, and sent to an external organisation for collation and reporting. For the period January 2015 to March 2016, service users had rated the service at 96% for the overall quality of care.
- Counselling services were available to help and support patients if required, either by telephone or face to face.
- The layout of the recovery room meant there was limited privacy for patients. Staff at the time of our inspection did not seem to be aware of this or sensitive to the need to adapt practice when required to ensure patients' privacy and dignity was not compromised.

Are services responsive at this service

- Services were responsive to patients' needs. Appointments were offered in a timely manner and patients were given options to choose the procedure that was the best option for them. Waiting times for consultation from initial contact and treatment from initial contact were consistently within the Royal College of Obstetricians and Gynaecologists' (RCOG) recommended timeframes.
- Records we reviewed showed pre-existing medical conditions were considered and risk assessed in the medical review. If a patient was deemed at risk and could not be managed in the clinic they were referred to the local NHS provider.
- A 24 hour telephone line was available to provide advice and support outside service hours. In the event a patient deteriorated, the patient could be brought back to a clinic for consultation or if it was an emergency could be directed to their local accident and emergency department.
- There was disabled access on the basement level, where a patient with reduced mobility could be treated, whether receiving a medical or surgical termination of pregnancy.
- A telephone interpreter service was available for non-English speaking patients, as well as written information, in the form of leaflets and on the website.. A hearing loop had been introduced on 12 May 2016.
- Where possible any concerns raised whilst the patient was on site would be dealt with by staff. Formal complaints were reviewed and responded to by the head of quality and customer service with involvement from the registered manager.
- We were not assured that patients were given information to make an informed choice with regards to disposal of pregnancy remains. We did not see any evidence of discussions in the patient record and did not see information about options given to patients. However information was available on the provider website.
- The post-operative area was cramped, there was little room for privacy and patients' dignity was at risk. The area was staffed with two staff, who were also responsible for collecting patients from theatre, watching a monitor and responding to patients' needs in a separate room.

Are services well led at this service

- The service had a clearly defined vision supported by the corporate mission statement "Children by choice, not chance". Staff we spoke with were able to articulate this and were 'pro-choice' in their approach to providing patients with care and treatment.
- There was a regional management structure in place that identified lines of accountability. Staff we spoke with told us they felt supported to learn and develop and liked working at the clinic.
- There was a corporate governance framework in place supported by both a corporate central governance committee and local integrated governance committees. Local compliance with governance standards and key performance indicators was monitored via a governance and quality dashboard that was submitted to head office on a monthly basis.

Summary of findings

- Review of best practice guidance and any changes to clinical policy were discussed and ratified during the corporate clinical leads meetings. Any decisions would then be signed off by the central governance committee. However, there was no evidence of local management involvement in decision making, with a top down approach being adopted by the provider. This was evident in the initial decision to implement simultaneous administration of medication for early medical abortions.
- There was no effective process in place to ensure policies were reviewed and updated in a timely manner.
- Staff stated that practising privileges were handled corporately and were reviewed by the medical director and lead doctor. However, there was limited oversight of this process at local level. For example, the registered manager was not involved in the decision to renew practising privileges and did not have sight of the doctor's most recent appraisal or revalidation. Similarly, pre-employment checks were carried out and stored at head office. The provider was in the process of transferring this information onto an online system so it could be accessed from any clinic but it was not in place at the time of our inspection.
- The process for signing HSA1 forms meant that abortifacient medication could be prescribed before two signatures had been obtained on the HSA1 form, we found this in two out of eight records reviewed.
- Patients were not informed about the statutory requirement of HSA4 forms. Staff did not explain to patients that these details were sent to the Department of Health and that it was a legal requirement.
- Clinical governance reports included data on failure rate by surgery and medical treatments, infections, and the reasons for any transfers. However, the reports included data at either national or regional level and were not broken down by clinic so it was not clear how the data was used to drive local improvement.

We saw some areas of practice where the provider needs to make improvements.

Importantly, the provider must:

- Ensure all staff have received the appropriate level of safeguarding training in line with intercollegiate guidelines.
- Ensure that staffing levels in theatre have been risk assessed and adhere to recommended guidance at all times.
- Ensure staffing levels in the recovery area are sufficient to meet patients' needs at all times.
- Consider how best to ensure patients' privacy and dignity is maintained in the recovery area.
- Ensure patients are informed of the requirement to submit abortion data to the Department of Health and how this information is anonymised.
- Ensure syringes that are used to administer intra-venous medication are stored appropriately prior to use to prevent risk of cross infection,
- Ensure cleaning records in theatre are fully completed and that there is a clearly documented process for changing seat covers in the recovery area.
- Review how often resuscitation equipment is checked in line with best practice guidance.
- Ensure the registered manager has clear local oversight of the practising privileges review and renewal process.
- Ensure the registered manager has clear local oversight and assurance with regards to the completion of pre-employment checks prior to new members of staff commencing employment.
- Consider how data included in quarterly governance reports can be broken down to clinic level so they can be used meaningfully to identify local issues and improve local performance and patient outcomes.
- Ensure both the ultrasound policy and the medicine management policy are reviewed to ensure they contain current information in line with best practice. This should include being clear whether scanning post treatment is a routine requirement or not.
- Ensure that there are effective processes in place to ensure that the certificate(s) of opinion HSA1 forms are signed by two medical practitioners in line with the requirements of the Abortion Act 1967 and Abortion Regulations 1991.
- Ensure that staff are appropriately trained to assess and respond to a deteriorating patient and staff with advanced life support training remain on site whilst patients are recovering from surgical termination of pregnancy.

In addition the provider should:

Summary of findings

- Ensure there is an effective system in place to provide patients with information to make an informed choice with regards to disposal of pregnancy remains, including documentation of discussion and decision.

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 12 October 2016.

CQC also issued warning notices for breaches of the following regulations, which are relevant to this location:

Regulation 11 Consent

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 warning notices in order to ensure that services are operated in a manner which protects patients from abuse and avoidable harm.

Professor Sir Mike Richards
Chief Inspector of Hospitals

Summary of findings

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Background to Marie Stopes International Manchester Centre

Marie Stopes International Manchester Centre (MSI Manchester) is part of the provider group Marie Stopes International and was acquired in November 2004. The clinic is located four miles from Manchester town centre and eight miles from Manchester Airport in Fallowfield, a residential area with good transport links.

MSI Manchester provides surgical termination of pregnancy procedures (SToP) up to 23 weeks and six days gestation and medical termination of pregnancy (MToP) up to nine weeks and four days gestation. Treatments can be provided under no-anaesthesia, conscious sedation anaesthesia and general anaesthesia. The service does not carry out manual vacuum aspiration procedures.

In terms of medical abortions, the provider offers three treatment options. Medication can be administered at the clinic in two stages with six hours, 24 hours,48hours or 72 hours in between each stage. The service had previously offered simultaneous medical abortions (whereby both stages of medication are administered without a gap between each stage) but had suspended this treatment at the time of our inspection until more outcome data has been collected.

The clinic also provides advice on contraceptive options, provides oral contraception, long acting reversible contraception (LARC) and male sterilisation (vasectomy).

The clinic is open Tuesday to Saturday and alternate Thursdays for vasectomy patients. It provides services for private patients and patients referred by their GP or self-referral for a number of clinical commissioning groups (CCGs). The service has four consulting rooms, one operating theatre and nine day case beds.

In addition, MSI Manchester has 10 satellite clinics across Greater Manchester and Lancashire where consultations and early medical abortions up to nine weeks and four days are provided. Staff work on a rotational basis between the satellite clinics and MSI Manchester.

Our inspection team

Our inspection team was led by an inspection manager and included two CQC inspectors who have received specialist training in 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?

Before visiting, we reviewed a range of information we held about the service. Patients were invited to contact CQC with their feedback.

We carried out an announced comprehensive inspection on 19 May 2016. We also carried out an unannounced inspection on 16 June 2016 to see how patients were cared for during a busy surgery day.

To inform our inspection we reviewed data provided by the service and spoke to a range of staff which included: registered nurses and midwives, healthcare assistants (HCAs), surgeons, anaesthetists, the regional manager (also the registered manager), the regional operations manager and reception staff.

Summary of this inspection

We spoke with three patients and observed care and treatment. We looked at 16 records for both medical and surgical termination of pregnancy patients. We also reviewed other relevant records held by the service such as complaints, incidents and relevant policies.

We did not visit any of the satellite clinics as part of this inspection but did review relevant supporting records in relation to the satellite clinics such as audits, incident reports and maintenance records.

We have not provided ratings for this service. 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.

Information about Marie Stopes International Manchester Centre

The service is registered with the Care Quality Commission to provide the following regulated activities:

- Diagnostic and screening procedures
- Family planning
- Surgical procedures
- Termination of pregnancies
- Treatment of disease, disorder or injury

The registered manager has been in post since 2010.

MSI Manchester prescribes and administers abortifacient medication. From January to December 2015 the service carried out 1403 early medical abortions, which accounted for 26% of the overall ToP activity.

In the same period, the service performed 4019 surgical abortions (74% of ToP activity), of which 285 were undertaken after 19 weeks gestation.

Staff employed consisted of one medical doctor (wte 1.0), 11 registered nurses (wte 4.8) and eight administration staff (wte 7.4). There was one vacancy for a registered nurse (0.6 wte) at the time of inspection. The total number of shifts of agency cover for registered nurses in the three months prior to inspection had been two.

Termination of pregnancy

Safe	
Effective	
Caring	
Responsive	
Well-led	

Information about the service

Marie Stopes International Manchester Centre (MSI Manchester) is located four miles from Manchester town centre and eight miles from Manchester Airport in Fallowfield, a residential area with good transport links.

MSI Manchester provides surgical termination of pregnancy procedures (Top's) up to 23 weeks and six days gestation and medical Top's up to nine weeks and four days gestation. Treatments can be provided under no-anaesthesia, conscious sedation anaesthesia and general anaesthesia. The service does not carry out manual vacuum aspiration procedures.

The clinic also provides advice on contraceptive options, provides oral contraception, long acting reversible contraception (LARC) and male sterilisation (vasectomy).

The clinic is open Tuesday to Saturday and alternate Thursdays for vasectomy patients. It provides services for private patients and patients referred by their GP or self-referral for a number of clinical commissioning groups (CCGs). The service has four consulting rooms, one operating theatre and nine day case beds.

In addition, the service has 10 satellite clinics across Greater Manchester and Lancashire where consultations and early medical abortions up to nine weeks and four days are performed. Staff work on a rotational basis between the satellite clinics and MSI Manchester.

Marie Stopes International operate a dedicated telephone helpline via the MSI One Call centre. This operates 24 hours a day throughout the year to provide patients with a contact for support and advice during periods when the service is closed.

Summary of findings

There was an electronic system in place to report incidents, with triggers to alert senior management. Staff we spoke with were aware of the process and understood their responsibilities. Serious incidents had been investigated locally, with identified actions to prevent reoccurrence. Staff understood the requirements of duty of candour.

The service had systems in place to identify and report any safeguarding concerns.

There was a clear transfer policy agreement in place with the local NHS trust. The governance and quality dashboard showed there had been no returns to theatre or transfers from January to March 2016.

The provider was adhering to policies and guidelines in relation to: offering patients a choice of procedure, discussion and options for future contraception, screening for sexually transmitted disease.

The service had locally agreed performance standards in place with commissioners.

For new staff, an induction and training programme was in place where competencies were assessed with mentor support and supervision. Staff we spoke with said that staff were assessed against these before being allowed to practice unsupervised. All of the medical and nursing staff had received an appraisal in 2015.

Staff across the service were aware of appropriate procedures in obtaining consent. Healthcare assistants and nurses had been trained in line with the provider's own policy and would go through the consent process with patients during consultation. However, none of the staff had received safeguarding training at level three,

which meant we were not assured that staff taking consent had the appropriate knowledge, skills and competence to support patients who may be vulnerable or lack capacity to make a decision.

We observed that staff took time to interact with patients; in the majority of cases they were attentive to their needs and tried to put the patient at ease. Feedback questionnaires showed the majority of patients were positive about the quality of care they received. Counselling services were available to help and support patients if required, either by telephone or face to face.

Appointments were offered in a timely manner and patients were given options to choose the procedure that was the best option for them. Waiting times for consultation from initial contact and treatment from initial contact were consistently within the Royal College of Obstetricians and Gynaecologists' (RCOG) recommended timeframes.

Records we reviewed showed pre-existing medical conditions were considered and risk assessed in the medical review. If a patient was deemed at risk and could not be managed in the clinic they were referred to the local NHS provider.

A 24 hour telephone line, via MSI One Call centre, was available to provide advice and support outside service hours. In the event a patient deteriorated, the patient could be brought back to a clinic for consultation or if it was an emergency could be directed to their local accident and emergency department.

There was disabled access on the basement level, where a patient with reduced mobility could be treated, whether receiving a medical or surgical termination of pregnancy. A telephone interpreter service was available for non-English speaking patients, as well as written information, in the form of leaflets and on the website. A hearing loop had been introduced on 12 May 2016.

The service had a clearly defined vision supported by the corporate mission statement "Children by choice, not chance". Staff we spoke with were able to articulate this and were 'pro-choice' in their approach to providing patients with care and treatment.

There was a regional management structure in place that identified lines of accountability. Staff we spoke with felt supported to learn and develop and liked working at the clinic.

There was a corporate governance framework in place supported by both a corporate central governance committee and local integrated governance committees. Local compliance with governance standards and key performance indicators was monitored by the registered manager via a governance and quality dashboard. This was also submitted to head office on a monthly basis for corporate overview, although it was unclear how the provider used this information.

Review of best practice guidance and any changes to clinical policy were discussed and ratified during the corporate clinical leads meetings. Staff stated that any decisions would then be signed off by the central governance committee.

However:

Both the ultrasound policy and the medicines management policy we reviewed were out of date at the time of inspection. The ultrasound policy had been due for review in July 2015 and the medicines policy had been due for review in March 2016.

Records showed only 57% of staff had completed level two training in safeguarding children and adults. Staff treating those under 18 were not routinely trained to level three in children's safeguarding. The regional manager informed us that a new head of safeguarding had been appointed in the last six months and was reviewing training requirements in line with intercollegiate guidelines.

We were not assured that staffing in theatres met the minimum recommended staffing standard identified by the Association for Perioperative Practice (AFPP) of two scrub practitioners, one circulating staff member and a registered anaesthetic practitioner.

Resuscitation equipment was not checked daily, which is identified as best practice by the Royal College of Anaesthetists (2012).

The post-operative area was cramped with little room for privacy and patients' dignity was at risk. At the time

of our inspection, staff did not seem to be aware of this or sensitive to the need to adapt practice when required to ensure patients' privacy and dignity was not compromised. The area was staffed with two staff, who were also responsible for collecting patients from theatre, watching a monitor and responding to patients' needs in a separate room.

We were not assured that patients were given information to make an informed choice with regards to disposal of pregnancy remains, however information was available on the provider website.

There was no evidence of local management involvement in decision making, with a top down approach being adopted by the provider.

Processes in place to ensure that the certificate(s) of opinion HSA1 forms were signed by two medical practitioners in line with the requirements of the Abortion Act 1967 and Abortion Regulations 1991 were not always effective.

The process for signing HSA1 forms meant that abortifacient medication was sometimes prescribed before two signatures had been obtained on the HSA1 form.

Patients were not informed about the statutory requirement of HSA4 forms. Staff did not explain to patients that these details were sent to the Department of Health and that it was a legal requirement.

Are termination of pregnancy services safe?

- Records showed only 57% of staff had completed the level two training in safeguarding children and adults. Staff were not routinely trained to level three in children's safeguarding. The regional manager informed us that a new head of safeguarding had been appointed in the last six months and was reviewing training requirements in line with intercollegiate guidelines.
- We were not assured that staffing in theatres met the recommended staffing standard identified by the Association for Perioperative Practice (AFPP) because in the absence of anaesthetic support, the scrub nurse was required to back fill that role and a healthcare assistant then supported as scrub nurse.
- The provider had set up a room, other than the recovery area, which was used for patients. However, this was not staffed and a camera was in use to observe patients remotely. Staff had raised this as a safety concern.
- We were not assured that a member of staff trained in advanced life support was always present on site when patients who had received an anaesthetic were still recovering post-surgery.
- Resuscitation equipment was not checked daily, which is identified as best practice by the Royal College of Anaesthetists (2012).
- Data provided indicated that an early warning scoring (EWS) system was used to identify and escalate the deteriorating patient. However, there was no evidence during inspection that the EWS was consistently being used.
- Medication was drawn up in syringes in theatre but the tips of the syringes were not covered. This could present a risk of cross-infection.
- Cleaning schedule checklists for the theatre had not been completed consistently and there was no record of how often and when the fabric covers for chairs in the ward area had been cleaned or changed.

However:

- Serious incidents had been investigated locally, with identified actions to prevent reoccurrence. It was clear from the reports and resulting action plans that the identified actions had been completed in a timely manner.

- All areas we visited were visibly clean, well-organised and free from clutter.
- Equipment had been appropriately maintenance checked.
- The service had clear systems in place to identify and report safeguarding concerns. Staff we spoke with were able to articulate the process of referral if they identified any concerns such as female genital mutilation (FGM) or child sex exploitation (CSE).

Incidents

- There was an electronic system in place to report incidents, with triggers to alert senior management. Staff we spoke with were aware of the process and understood their responsibilities.
- From 25 April 2015 to 9 March 2016 the service had reported 120 incidents; 29 of which were related to retained products of conception and 15 were in relation to continuing pregnancy (of which nine were following simultaneous administration of abortifacient medication).
- From January 2015 to December 2015 there were no never events. Never events are serious incidents that are wholly preventable as guidance or safety recommendations that provide strong systemic protective barriers are available at a national level and should have been implemented by all healthcare providers.
- From January 2015 to December 2015 there were two serious incidents requiring investigation (SIs). One occurred in May 2015 and was in relation to suspected damage to a uterine scar during a surgical abortion. The second incident occurred in September 2015 at the Blackpool satellite clinic and was in relation to a missed ectopic pregnancy. Both incidents had been investigated using a root cause analysis (RCA) approach, with identified actions to prevent reoccurrence. It was clear from the reports and resulting action plans that the identified actions had been completed in a timely manner. The regional manager had completed the RCA investigations and they had received training in RCA methodology.
- Staff we spoke with understood duty of candour as being open and transparent with patients. A duty of candour policy had been introduced in April 2016. .Although the duty of candour process had been followed with regards to both serious incidents, it was not clear from the other incident information provided if and when duty of candour was flagged or considered; there was no formal trigger seen in the application of it. Details were requested, however no further information was provided.
- Feedback from incident investigations along with learning from incidents across MSI was provided at monthly team meetings or by emails. Staff had access to computers and could check emails during their shift.
- Doctors' meeting minutes from March 2016 showed that serious incidents were presented as case studies to share learning and standardise approach.
- There had been no incidents of patient death at MSI Manchester. However, systems were in place to notify the CQC and the Department of Health in the event of such an incident. The regional operations manager explained that all incidents were reported via the electronic reporting system. In the event of a patient death this would trigger an automated alert to the nominated individual, who would instigate an investigation and a notification would be submitted to the CQC and the Department of Health.

Cleanliness, infection control and hygiene

- There were no MRSA cases reported by the service between January 2015 and January 2016.
- Infection control audits were completed every six months. The most recent audit was dated 12 May 2016 and showed a compliance rate of 98.6%. Points had been deducted because all high level surfaces were not free from dust.
- Hand hygiene audits were also completed every six months. The most recent audit was dated 17 March 2016 and showed a compliance rate of 94.4%. Points had been deducted because wall mounted hand cream was not available for use in all areas.
- All areas of non-compliance were logged on an audit master action plan which allowed both local and corporate oversight. Required actions were clearly identified with the deadline for completion and responsible person. The plan was updated with progress comments each month and showed appropriate action had or was being taken to address the issues identified.
- The reception area, consultation rooms, ward, and theatre were visibly clean and well organised. The theatre had a separate sluice and an area for the storage of sterile equipment.

- Hand gel and sanitizers were readily available on entry to clinical areas and staff were observed using sanitizing hand gels and hand washing procedures prior to providing care to patients. All clinical staff we observed adhered to the 'bare below the elbows' policy in clinical areas. Protective equipment was readily available and included gloves and aprons.
- Gels applied during ultrasound examinations were available in single use sachets to reduce the risk of cross infection.
- In theatre we observed trolleys being cleaned after each use and sterile surgical equipment being set up using the aseptic non-touch technique, which is a technique used to reduce the risk of healthcare associated infections.
- At the time of our inspection we observed syringes containing an induction agent (drug used to help patients relax before and during general anaesthesia) in a kidney dish on the anaesthetic machine in theatre. The tips of the syringes were not covered to protect them from the risk of cross infection. The syringes were being used to administer the medication to the patient via an intra-venous cannula. We asked the anaesthetist if this presented a risk of infection and they told us they usually placed the tip of the syringe back into the sterile wrapping. At the time of our inspection we observed additional syringes being prepared and the tips were covered in the sterile packaging until used.
- We reviewed daily cleaning schedules for theatre and the ward completed for the month of April 2016. We also reviewed the theatre checklist for cleaning and stock checks for May 2016. Whilst we found the checklist completed for the week commencing the 16 May 2016, the checklist was not completed for the week commencing 2 May 2016.
- The chairs on the ward were made of fabric and each was covered with a square shaped cover which was changed in between patients. We asked staff about the fabric on the chairs and we were told that the covers were changed every couple of days or at least weekly. However, there was no record available to determine when the covers had last been changed.

Environment and equipment

- The service was located in a large house with three floors and a basement. Access to each floor was by stairs. The basement included the surgical services with a theatre, a small ward and a waiting area. The ground floor included the reception and initial waiting room and the two other floors included the consulting rooms, one of which stored all the medications for medical terminations of pregnancy.
- The entrance to the clinic was controlled via an intercom system. Key code locks were on the client changing room door, the theatre door and the doctors changing room. At the time of inspection all patients were escorted by a member of staff when moving through the clinic.
- In the consulting rooms and theatre, all electrical equipment that we observed at the time of our inspection was clearly marked as being maintenance checked within the previous 12 months and included: ultrasound machines, suction machines, and the anaesthetic machine.
- There was a maintenance file for medical and non-medical equipment that included a planned preventative maintenance schedule and a log that showed equipment had been subject to the required maintenance checks.
- The resuscitation equipment was stored in the recovery area of theatre (which was located in the basement level). It was maintained on a wheeled trolley that could be transported to the other two upper floors if needed. There was no emergency equipment stored on other floors in the building. In addition, emergency medication was stored in the medicines cabinet in the theatre, which was left unlocked during surgery for quick access in case of emergency. There was also an emergency tracheostomy kit in theatre.
- The resuscitation trolley and defibrillator was checked monthly, with additional checks made if the equipment was used. We reviewed the checklist for the two months prior to our inspection and it was fully completed. However, the Royal College of Anaesthetists (2012) advocate daily checks in all clinical areas.

Medicines

- Medications were provided by third party arrangements with a local trust and a private pharmaceutical company. Staff gave examples of when they had contacted the pharmacy for advice and support.
- There were no controlled medications stored in the consulting rooms. All other prescription medications were stored in a locked cabinet, within a locked store cupboard, in one of the consulting rooms. There was a controlled drug cupboard in the theatre, which was left

unlocked during surgery for emergency access. We returned to the theatre during the staff lunch break, when theatre was empty, and found the drug cupboards were locked and there was no medication left out in theatre.

- There was also a controlled drug stock in the recovery ward. We observed two staff checking medication to be administered to a patient and both staff signed the entry in the book prior to administering.
- There was a locked drug cupboard on the ward and we observed staff following policy when administering medication, which included: documentation, asking the patient their name, checking with the patient and the wristband their date of birth.
- The consulting room included a drug fridge that had been in place for six months. Daily records of fridge temperatures were present, although the range had only been recorded since 19 April 2016. On that date, the fridge showed that the temperature of the fridge had reached 19 degrees. The acceptable range would be two to eight degrees, as documented in the Medicines Management Policy. At the time of the increase, we were told that staff contacted the pharmacy at the local trust for guidance. Staff were informed that the medication could remain out of the fridge and did not need to be removed or destroyed. There was no evidence of the recording of the incident when checked on the unannounced inspection. On the unannounced inspection, we identified that different recording forms were in use in different areas of the service that led to inconsistencies in recording of fridge temperatures and ranges. We raised this with the manager and this was addressed on – site and rectified.
- At the time of inspection, all medication for both medical and surgical treatments was being stored in the consulting room due to the mechanical failure of the surgical medication fridge. A replacement fridge had been delivered but not installed at the time of inspection. At the time of our unannounced visit the theatre fridge was in operation and we observed fridge temperatures had been recorded daily and were within range. The theatre nurse told us she checked it daily, rotated stock and was aware of the importance of storing medication at the appropriate temperature to maintain the quality of the drug. We checked two boxes of drugs and found them to be in date.
- Any ampoule where the whole content of the drug was not required for a patient was disposed of.
- There was clear documentation of information about allergies; we reviewed eight surgical patient records and eight medical patient records and found all had allergies recorded. We observed the surgeon asking the patient about allergies prior to commencing surgery.
- All patients were prescribed antibiotics as prophylaxis treatment for infection and the medication was administered prior to discharge.
- The medicines policy provided was due for review in March 2016, meaning the policy was out of date and overdue a review at the time of our inspection.

Records

- We reviewed eight early medical abortion patient records and eight surgical abortion patient records. The records we reviewed were legible, complete and up to date.
- Patients' records were a combination of paper- based notes and electronic records. Electronic records included the initial and ongoing consultation and assessments record, prescriptions and Department of Health referrals (HSA4 forms – notification of a termination of a pregnancy). Paper records included a consent to treatment form, a venous thromboembolism (VTE) (a condition where blood clots form in a vein) risk assessment, the HSA1 form (needs to be signed by two medical practitioners prior to a termination of pregnancy) and the World Health Organisation (WHO) Five Steps to Safer Surgery checklist.
- The electronic client record system had a reporting function that held a treatment register for the duration of the system for surgical and medical TOP (this meant the information was retained for a period of not less than three years beginning on the date of the last entry). Clients' details were automatically submitted to the register at the time of treatment
- The written notes were transferred from reception to an unlocked, former counselling room prior to a consultation rather than passing to nursing staff directly. This meant other patients could potentially access other patients' notes and breach confidentiality.
- A medical records audit was completed every three months and included a review of 30 sets of patient records. The most recent audit was dated 27 April 2016 and showed an overall compliance of 99.1%. Records were audited against each stage of the patient journey. The' Pre-operative' stage had achieved the lowest compliance score (97.9%). This was because one record

did not contain a completed VTE assessment and three records did not have a fully completed and signed World Health Organisation (WHO) Five Steps to Safer Surgery checklist.

- All areas of non-compliance were logged on an audit master action plan which allowed both local and corporate oversight. Required actions were clearly identified with the deadline for completion and responsible person. The plan was updated with progress comments each month and showed appropriate action had or was being taken to address the issues identified.

Safeguarding

- The service had clear systems and policies in place to identify and report any safeguarding concerns. Staff we spoke with were familiar with the service's safeguarding policy. The corporate safeguarding policy had been reviewed in April 2016 to take account of current statutory guidance such as Working Together to Safeguard Children (March 2015).
- Staff we spoke with were aware of female genital mutilation and child sexual exploitation risks. However, they had not received formal training in these areas.
- Training for safeguarding adults and children was delivered simultaneously. Level one was delivered as e-learning and level two was delivered as a face-to-face classroom based session.
- Records showed 100% of staff had received level one training in safeguarding adults and children.
- However, the Manchester governance and quality dashboard 2016 showed that in March 2016 only 57% of staff had completed the level two training. An action plan showed the regional manager and the head of safeguarding were in the process of sourcing suitable level two training. The completion date for this action was June 2016.
- There were two regional leads trained to level three children's safeguarding together with the regional manager, regional operations manager and head of safeguarding. However, other staff were not routinely trained to level three in children's safeguarding. The regional manager informed us that a new head of safeguarding had been appointed in the last six months and was reviewing training requirements in line with intercollegiate guidelines.
- The Intercollegiate Document for Healthcare Staff (2014) advises that "all clinical staff working with children, young people and/or their parents/carers and who could potentially contribute to assessing, planning, intervening and evaluating the needs of children and young people and parenting capacity where there are safeguarding/child protection concerns" should be trained to level three. This meant that there were insufficient numbers of appropriately trained staff to appropriately assess, plan, intervene and evaluate the needs of children and young people attending the service.
- All staff we spoke with who were in contact with children were aware of their roles and responsibilities to report safeguarding concerns.
- Under 18's pro-forma forms were completed with patients under the age of 18 years. We were told that any patient aged 13 years to 16 years was required to attend face to face counselling with a responsible adult prior to consultation and treatment. Any concerns would be discussed with social services.
- The service reported treating 47 children aged 13 to 15 years old between January and December 2015. The service did not treat any children under the age of 13 from January 2015 to December 2015. The Safeguarding Children at Risk Policy and Procedure states that "all clients access the service who are under 13 years old, or who have conceived under the age of 13, must be referred to the local children's social services department."
- From January to December 2015 the service made nine safeguarding referrals.
- In reception, first names of patients were used to maintain confidentiality. Full name and date of birth were confirmed in the one to one consultations. In addition, the reception area and waiting areas were separate rooms.
- Patients were issued with PIN numbers and security questions for data protection purposes.
- All patients at the clinic were seen on their own for the first part of their consultation and for consent to be taken. This also gave the patient the opportunity to discuss any concerns they may have. Patients could then be accompanied, by a friend / relative for the subsequent consultation and treatment if required.
- Safeguarding was discussed at regular team meetings where staff could discuss and learn from any shared

information or incidents locally and at satellite clinics. We reviewed the meeting minutes for the last three integrated governance committee meetings and found safeguarding was a mandatory agenda item.
- The service held a local resource file within the clinic which had contact numbers for local social services, children's social services, and vulnerable adult information.
- Counselling appointments were offered to all patients irrespective of age and were a mandatory requirement for patients under the age of 16.

Mandatory training

- Training was provided on a range of subjects, including health and safety, infection prevention and control, and information governance. The Manchester governance and quality dashboard 2016 showed that in March 2016 the overall compliance for completion of statutory mandatory training was 95%.
- Basic life support training was provided to healthcare assistants and front of house staff, nurses were trained in immediate life support and anaesthetists were trained in advanced life support. Records showed 86% of staff had completed the relevant training in the past 12 months and further immediate life support training sessions were scheduled for August 2016.

Assessing and responding to patient risk

- Records showed that prior to surgery patients underwent a pre-operative assessment by trained nurses or healthcare assistants to identify any areas of concern. Consultations were completed prior to treatment either by phone or face to face. Part of the consultation, by trained nurses or healthcare assistants, was to collect the patient's medical history and any other current relevant information that assists in assessing the patient's suitability for treatment.
- The organisation's pre-existing conditions guidelines was referenced to ascertain if the patient was suitable to be offered treatment within the service. Each condition, we were told, was risk assessed and scored. Dependant on the guidelines, if the risk was too high to treat within the service then the patient was referred to an NHS provider. There was a dedicated team at the national call centre, where referrals were processed onto an NHS facility to ensure the patient's treatment was not delayed.
- One-hundred per cent of patients who underwent surgical abortion were risk assessed for VTE from January 2015 to December 2015. We reviewed eight surgical records and eight medical abortion records at the time of our inspection and found all records had a completed VTE risk assessment.
- At the time of our announced inspection the anaesthetist on duty informed us that each morning they reviewed the patient medical records and if they identified any concerns they would see the patient prior to surgery. Otherwise, patients were first seen by a doctor at the time of surgery. We observed the surgeon and anaesthetist review the medical records and the surgeon provided the second HSA1 signature. They both confirmed treatment and verbal consent with the patient before proceeding with treatment.
- The World Health Organisation (WHO) Five Steps to Safer Surgery checklist is a system to reduce errors and adverse events for patients having surgery. We reviewed eight surgical records and found the (WHO) Five Steps to Safer Surgery checklist had been completed in all cases. At the time of our inspection we observed three patients arriving in theatre and the surgeon checking details against the (WHO) Five Steps to Safer Surgery checklist. Adherence to this was audited as part of the medical records audit, and, we were told that, at the end of every day, the medical notes (including the (WHO) Five Steps to Safer Surgery checklist) were checked and audited. Any issues were picked up immediately and recorded on the electronic system and raised with the individual concerned.
- All patients we observed had their physical observations recorded in theatre, which were documented on the patient's record. A set of observations were repeated upon arrival to the recovery ward from theatre. At the time of our unannounced inspection we observed three patients arriving to the ward who did not have their observations recorded until 10 minutes after arrival.
- Prior to reaching the recovery ward, patients were taken to a small recovery room at the side of the theatre where they were wakened and made to transfer immediately into a wheelchair, to be taken to the next room which was the recovery ward. There were two staff present during this transfer. We observed this process in place for two patients that had received a general anaesthetic. We observed one patient who had been transferred to the recovery room following a general anaesthetic and who staff were unable to rouse. The

surgeon and anaesthetist were called, the suction machine was made available and observations were recorded. The patient remained in the recovery room for approximately 10 minutes until she was conscious and able to be transferred to the ward.

- The provider had set up a room, other than the recovery area, with an additional two chairs which was not staffed but had a camera in place so ward staff could observe patients remotely. This room was used for clients up to 18+6 week requiring cervical preparation prior to treatment. Patients' carers could sit with them if they were anxious. Staff raised concerns about staffing the areas as if they noticed a problem and had to attend the other room and a patient was being collected from theatre, the ward would be unstaffed.
- At the time of our inspection we did not see post-surgery patients left in the ward without staff present. However, staff told us when the surgical list was busy and there were only two staff on duty collecting patients from theatre, monitoring patients in the separate room and caring for patients on the ward was difficult.
- We saw in theatre there was a large call button readily available to call for assistance should an emergency occur. In the event of an emergency, there was a dedicated phone number that called throughout the building to alert assistance.
- The data we received about the service identified that they used an early warning scoring system to identify and escalate the deteriorating patient. However, we did not see a score recorded in any of the patient records. Nursing staff told us there was a section on the observation charts to calculate the early warning score but it was not consistently used.
- A set of observations were performed once again before discharge. However, there was no guidance used to determine what the baseline for safe parameters were as staff were not consistently completing the early warning scores on the observation charts.
- The provider's schedule of services for anaesthetists and surgeons states that they should "assess all remaining clients and liaise with the senior nurse before leaving the centre". This meant that they were able to leave the centre before all patients have been discharged and potentially leave the clinic with no staff trained in advanced life support should a patient deteriorate post-operatively.
- Marie Stopes International provides a two-day introduction to anaesthetic course. We had concerns that a two day course would not be sufficient to fully equip nursing staff with the knowledge and skills to assist in an emergency situation of a patient with a difficult airway.
- There was a clear transfer policy agreement in place with the local NHS trust. If a patient required an emergency transfer to the local NHS provider, the transfer policy stated that patients would be transferred by a member of clinical personnel and the theatre list would be stopped until staff were available.
- Protocols were in place to identify if patients were suitable for a termination, for example bloods were taken to make sure iron levels were within normal ranges. Haemoglobin levels were tested by a point-of-contact finger prick test. If patients were anaemic the service would transfer them to a local NHS trust to avoid complications during and after surgery.
- The majority of post procedural enquiries were handled by the national 24 hour call centre team and if required the team were able to book appointments within the provider's clinics where each patient could be assessed, including ultrasound investigation if indicated. Should the need arise, each clinic was able to offer surgical and medical interventions as well as further post-operative visits and consultations if required.
- Four patients were transferred from the service to another health care provider in the last 12 months. All four were emergency transfers although only two resulted in serious incidents (the other two were precautionary and resulted in no further treatment being required).

Nursing staffing

- Fourteen registered nurses were employed in the service, 4.80 of which worked as full time equivalents (FTE) in the last three months.
- There was little reliance on agency staff to cover shifts; only two shifts had required agency cover in the last three months. We were told that agency staff received an induction. However, we did not request or view any completed forms.
- There was a 0.6 FTE vacancy for a registered nurse.

- The unit was covered by seven clinical staff, which consisted of one nurse (with anaesthetic training) and one healthcare assistant (HCA) in theatre, two nurses on the ward and two nurses and one HCA in the consultation rooms.
- The nursing staff teams worked as separate teams across the service (for example, theatre staff and staff providing medical abortion treatments). Managers told us that daily morning huddles were in place to cascade information amongst the wider team. However, all staff we asked at the time of our inspection were unaware of these and had never attended one.
- When patients were undergoing a general anaesthetic, the theatre was staffed with a surgeon, an anaesthetist, a scrub nurse with anaesthetic training and a healthcare assistant (HCA). There was no operating department practitioner available to support the anaesthetist. We were told that the scrub nurse was anaesthetic trained and therefore could assist the anaesthetist if required. This meant that if the scrub nurse was assisting the anaesthetist there was no additional nurse available to backfill the position of scrub nurse which could result in staffing in theatre falling below the recommended standard. Therefore we were not assured that staffing in theatre always met the recommended minimum staffing standard identified by the Association for Perioperative Practice (AFPP) of two scrub practitioners, one circulating staff member and a registered anaesthetic practitioner.

Medical and surgical staffing

- The service told us they only utilised experienced doctors in the provision of termination of pregnancy (TOP) treatments and the consultants were on the General Medical Council (GMC) Specialist Register for TOPs.
- Medical staffing was provided by doctors working both remotely and within the centre. The remote doctors were employed by Marie Stopes International and their role was to review patients' case notes and medical histories prior to signing the HSA1 forms and prescribing medications.
- The service employed one surgeon to work at the centre on a full time basis.
- There were no vacancies for medical staff and surgeons working at other MSI centres provided cover if necessary.
- Surgery was performed at the clinic five days per week. On surgery days, there was an anaesthetist present who was employed on a sessional basis under practising privileges.

Major incident awareness and training

- There was a business continuity plan dated 21 April 2016. The plan detailed what action staff should take in the event of a major event, utility failure or an emergency situation.
- An emergency backup generator was on site in case of electricity failure; staff we asked at the time of our inspection were aware of the generator.

Are termination of pregnancy services effective?

- The provider had policies and guidelines in place in relation to: offering patients a choice of procedure, discussion and options for future contraception and screening for sexually transmitted disease.
- The service had service specification agreements and performance standards in place with commissioners. Medical records audits included monitoring of pathways of care, information provision and pre-abortion assessment.
- Processes were in place to provide pain relief to patients and patients told us they thought their pain was controlled.
- There were processes in place, which we observed, to ensure consent was gained and recorded. Healthcare assistants and nurses had been trained in line with the provider's own policy and would go through the consent process with patients during the consultation.

However:

- Policies were not always updated to reflect practice changes in a timely manner. Both the ultrasound policy and the medicines management policy we reviewed were out of date at the time of inspection
- It was not clear from the ultrasound policy whether scanning post treatment should be routine or if it was discretionary.
- On a quarterly basis the provider produced national clinical governance reports that included data on failure rate by surgery and medical treatments, infections, and the reasons for any transfers. However, the reports

included either national or regional data and were not broken down by clinic and it was therefore not clear how this data was used to improve local performance or outcomes.

- MSI Manchester did not routinely give the patients a letter detailing the treatment they had received unless this was requested by the patients.
- We were not assured that staff taking consent had the appropriate knowledge, skills and competence to support patients who may be vulnerable or lack capacity to make a decision.

Evidence-based care and treatment

- Patients were offered a choice of procedure within appropriate timeframes, processes were in place to support patients with options for future contraception and screening for sexually transmitted disease was available. This was in line with National Institute for Health and Care Excellence (NICE) and Royal College guidelines.
- The service complied with the requirements of RSOP 13 'contraception and sexually transmitted infection (STI) screening', which states that providers should be able to supply all reversible methods of contraception, including long acting reversible methods (LARC) which are the most effective. All patients should be offered testing for chlamydia, offered a risk assessment for other STIs (e.g. HIV, Syphilis etc.), and tested as appropriate. All patients attending MSI Manchester were offered a chlamydia screening test. Patients were also offered testing for other STIs dependent on the standards agreed with each clinical commissioning group. If other screening was not commissioned there was no process seen to signpost patients for screening elsewhere.
- In terms of medical abortions, the provider offered three treatment options. Medication could be administered at the clinic in two stages with six hours, 24 hours or 48 hours in between each stage. The service had previously offered simultaneous medical abortions (whereby both stages of medication are administered without a gap between each stage) but had suspended this treatment at the time of our inspection until more outcome data had been collected.
- Patients were offered a choice of medical termination or surgical termination, using vacuum aspiration, under conscious sedation if they did not want to receive a general anaesthetic.
- On request, the service provided us with a copy of the ultrasound policy that we noted was dated July 2013 and was due for formal review in July 2015. This meant that either the policy was overdue review or that the service was using an out of date policy.
- At the time of our inspection we were told by the surgeon that the ultrasound scan was always used to ensure that the contents of the pregnancy had all been removed. During our unannounced inspection we observed two surgical terminations and the ultrasound scan was not used. We asked the surgeon about this at the time of our inspection, who advised that she took all the remains to the sluice and examined them to ensure all were removed and if she was concerned she could call the patient back into theatre to be scanned. We reviewed eight surgical records and found that a scan had been performed in theatre in six cases. This indicated that depending on which surgeon was performing surgery, different processes were being followed. The corporate ultrasound policy did not state that ultrasound would be routinely used in theatre unless there was a suspected perforation or similar emergency. Appendix K of the policy stated that post treatment ultrasound scanning would be carried out to determine whether all products of conception had been removed and whether there had been an injury sustained to the uterus or surrounding structures. It was not clear from the policy, however, whether scanning post treatment should be routine or if it was discretionary.
- There was an audit schedule in place to monitor the implementation of risk management policies. All audits and audit results were logged on an electronic central spreadsheet. All areas of non-compliance or identified issues were then logged on the central audit master action plan. The action plan included the required actions, the responsible person, and the deadline for completion and progress comments.

Nutrition and hydration

- Patients were given advice and information on restricting diet and fluids prior to attending surgery.
- Patients were given biscuits and water after surgery to aid recovery.

Termination of pregnancy

Pain relief

- We observed patients on the ward being regularly asked if they were in any discomfort or pain. On entering the ward, patients were given a heat pack to place on their abdomen to provide comfort.
- At the time of our inspection we asked two patients if they felt their pain was controlled and both did. However, we observed one patient stating she was in pain and a member of staff telling her 'its normal' and then proceeded to give the patient a heat pad.
- We observed eight surgical patient prescription charts and eight early medical termination records and found all patients were prescribed analgesia.
- Discharge advice following termination of pregnancy included pain relief, for example ibuprofen and co-codamol, which is recommended in the RCOG Guidelines.

Patient outcomes

- The service had specification agreements and performance standards in place with the clinical commissioning groups. There were targets for waiting times, STI testing and the uptake of long acting reversible contraceptives (LARC). The service also reported any instances of ectopic pregnancy to the commissioners.
- The service achieved an average of 48% uptake in LARC from January 2016 to March 2016. Target rates varied dependent on what had been agreed with each commissioner.
- The service achieved an average of 85% uptake in STI screening from January 2016 to March 2016. Target rates varied dependent on what had been agreed with each commissioner.
- Incident data from 25 April 2015 to 9 March 2016 showed the Manchester clinic had reported 120 incidents, of which 29 were classified as 'retained products of conception' and 15 were classified as 'continuing pregnancy'. On a quarterly basis the provider produced national clinical governance reports that included data on failure rate by surgery and medical treatments, infections, and the reasons for any transfers. However, the reports included either national or regional data and were not broken down by clinic and it was therefore not clear how this data was used to improve local performance or outcomes.
- The service had key performance indicators in place and these were reported each month via the governance and quality dashboard. The dashboard showed on average 10% of patients each month did not attend their appointment.
- The dashboard also showed there had been no returns to theatre or transfers from January to March 2016.
- Medical records audits included monitoring of pathways of care, information provision and pre-abortion assessment in line with RCOG guidelines. The pre-abortion assessment was performed in conjunction with the corporate pre-existing conditions guidelines. Details about the type of abortion procedures that were carried out were captured and monitored via centrally produced capacity reports.

Competent staff

- Records showed all of the medical and nursing staff had received an appraisal in 2015.
- For new staff, an induction and training programme was in place where competencies were assessed with mentor support and supervision.
- 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. Senior staff we spoke with stated that staff were assessed against these before being allowed to practice unsupervised.
- Ultrasound scanning was undertaken by staff who received internal non-accredited training. Diagnostic ultrasound was used within MSI to: confirm presence of an intra-uterine pregnancy; confirm gestational age; reveal the presence of multiple gestations; reveal the presence of any pelvic conditions, which could influence the choice of ToP approach. As part of the training, the ultrasound policy stated that to be deemed competent, staff must attend a minimum of two days continuous professional development every three years; must scan at least 30 patients trans-abdominally per month (for those trained to perform trans-vaginal scans they must scan at least 10 patients trans-vaginally per month) and must, when required, demonstrate competence to the MSI ultrasound mentor.
- The training matrix provided showed refresher training in ultrasound scanning was due and competence was re-assessed every three years.

- Clinical team members worked across the different departments within the clinic. The regional operations manager maintained a skills matrix to identify any skills gaps or additional training requirements.
- Nurses we spoke with at the time of our inspection felt supported to learn and told us they received training in all areas within the service.
- Registered nurses said they were encouraged to maintain records for their revalidation with the Nursing and Midwifery Council.
- Records showed all nursing staff had received training in immediate life support and anaesthetists had received training in advanced life support. There were also quarterly scenario based resuscitation refresher training days, in addition to annual training requirements.
- Counselling, we were told, was provided by trained (diploma level) professional counsellors and could be accessed via the centre or over the telephone.

Multidisciplinary working

- We observed good team working between all the nurses, healthcare assistants, anaesthetists and consultants. However, this was only seen within each area and each area worked in a silo from the rest of the clinic service. For example, no daily huddle took place to discuss any issues prior to patients arriving for treatment.
- There was a service level agreement in place with a local NHS provider should an unplanned transfer be required.
- The service had good links with the local safeguarding team and with the local police. At the time of our inspection the police had requested a statement from the surgeon to assist with investigations.
- At the time of our inspection, staff were clear that the medical consultant/surgeon held the responsibility for patients receiving treatment.

Seven-day services

- The clinic was open Tuesday to Saturday and alternate Thursdays for vasectomy patients.
- However, all patients accessed the service via MSI One Call centre so alternative appointments could be provided at other centres across the UK to meet patients' needs.
- MSI One Call operated a dedicated telephone helpline 24 hours a day throughout the year to provide patients with a contact for support and advice during periods when the service is closed.

Access to information

- Staff had access to policies and procedures via the provider's intranet.
- At the time of the inspection all patients were given information about post-operative care and information about their procedure in the form of a 'purse – size' booklet for either a medical or a surgical treatment.
- RCOG guidance sets out in recommendation 8.2 that "On discharge, all women should be given a letter providing sufficient information about the procedure to allow another practitioner elsewhere to manage any complications." MSI Manchester did not routinely give the patients a letter detailing the treatment they had received unless this was requested by the patients.

Consent, Mental Capacity Act and Deprivation of Liberty Safeguards

- We observed nurses, doctors, and healthcare assistants obtaining consent from patients before clinically assessing them and providing treatment. Healthcare assistants (HCA) and nurses had been trained in line with the provider's own policy and would go through the consent process with patients during the consultation. We were advised that the consent form was completed at consultation and signed, usually by the registered nurse. Consent was then confirmed again verbally on the day of treatment (if consultation was on a different day to treatment).
- We observed two consultations in which consent was obtained for treatment. One was performed by a HCA and was for a surgical termination of pregnancy, the second was performed by a registered nurse and was for a contraceptive injection. We saw that staff were knowledgeable about the care they provided in these instances. Staff discussed the treatment options in these cases, provided information about risks and complications and described what to expect.
- We observed the surgeon and anaesthetist confirm treatment and verbal consent with patients before proceeding with surgical treatment.
- We reviewed records for 16 patients and found that all 16 records had signed consent forms in place confirming the patients had consented to treatment. Of the 16 consent forms, 15 were found to be signed by a trained nurse. However, one had been signed by a healthcare assistant, which was not in line with the provider's policy that stated these would be countersigned by a clinician.

Termination of pregnancy

- The service made sure that patients were seeking abortions voluntarily. They did this by discussing reasons why and how they had reached their decision to terminate their pregnancy. The initial consultation was always performed with the patient on their own. This discussion was also picked up by the consultant before forms were signed.
- Staff we spoke to across the service were aware of appropriate procedures in obtaining consent. These staff described how they established if a child under the age of 16 years could make their own decisions and understood the implications of the treatment by using Gillick competency and the Fraser guidelines.
- We were told that healthcare assistants received training in delegated consent from an external law company using the NHS consenting tool. We asked staff what they would do if a patient under 18 attended and they explained they would direct them to see a face to face counsellor prior to consultation in line with the provider's policy.
- If a patient was identified with a learning disability, we were told staff would liaise with the safeguarding lead and the patient would be assessed following the suitability guidelines and signposted to alternative providers if needed.
- Nursing staff and HCAs taking consent from children and young persons were not appropriately trained to explore safeguarding issues and were reliant on their own knowledge. None had undertaken safeguarding level three training or received formal training in issues such as female genital mutilation or child sexual exploitation.
- Language Line (a telephone interpreter service) was available for non-English speaking patients as part of the consent process.

Are termination of pregnancy services caring?

- Feedback questionnaires from people who used the service were mostly positive about the way they were treated.
- For the period January 2015 to March 2016, patients had rated the service at MSI Manchester 96% for the overall quality of care.
- We observed staff being considerate and compassionate to patients, particularly in theatre prior to surgery.
- Staff were proud of the care they gave, and we observed that they were non-judgemental.

However:

- The layout of the recovery room meant there was limited privacy for patients. Staff at the time of our inspection did not seem to be aware of this or sensitive to the need to adapt practice when required to ensure patients' privacy and dignity was not compromised.

Compassionate care

- We observed that staff took time to interact with patients; they were attentive to their needs and spoke in a compassionate manner most of the time. Staff in theatre were supportive and tried to put the patient at ease.
- All patients were provided with a feedback questionnaire prior to discharge, to be completed in the clinic or later at home. They were anonymous, sealed, and sent to an external organisation for collation and reporting. For the period January 2015 to March 2016, patients had rated the service at this location 96% for the overall quality of care.
- Comments received by patients who had used the service included: 'found the overall experience friendly and professional', 'really made to feel at ease, lovely staff' and 'really caring and compassionate'.
- Staff were observed to be non-directive, non-judgemental and supportive to patients receiving treatment for abortion. On arrival, patient details were checked individually while others remained in the waiting room so as to provide a private space to talk.
- However, the layout of the recovery room meant there was limited privacy for patients. Staff at the time of our inspection did not seem to be aware of this or sensitive to the need to adapt practice when required to ensure patients' privacy and dignity was not compromised.
- At the time of our inspection we observed one patient in the ward who was nauseous, vomiting and visibly upset. We observed a member of staff giving her a hug. However, there were five other patients on the ward and the staff did not provide the patient with a screen to give her some privacy whist she was distressed. This was only provided when one of our inspectors requested it. At this time another patient was brought to the ward following surgery and was left to sit in a wheelchair for approximately 10 minutes as there was no cleaned chair for her to sit in.

Termination of pregnancy

Understanding and involvement of patients and those close to them

- Patients were able to be accompanied by a friend / relative in the consultation if required.
- Patients were given the opportunity to make an informed choice about all available ToP methods. As part of the initial assessment, the risks were discussed and patients were asked to sign a consent form to any treatment. The consent form included the risks and success rates for the time options of six hour, 24, 48 and 72 hour gaps in treatments.

Emotional support

- Staff demonstrated that they understood the importance of providing patients with emotional support. We observed staff providing reassurance to patients who were anxious.
- Counselling services were available 24 hours a day, seven days a week through a national telephone service or one day a week face to face. Patients could access counselling support either directly at the centre of via telephone.
- 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.

Are termination of pregnancy services responsive?

- Services were responsive to patients' needs. Appointments were offered in a timely manner and patients were given options to choose the procedure during the consultation that was the best option for them.
- Data showed that from January to December 2015 no patients waited longer than 10 working days from first appointment to termination of pregnancy.
- Performance figures for April 2016 and year to date showed the service was meeting or exceeding targets for the percentage of medical abortions carried out within 10 weeks of pregnancy. The target was 40% and rates achieved varied between regions from 50% to 100%.
- The daily wait times report for the day of our inspection showed no patients had waited longer than three working days for a consultation from initial contact.
- There were policies in place to support patients with pre-existing medical conditions and processes in place to ensure they were considered in the medical review. If a patient was deemed at risk and could not be managed in the clinic they were referred to the local NHS provider. We were told that this included individuals with learning disabilities.
- A telephone interpreter service was available for non-English speaking patients, as well as written information in the form of leaflets and on the website.
- There were systems in place to ensure the service responded to and learnt from any complaints or concerns it received.

However:

- We were not assured that patients were given information to make an informed choice with regards to disposal of pregnancy remains. We did not see any evidence of discussions in the patient record and did not see information about options given to patients. However information was available on the provider website.
- The post-operative area was cramped, there was little room for privacy and patients' dignity was at risk. The area was staffed with two staff, who were also responsible for collecting patients from theatre and watching a monitor and responding to patients' needs in a separate room.

Service planning and delivery to meet the needs of local people

- A service level agreement was in place with commissioners that clearly outlined the specifications of the service, expectations and pathways of care.
- The service received patients from a variety of referral methods; these included GPs, hospitals, family planning service, intranet, self-referrals and recommendations.
- The provider offered a comprehensive service to support patients who wanted to access services at this location. A central MSI One Call centre was available 24 hours a day, 365 days a year. There was a 0345 number

which was included in free call packages from landline and mobiles. Patients could also access the service by email, text and website enquiry forms. This provided patients with speedy access to appointments.
- Appointments were designed to ensure short wait times and fast access to the full range of services. Across Marie Stopes International UK (MSI UK) there was a network of clinicians and flexibility to re-arrange appointments at very short notice to meet the needs of the patient.
- The MSI Manchester centre was easily accessible by public transport; the regional manager explained that MSI UK had identified areas of deprivation and population density, and sited clinics accordingly.
- Consulting rooms were for single consultations and were used to speak to patients privately.
- We found the recovery ward area, which housed eight reclining chairs where patients were transferred after theatre, was small, cramped and compromised patients' privacy, confidentiality, and dignity.
- There was a free, discrete taxi service available to transport patients to and from the airport.
- The clinic worked with the Abortion Network for patients who needed to stay overnight in order to subsidise fees and travel.
- A private patient asked about how to provide the payment and was directed to the reception staff. Payments were received in a room separate to the reception area.
- The clinic ran two to three vasectomy lists each month which could be flexed depending on need.

Access and flow

- A central business support team, located at head office, provided a daily report on wait times and monitored the wait times to ensure the service was offering a range of treatments within three working days. The information was taken from the 'live' patient records system which gave up to the minute reports on capacity issues and availability of the full range of treatments. The clinic appointment diaries were constantly reviewed and adjusted to ensure full availability. There was an internal target set so all treatment options and appointments were available within three working days.
- As a result, waiting times for consultation from initial contact and treatment from initial contact were consistently within the Royal College of Obstetricians and Gynaecologists' recommended timeframes.
- Data showed that from January to December 2015 no patients waited longer than 10 working days from first appointment to termination of pregnancy.
- Performance figures for April 2016 and year to date showed the service was meeting or exceeding targets for the percentage of medical abortions carried out within 10 weeks of pregnancy. The target was 40% and rates achieved varied between regions from 50% to 100%.
- The daily wait times report for the day of our inspection showed no patients had waited longer than three working days for a consultation from initial contact.
- In the eventuality of unplanned staff absence, the service was operated by management resource within the region and, where necessary, from a wider national team. This enabled staff to be transferred between services and reduced the need for agency and bank staff as well as providing a timely response.
- A 24 hour telephone line was available to provide advice and support outside service hours. In the event a patient deteriorated, the patient could be brought back to a clinic for consultation or if it was an emergency could be directed to their local accident and emergency department.

People's individual needs

- We were told that patients were given the option to receive an initial medical assessment by phone or at the Manchester clinic. The consultations that we observed covered comprehensive medical history checks to identify any existing health conditions.
- The records we reviewed showed that pre-existing conditions were risk assessed in accordance with the provider's policy. We were told that with the patient's consent, the service could make contact with the relevant medical practitioners to obtain additional medical information and work with the patient's GP or consultant to ensure the information was up to date and that the patient's representatives understood how the patient could be affected.
- We were told that where a condition was identified that did not require onward referral, an assessment would be made and a pathway followed. The lead clinicians then made the decision as to the most appropriate treatment for the patient, taking into account existing conditions, access, mobility, and any other issues such as a learning disability.

- Staff gave us examples of how they supported young patients, or patients with an identified complex health need, which included: placing them first on the theatre list so those close to them could sit with them on the ward while no other patients were there.
- We were told that if the health condition related to mental health and capacity issues, the service would work with the relevant agencies and principle care workers to ensure that the patient experience and care pathway fulfilled their physical and mental health needs.
- Treatment options were presented to the patient determined by their specific needs and requirements. During the consultation their reasons were discussed along with their contraception requirements. The regional manager and regional operations manager explained that any patients showing signs of uncertainty would be signposted for counselling before any decision as to whether to proceed to treatment was made. Counselling services were outlined on the website and also included in the 'purse size' booklet provided post treatment.
- There was a contracted female surgeon that worked across the Manchester and Leeds clinics who offered a TOP list one day a week at each centre. Each patient pathway concluded within the clinic with a discharge process. During the discharge process possible complications were explained to the patient as well as advice around their recovery process. Each patient was handed a discreet purse sized booklet detailing the provider's 24 hour helpline arrangements and they were offered a follow up appointment if required.
- Patients were considered for discharge once they were recovered enough to have had something to eat and drink, passed urine, bleeding was minimal, and they were fully alert and orientated. We observed staff asking patients if they had someone to accompany them home before commencing treatment.
- The provider had a policy in place for the management of disposal of pregnancy remains. Fetal tissue was managed in two separate stages of the treatment process, which included: examination of fetal tissue following a termination and storage and disposal of tissue. Following surgical termination the fetal contents were examined to ensure the procedure was complete.
- Incineration of fetal waste is recognised as the appropriate method of disposal (when a patient does not express any personal wish for any other method of disposal).The provider stored the tissue in a sealed waste receptacle in the clinical specimen freezer until the tissue was collected for incineration by the registered clinical waste contractor. Where products were required to be retained for DNA testing, criminal investigation or patient choice, new equipment was used and a separate storage container was utilised. The contents were labelled with the patient's name, MSI number, the patient's date of birth and date of procedure. Any non-standard disposal option was documented in the patient's record and on a freezer log sheet indicating reason for keeping and date for either collection or disposal.
- Patients were informed of the options for disposal of pregnancy remains on request. We were advised that a client information leaflet was provided which detailed the options available. Patients would be advised what documentation is required in order to procure a cremation or burial. We were also told that where possible (and with the patient's permission), the service would also liaise with the funeral directors to facilitate as smooth a process as possible to alleviate stress.
- However, we observed no evidence of this discussion in the eight surgical records we reviewed and did not see this information within the information booklet given to patients.
- Staff told us that following a medical termination of pregnancy, patients were advised to observe for any excess bleeding, however; not to examine the contents for any pregnancy remains.
- There was disabled access on the basement level, where a patient with reduced mobility could be treated, whether receiving a medical or surgical termination of pregnancy.
- A telephone interpreter service was available for non-English speaking patients, as well as written information in the form of leaflets and on the website. A hearing loop had been introduced on 12 May 2016.

Learning from complaints and concerns

- In 2015, MSI Manchester received four formal complaints and 16 concerns via the patient feedback questionnaires. Where possible any concerns raised whilst the patient was on site would be dealt with by staff. Formal complaints were reviewed and responded to by the head of quality and customer service with involvement from the registered manager.

- Responses to complaints were monitored to ensure they were within the provider's timeframes via the governance and quality dashboard which was submitted to head office on a monthly basis for corporate overview and scrutiny.
- If a patient indicated a less than 'very good' response on the patient feedback questionnaire or documented a particular issue then a record of this was sent to the centre management team as a "Red Alert" and action plans were put into place (where relevant). The information was then shared with staff during team meetings to promote learning.

Are termination of pregnancy services well-led?

- Clinical governance reports included data on failure rate by surgery and medical treatments, infections, and the reasons for any transfers. However, the reports included data at either national or regional level and were not broken down by clinic so it was not clear how the data was used to drive local improvement.
- Practising privileges for medical staff were handled corporately with limited local oversight. The registered manager did not have sight of the doctor's most recent appraisal or revalidation.
- Similarly, pre-employment checks were carried out and stored at head office. The provider was in the process of transferring this information onto an online system so it could be accessed from any clinic but it was not in place at the time of our inspection.
- There was no effective process in place to ensure policies were reviewed and updated in a timely manner.
- Processes in place to ensure that the certificate(s) of opinion HSA1 forms were signed by two medical practitioners in line with the requirements of the Abortion Act 1967 and Abortion Regulations 1991 were not always effective.
- We found instances when medication had been prescribed before two signatures had been obtained on the HSA1 forms. This means that the treatment for the termination of pregnancy had commenced before the legal requirements were in place for that to happen.

However:

- The service had a clearly defined vision supported by the corporate mission statement "Children by choice, not chance". Staff we spoke with were able to articulate this and were 'pro-choice' in their approach to providing patients with care and treatment.
- There was a corporate governance framework in place supported by both a corporate central governance committee and local integrated governance committees. The committee structure showed how information regarding governance, quality and safety was shared across the organisation with both local and corporate oversight.
- Local compliance with governance standards and key performance indicators was monitored by the registered manager via a governance and quality dashboard. We were told this was submitted to head office on a monthly basis for corporate overview and scrutiny.

Vision and strategy for this this core service

- Marie Stopes International had a clearly defined vision which was "A world in which every birth is wanted". This was supported by their mission statement, which was "Children by choice, not chance".
- We asked staff what the corporate values and vision were and they quoted the phrase 'Children by choice'.
- The service aimed to provide "accessible, safe, professional, caring, responsive, effective and non-judgmental services for every patient". The service worked closely with commissioners to ensure there were clearly agreed standards, service specifications and pathways in place.
- The certificate of approval (as issued by the Department of Health) was prominently displayed in the reception area as well as the CQC registration certificate.

Governance, risk management and quality measurement for this core service

- There was a corporate governance framework in place supported by both a corporate central governance committee and local integrated governance committees.
- Local compliance with governance standards and key performance indicators was monitored by the registered manager via a governance and quality dashboard. We were told this was submitted to head office on a monthly basis for corporate overview and scrutiny. The dashboard we viewed included monitoring of training completion, serious incidents, complaints, number of

transfers and number of returns to theatre. Areas such as the requirement to hold bi-monthly team meetings and quarterly local governance meetings were also reported on. An exception report and action plan had to then be submitted for any areas where the service did not meet set targets.

- Team meeting minutes for MSI Manchester showed team meetings were held monthly and included key messages and learning from incidents (both local and from other areas across MSI) and complaints.
- On a quarterly basis the MSI UK governance support team produced national clinical governance reports that were shared with regional teams. The reports included data on failure rate by surgery and medical treatments, infections, and the reasons for any transfers. However, the reports included data at either national or regional level and were not broken down by clinic so it was not clear how the data was used to drive local improvement.
- A quality assurance visit for smaller providers was completed by Fylde & Wyre clinical commissioning group (CCG) on 1 December 2015. No immediate concerns were identified and the service achieved an assurance score of 100%. The report concluded: "In general, the findings of this visit indicate a service that delivers against the commissioned specification, meeting the individual needs of service users in a safe, effective and considerate manner".
- An external review was also completed by Manchester and Trafford CCGs on 23 June 2015.The review was completed following the serious incident in May 2015. There were no significant findings and three minor areas for improvements were included in the report: "There should be a process in place for regular checks of the hand gel dispensers"; "The basement areas including the treatment waiting room are quite small and dark" (The provider was aware of this and refurbishment plans were being developed); "the placement of a TV in the recovery room would be of particular benefit to the patients who spend a number of hours there". The provider was also considering whether this would be a suitable option and other possible alternatives.
- There was an audit schedule in place to monitor the implementation of risk management policies. All audits and audit results were logged on an electronic central spreadsheet. All areas of non-compliance or identified issues were then logged on the central audit master action plan. The action plan included the required actions, the responsible person, the deadline for completion and progress comments. Audits included hand hygiene, infection prevention and control, medicines management, safeguarding, medical records and health and safety. However, there remained areas in infection prevention and control that had not been identified by internal audit.
- There was a local risk register in place that identified potential local risks within the clinic. Each risk had mitigating actions in place to reduce the risk. Each risk was given an initial risk score and a residual risk score after mitigating actions had been implemented. These showed the majority of risks were rated as either minor or low. It was clear who was responsible for monitoring each risk and when they were due for review. The majority of risks had been added to the register in April or May 2015 and were due for review in 2016.
- However, the risk register did not include the issue we identified in relation the potential for not meeting staffing standards in theatre and potential staffing issues in the recovery area. Nor did it include the risk in relation to access to resuscitation equipment.
- Review of best practice guidance and any changes to clinical policy were discussed and ratified during the corporate clinical leads meetings. Any decisions would then be signed off by the central governance committee. However, there was no evidence of local management involvement in decision making, with a top down approach being adopted by the provider. This was evident in the initial decision to implement simultaneous administration of medication for early medical abortions.
- Both the ultrasound policy and the medicines management policy we reviewed were out of date at the time of inspection. The ultrasound policy had been due for review in July 2015 and the medicines policy had been due for review in March 2016.
- Practising privileges were handled corporately and were reviewed by the medical director and lead doctor. However, there was limited oversight of this process at local level. For example, the registered manager was not involved in the decision to renew practising privileges and did not have sight of the doctor's most recent appraisal or revalidation.
- Similarly when we asked to review three staff HR files to review what pre-employment checks had been carried out, we were advised that these were stored at head office. The provider was in the process of transferring

this information onto an online system so it could be accessed from any clinic but it was not in place at the time of our inspection. The regional operations manager explained that copies of references and confirmation of a Disclosure and Barring Service (DBS) check were emailed to them before any new member of staff commenced employment.

- Registration with the General Medical Council (GMC) and Nursing and Midwifery Council (NMC) was monitored through the corporate human resource team and the registered manager received a quarterly report flagging any issues. The report for April 2016 showed all medical and nursing staff working at MSI Manchester had up to date registration with either the GMC or NMC. This was then cross checked and monitored at a local level by the regional operations manager.
- 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. Patients could either opt to have a telephone consultation carried out by the provider's central team, or a face to face consultation within the clinic. During the consultation the patient would be assessed for eligibility under the Abortion Act criteria. This was clearly documented on the electronic centralised record system that, we were told, could be viewed by the clinicians before prescribing any treatments.
- We were told that the HSA1 form was only completed once a full medical history and criteria had been established. Two doctors, either the surgeon or doctor on site or doctors working remotely, signed the form and the copy was held in the medical record to be checked prior to any treatment being initiated.
- However, from the records we reviewed, we found the process for signing HSA1 forms meant that abortifacient medication was sometimes prescribed before two signatures had been obtained on the HSA1 form. Medication was prescribed electronically following consultation. We reviewed eight medical records and found two had medication prescribed by the remote doctor following consultation but before two signatures had been obtained on the HSA1 forms. However, we did not see any evidence of medication being administered before two signatures had been obtained.
- The surgeon in theatre had access to the patient's electronic record to review prior to signing the HSA1 form. We observed three patients entering theatre, the surgeon having a discussion with them and two medical signatures on the HSA1 form prior to surgery. Of the 16 records reviewed, the HSA1 form for one patient had not been dated by one of the medical practitioners. All other HSA1 forms we reviewed were fully completed and signed by two medical practitioners.
- Patients were not informed about the statutory requirement of HSA4 forms. Staff did not explain to patients that these details were sent to the Department of Health and that it was a legal requirement and it wasn't included in any of the information provided.
- We were told that information was gathered directly from the 'live' patient record system and automatically populated the HSA4 forms. At the point of discharge the HSA4 data was checked for completeness, before sending to the Department of Health. If the electronic process was not available, hard copies were kept on site and were completed by the doctors once the procedure had taken place. The information was then sent by post in the appropriate Department of Health envelopes. All the records we reviewed showed that HSA4 forms had been sent.

Leadership / culture of service

- Managers told us that they had an open door approach and encouraged team members to discuss issues and work together to find solutions.
- Staff we spoke with told us they felt supported to learn and develop and liked working at the clinic.
- Training was available for all team members on customer care, complaints handling and investigations using examples and experiences from other clinics to ensure lessons were learnt and used as an opportunity to improve. The regional manager had received training in root cause analysis methodology.
- There was an appraisal system in place that rewarded staff with additional bonus payments for reaching their individual targets. Staff assessed themselves against the provider's values and learning and development needs and opportunities were identified.
- There was a clear regional management structure in place that identified lines of accountability.

Public and staff engagement

Termination of pregnancy

- All patients were provided with a feedback questionnaire prior to discharge to be completed in the clinic or later at home. They were anonymous, sealed, and sent to an external organisation for collation and reporting.
- The provider had instigated a communication and engagement panel (made up of team members) to improve communication at all levels. However, we did not see evidence at the time of inspection of how this was being implemented to improve staff engagement.
- One member of staff had been awarded employee of the year and had been able to visit a location overseas to understand the work that Marie Stopes International carried out there.
- Staff 'away days' were arranged by managers, that included all staff meeting 'off site' in activities not related to work.
- The provider produced a staff magazine, which included information on areas such as information from staff surveys, planned developments across the organisation, what was happening about recruitment and retention, training and staff awards.

Outstanding practice and areas for improvement

Areas for improvement

Action the provider MUST take to improve

- Ensure all staff have received the appropriate level of safeguarding training in line with intercollegiate guidelines.
- Ensure that staffing levels in theatre have been risk assessed and adhere to recommended guidance at all times.
- Ensure staffing levels in the recovery area are sufficient to meet patients' needs at all times.
- Consider how best to ensure patients' privacy and dignity is maintained in the recovery area.
- Ensure patients are informed of the requirement to submit abortion data to the Department of Health and how this information is anonymised.
- Ensure syringes that are used to administer intra-venous medication are stored appropriately prior to use to prevent risk of cross infection.
- Ensure cleaning records in theatre are fully completed and that there is a clearly documented process for changing seat covers in the recovery area.
- Review how often resuscitation equipment is checked in line with best practice guidance.
- Ensure the registered manager has clear local oversight of the practising privileges review and renewal process.
- Ensure the registered manager has clear local oversight and assurance with regards to the completion of pre-employment checks prior to new members of staff commencing employment.
- Consider how data included in quarterly governance reports can be broken down to clinic level so they can be used meaningfully to identify local issues and improve local performance and patient outcomes.
- Ensure both the ultrasound policy and the medicine management policy are reviewed to ensure they contain current information in line with best practice. This should include being clear whether scanning post treatment is a routine requirement or not.
- Ensure that there are effective processes in place to ensure that the certificate(s) of opinion HSA1 form are signed by two medical practitioners in line with the requirements of the Abortion Act 1967 and Abortion Regulations 1991.
- Ensure that staff are appropriately trained to assess and respond to a deteriorating patient and staff with advanced life support training remain on site whilst patients are recovering from surgical termination of pregnancy.

Action the provider SHOULD take to improve

- Ensure there is an effective system in place to provide patients with information to make an informed choice with regards to disposal of pregnancy remains, including documentation of discussion and decision.

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
Surgical procedures Termination of pregnancies Treatment of disease, disorder or injury	Regulation 12 HSCA (RA) Regulations 2014 Safe care and treatment (1) Care and treatment must be provided in a safe way for service users. (h) assessing the risk of, and preventing, detecting and controlling the spread of infections, including those that are health care associated. We observed syringes containing an induction agent (drug used to help patients relax before and during general anaesthesia) in a kidney dish on the anaesthetic machine in theatre. The tips of the syringes were not covered to protect them from the risk of cross infection. The syringes were being used to administer the medication to the patient via an intra-venous cannula. Daily cleaning schedules for theatre and the ward were not consistently completed. The chairs on the ward were made of fabric and each was covered with a square shaped cover which was changed in between patients. There was no record available to determine when the covers had last been changed.