

Marie Stopes International Manchester Centre

Quality Report

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

Overall summary

Marie Stopes International Manchester Centre (MSI Manchester) is part of the Marie Stopes International group. The service provides surgical termination of pregnancy procedures (SToP) up to 23 weeks and six days gestation along with medical termination of pregnancy and early medical termination of pregnancy (MToP) up to nine weeks and four days gestation.

Treatment can be provided under no-anaesthesia, conscious sedation and general anaesthesia, according to patient choice and needs but the service does not carry out manual vacuum aspiration procedures. Women are provided with advice on contraceptive options, oral contraception and long acting reversible contraception (LARC). The service also provides male sterilisation (vasectomy).

In terms of medical abortions, the provider offers four 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. At the time of inspection the service did not currently offer simultaneous medical abortions, but plans were in place to pilot the reintroduction of simultaneous

administration in August 2017 (whereby both stages of medication are administered at the same appointment with a 30 minute gap between each stage). This would prevent women from having to attend twice for treatment.

In addition, MSI Manchester has 10 satellite clinics, (early medical units EMU) 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.

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

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

Summary of findings

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

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

- There had been changes to the way syringes containing an induction agent were stored. Each syringe was covered with a cap to reduce the risk of cross infection.
- Daily cleaning schedules had been fully completed.
- The service had implemented a system to ensure chair covers in the recovery area were checked and cleaned between each patient

We found the following areas of good practice:

- Staff demonstrated they understood the principles of safeguarding adults and children and knew what actions they needed to take in cases of suspected abuse.
- World Health Organisation (WHO) and five steps to safer surgery checklists were completed for all patients undergoing surgical procedures.
- There were locally agreed and up to date policies and standards that referred to evidence based practice and against which performance was audited.
- Records indicated that pain was assessed and treated in accordance with national guidelines.
- Staff treated patients attending for consultation and procedures with compassion and respect; staff were non-directive and non-judgemental.
- The service worked towards key performance indicators to assess and monitor performance. These were reported each month via the governance and quality dashboard.
- All new staff, were inducted and followed a training programme; this included a competencies framework and continuous assessments by their mentor and senior manager.

- Ultrasound scanning was undertaken by staff who received a bespoke ultrasound training course to date pregnancy provided by a qualified external sonographer delivered in line with the requirements of MSI policy.
- Staff across the service were aware of appropriate procedures in obtaining consent. They were familiar with guidance, such as Fraser guidelines.
- People could access the service when they needed it. Waiting times from treatment and arrangements to admit, treat and discharge patients were in line with good practice.
- A governance framework supported staff to deliver good quality care through the identification and monitoring of risks. As part of the wider corporate organisation, the clinic had a clear governance and committee structure in place, including clinical governance, medical advisory and health and safety committees.

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

- The registered manager had not reported a notifiable serious incident to the CQC.
- Two nursing staff were not up to date with either basic life support training or immediate life support training.
- Although the April 2016 hand hygiene audit showed 100% of staff complied with infection prevention control protocols, observations whilst on inspection indicated that staff did not always follow protocols when performing patient care.
- The clinic's counsellor was not trained to safeguarding level three. We raised this as a concern and all face to face counselling sessions for patients were immediately changed to telephone sessions.
- There was a lack of local oversight for training and revalidation for surgeons and anaesthetists attending the clinic. The senior manager was unable to show us hard copies or electronic personnel files that belonged to doctors who worked at the clinic. At the time of inspection the Registered Manager was unaware how to access these documents.

Summary of findings

- Records showed not all nursing and medical staff had received an appraisal in 2016.
- Contraception arrangements included long acting reversible contraceptive (LARC); the clinic did not achieve their target of 50% between the reporting period of April – June 2017.
- Evidence of discussion in relation to disposal of pregnancy remains was not always documented in records.
- Women were not routinely informed and did not receive a discussion to explain to them that their details were sent to the Department of Health.

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

- The provider must ensure that the layout of the day room, where patients recover following surgical treatment, does not compromise patients' privacy and dignity.
- Ensure effective medicines management processes are in place and improve recording of controlled drugs to ensure stock levels and doses administered are recorded accurately

- The provider must ensure an effective process for complaints handling, sharing information and taking actions to identify areas for development to improve services.
- Ensure an effective appraisal process is embedded, involving full participation and discussion to enable staff development.
- Ensure improvements in corporate and location level communication and engagement to ensure an effective process for governance, quality and risk oversight of services at local level

The provider must ensure records for the disposal of pregnancy remains are completed and available

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

Ellen Armistead

Deputy Chief Inspector of Hospitals

Summary of findings

Our judgements about each of the main services

Service

Termination of pregnancy

Rating

Summary of each main service

We regulate this service, but we do not currently have a legal duty to rate when it is provided as an independent healthcare single speciality service. We highlight good practice and issues that service providers need to improve and take regulatory action as necessary. We have a duty to rate this service when it is provided as a core service in an independent hospital.

Summary of findings

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Services we looked at

Termination of pregnancy

Summary of this inspection

Background to Marie Stopes International Manchester Centre

Termination of Pregnancy (ToP) refers to the termination of pregnancy by surgical or medical methods. Marie Stopes International Manchester is part of Marie Stopes International group, a not for profit organisation.

The service opened in 2004. The clinic is located in a residential area, four miles from Manchester town centre and eight miles from Manchester Airport, with good transport links.

The service has had a registered manager in post since 2010.

We carried out an unannounced inspection on 19 June 2017.

The service has been inspected four times and the most recent inspection, prior to this one, took place in May 2016. 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. There were some breaches in regulation that were relevant to this location, which we have followed up as part of this inspection.

The breaches were in respect of:

Regulation 12 HSCA (Regulated Activities) Regulations 2014 Safe care and Treatment.

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

At this inspection, we found the service had made improvements since our last inspection. These included: changes to the way syringes containing an induction agent were stored. Each syringe was covered with a cap to reduce the risk of cross infection. We also found daily cleaning schedules had been fully completed. The service had also implemented a system to ensure chair covers in the recovery area were checked and cleaned between each patient

Our inspection team

The team that inspected the service comprised a CQC lead inspector, one other CQC inspector, and a specialist advisor with expertise in termination of pregnancy. The inspection team was overseen by the inspection manager.

How we carried out this inspection

During the inspection we visited the surgical treatment room, the day room, medical abortion treatment rooms and the reception area. We spoke with 10 staff including: registered nurses, health care assistants, reception staff,

medical staff, operating department practitioners, consultants and senior managers. We spoke with 15 patients and four relatives. During our inspection we reviewed 21 sets of patient records.

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

Summary of this inspection

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

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

The service is located in a large house with three floors and a basement. Access to each floor is by stairs. The basement includes the surgical services, with a treatment room, two day rooms and a waiting area. The ground floor includes the reception and initial waiting room and the two other floors include the consulting rooms.

Women having medical abortions are offered four 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 clinic also provides oral contraception, long acting reversible contraception (LARC) and male sterilisation (vasectomy). Advice on contraceptive options is offered to all patients visiting the clinic.

Staff work on a rotational basis between the satellite clinics and MSI Manchester. The clinic employs a full time doctor who works in both the Manchester and Leeds clinic. A remote doctor is based at the clinic every Tuesday.

The clinic is open Tuesday to Saturday for abortion treatments and alternate Thursdays for vasectomy patients. It provides services for private patients, overseas patients, patients referred by their GP or self-referral for a number of clinical commissioning groups (CCGs).

During the inspection we visited the surgical treatment room, the day room, medical abortion treatment rooms and the reception area. We spoke with 10 staff including: registered nurses, health care assistants, reception staff,

medical staff, operating department practitioners, consultants and senior managers. We spoke with 15 patients and four relatives. During our inspection we reviewed 21 sets of patient records.

Activity (April 2017 – June 2017):

In the reporting period April to June 2017, there were 1,220 terminations recorded at MSI Manchester. The clinic saw 410 patients in May 2017.

One resident surgeon worked across Manchester and Leeds. When the surgeon was absent, another surgeon would be rotated from another Marie Stopes clinic, otherwise no surgical abortions sessions would be booked. The clinic employed eight registered nurses, four district nurses, five healthcare assistances and eight administration staff.

Track record on safety:

- There were six incidents relating to retained products of conception following surgical procedures between January and June 2017.
- There were 138 clinical incidents, these were categorised as 123 no harm, 10 low harm and four moderate harm. There were no incidents resulting in severe harm or death.
- There were 45 safeguarding disclosures reported on the electronic incident reporting system between February and June 2017.

There were:

No incidences of hospital acquired Methicillin-resistant *Staphylococcus aureus* (MRSA).

No incidences of hospital acquired Methicillin-sensitive *staphylococcus aureus* (MSSA).

No incidences of hospital acquired *Clostridium difficile* (C. diff).

No incidences of hospital acquired E-Coli.

The clinic reported three complaints between the reporting period of January 2017 and April 2017, of which one was related to poor care. The complaint was fully investigated by the Head of Quality and Customer care and the outcome of the complaint was 'Not Upheld'

A counselling service is available at the clinic during periods of activity and for pre-booked appointments.

Summary of this inspection

Services provided at the hospital under service level agreement:

- Clinical and or non-clinical waste removal.
- Central sterilisation services.
- Maintenance of medical equipment.

Summary of this inspection

The five questions we ask about services and what we found

We always ask the following five questions of services.

Are services safe?

We found the following areas of good practice:

- The service had measures in place to control infection risk. Staff kept themselves, equipment and the premises clean.
- Staff kept appropriate records of patients' care and treatment. Records were clear, up-to-date and available to all staff providing care.
- The service had suitable premises and equipment and looked after them well. Emergency equipment was checked on surgery days.
- When things went wrong, staff apologised and gave patients honest information and suitable support.
- Staff understood how to protect patients from abuse and the service worked well with other agencies to do so.
- There was a system in place to ensure that records were accurate, secure and complete for every patient who attended the clinic. 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

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

- Some nursing staff were not up to date with either basic life support training or immediate life support training.
- The clinic's counsellor was not trained to safeguarding level three. We raised this as a concern and all face to face counselling sessions for patients were immediately changed to telephone sessions.

Are services effective?

We found the following areas of good practice:

- The service provided care and treatment based on national guidance and evidence of its effectiveness.
- The service worked towards key performance indicators to assess and monitor performance. These were reported each month via the governance and quality dashboard.
- Medical records audits were undertaken bimonthly and included monitoring of pathways of care, information provision and pre-abortion assessment, in line with Royal College of Obstetricians and Gynaecologists' (RCOG) guidelines.

Summary of this inspection

- All new staff were inducted and followed a training programme; this included a competencies framework and continuous assessments by their mentor and senior manager.
- Ultrasound scanning was undertaken by staff who received a bespoke ultrasound training course to date pregnancy.
- Staff across the service were aware of appropriate procedures in obtaining consent. They were familiar with guidance, such as Fraser guidelines. 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.
- Information about the outcomes of patients' care and treatment was collected and audited annually by the corporate statistician, to review the quality of care and patient outcomes. This process was now available at a local level and was disseminated monthly to all locations.
- Patients receiving care at the clinic were carefully screened and their suitability for treatment was assessed to ensure correct treatment was provided.

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

- There was a lack of local oversight for training and revalidation for surgeons and anaesthetists attending the clinic.
- Records showed some staff were not up to date with all competency training.
- Records showed not all nursing and medical staff had received an appraisal in 2016.

Are services caring?

We found the following areas of good practice:

- Patient feedback was positive about the way they were treated by staff.
- Every patient had individualised plans to ensure they received the most appropriate treatment for them.

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

- The layout of the day room where patients recovered following surgical treatment had the potential to compromise the patients' privacy and dignity. We raised this as a concern at our previous inspection, however, staff told us the facilities in the dayroom did not always allow for patients' privacy, for example chairs in the dayroom remained located very close to one another which limited privacy.

Summary of this inspection

- It was evident from our observations and records we reviewed that the clinic followed RSOP 12 guidance, ensuring all women were fully informed about treatment options before making a decision.
- However, not all patients were informed that their information would be sent to the Department of Health for statistical purposes. We reviewed 11 sets of records and found 55% had evidenced a discussion referencing the contents of the HSA4 form and what it was used for. At the time of inspection, eight of the patients we spoke with had not been informed about the HSA4 form.

Are services responsive?

We found the following areas of good practice:

- The service planned and provided services in a way that met the needs of local people.
- The service took account of patients' individual needs.
- Staff and patients had access to interpreters when English was not the patient's first language. Patients were informed about this service at the booking consultation and it was also advertised on the website.
- Patients were asked to write down their date of birth and name on paper at the reception desk instead of confirming them verbally to maintain confidentiality.
- People could access the service when they needed it. Waiting times for treatment and arrangements to admit treat and discharge patients, were in line with Royal College of Obstetricians and Gynaecologists (RCOG) guidance.

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

- Contraception arrangements, included long acting reversible contraceptive (LARC), did not achieve their target of 50% between the reporting period of April – June 2017.
- Complaints were handled appropriately; however, there was no evidence that this information was shared with staff to support learning.
- Evidence of discussion in relation to disposal of pregnancy remains was not always documented in records.

Are services well-led?

We found the following areas of good practice:

Summary of this inspection

- Staff said they felt respected and they liked coming to work. Staff commented on the open and honest culture amongst the local workforce.
- Marie Stopes International had a corporate strategy and vision; this was clearly defined as: “A world in which every birth is wanted”.
- The vision set out behaviours and values expected of staff working for the organisation and was displayed for patients and staff to read.
- The HSA1 form was completed, signed, and dated by two registered medical practitioners before treatment took place. Clinicians recorded the reason for a patient’s decision for termination of pregnancy and they assessed each individual case against the criteria set out in the Abortion Act 1967.
- A governance framework supported staff to deliver good quality care through the identification and monitoring of risks. As part of the wider corporate organisation, the clinic had a clear governance and committee structure in place, including clinical governance, medical advisory and health and safety committees.

We also found the following issues that the service provider needs to improve:

- The registered manager had not notified the CQC following a notifiable serious incident and therefore we were not assured that all appropriate incidents were being reported.
- Women were not routinely informed and did not receive a discussion to explain to them that their details were sent to the Department of Health.
- The registered manager did not have oversight at a local level of the doctor appraisals and training, as this was handled at provider level. The Registered Manager was not aware how to access to these files.
- There was no assurance locally that the management team had local oversight of staff competencies. For example management team were not able to confirm if medical staff had completed all and correct training in line with MSI policy.

There was no formal staff platform to communicate information to staff, such as learning from incidents.

Termination of pregnancy

Safe	
Effective	
Caring	
Responsive	
Well-led	

Are termination of pregnancy services safe?

We regulate this service but we do not currently have a legal duty to rate single specialty termination of pregnancy services. We highlight good practice and issues that service providers need to improve and take regulatory action as necessary. We do have a duty to rate this service when it is provided as a core service by an independent hospital

Incidents and safety monitoring

- 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. At the time of the unannounced inspection, not all incidents had been reported which highlighted, whilst process were in place they were not always followed. For example, we found a discrepancy recorded in a controlled medication book in relation to Midazolam 50mg/1ml. On 1 November 2016 there was an entry documented, which identified 90 vials in stock. On 1 March 2017, which was the next entry, there were 88 vials documented. We reviewed the incident reporting system and found that no incident had been raised in relation to two missing vials. At the time of inspection, staff were unaware of the discrepancy and could not provide an explanation.
- During the unannounced follow up inspection, we identified two incidents that had occurred during July 2017; both incidents had been appropriately tracked and recorded.
- Staff told us that they were made aware of any issues or changes to practice at the daily 'huddles' and via emails. However, they struggled to give us examples of learning from incidents.

- Data received from the clinic identified that 151 incidents had been reported from February 2017 to June 2017. Of the 151 incidents reported, 31 had no impact reported and therefore the severity of the incident was not clear.
- 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. In the event of a patient death, an automated alert would be sent to the nominated individual, who would instigate an investigation and a notification would be submitted to the CQC and the Department of Health.
- When things went wrong, staff apologised and gave patients honest information and suitable support. A duty of candour policy had been introduced in April 2016. There was evidence of duty of candour in the investigations we reviewed.

Mandatory training

- The service provided mandatory training in key skills to all staff. The requirement to undertake mandatory training was determined by the staff member's role and timeframes for updates were identified.
- Training was a mixture of e-learning and face to face training.
- The data we received in June 2017 from the service, showed 100% compliance with fire essentials, informed consent, equality and diversity and safeguarding level 1 and level 2 training.
- Training data provided, showed 85% of the staff had received immediate life support (ILS) training. The remaining 15% of staff were not trained or training was out of date.

Termination of pregnancy

- There were also quarterly scenario based resuscitation refresher training days, in addition to annual training requirements.
- At the time of our inspection, an anaesthetist and an operating department practitioner both informed us that they were (ALS) trained, however, we found no information available locally to support or confirm that medical staff had completed mandatory training. The registered manager at the time of inspection could not confirm if medical staff were up to date with their training as this was held at corporate level. The clinic did not complete local checks of competency and training of clinicians despite this being raised at the last inspection in May 2016. Information provided following the inspection indicated this data was stored on the MSUK intranet to enable all managers to check compliance when required. However, at the time of inspection, the registered manager at MSI Manchester was unaware and no checks had been taken by them to provide assurance that medical staff were in date.

Safeguarding

- Staff understood how to protect patients from abuse and the service worked well with other agencies to do so.
- A provider wide safeguarding policy was available for staff to refer to; this contained information on safeguarding for both adults and children and young people. Since the previous inspection in 2016, MSI had introduced a system for policy ratification and both of these policies had been reviewed and ratified.
- Staff had training on how to recognise and report abuse and they knew how to apply it.
- The management team had introduced a revision of its safeguarding training and tailored it to strengthen the existing content of the course, to provide more relevance to the work of the local teams. Staff were given the opportunity to attend a safeguarding event that took place on 11 November 2016, to provide additional training to staff. Topics covered at the event included: child sexual exploitation (CSE), female genital mutilation (FGM) and domestic violence.
- 100% of staff had completed an electronic learning module that covered topics of CSE, FGM and 'Prevent' training. The aim of 'prevent' training was to provide

staff with the knowledge to enable them to be aware of people who are at risk of becoming radicalised and to stop them from supporting terrorism or becoming terrorists.

- Data showed that 95% of staff had been trained to safeguarding level three as of June 2017, which was in line with the Intercollegiate Document for Healthcare Staff (2014). However, we found that one nurse and a counsellor had not completed their training. Our concerns were escalated to head office and all face to face counselling sessions for patients were immediately changed to telephone sessions. On the unannounced inspection, we found that appointment slots reflected such changes.
- As part of the improvements made since the last inspection, the provider had introduced a safeguarding group in January 2017. The safeguarding group monitored safeguarding reports and compliance with policy.
- Safeguarding concerns were recorded as incidents and notes were put on the electronic system to ensure staff were aware of the patient's circumstances if they returned to the clinic.
- 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 counselling with a responsible adult prior to consultation and treatment. Any concerns would be discussed with social services.
- 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.

Cleanliness, infection control and hygiene

- The service controlled infection risk well. Staff kept themselves, equipment and the premises clean.

Termination of pregnancy

- There were no cases of methicillin-resistant staphylococcus aureus (MRSA) reported by the service in the previous six months prior to our inspection.
- The provider carried out a 55-point general Infection Prevention and Control (IPC audit) in April 2017. The clinic achieved 94% compliance rate. Areas for improvement were noted and were due to dust in the environment. Actions were identified and included immediate thorough cleaning. Emails were sent to all staff to share lessons learnt.
- The surgical treatment room had a separate sluice and an area for the storage of sterile equipment.
- All clinical staff in the surgical treatment room and dayroom adhered to the 'arms bare below the elbow' policy. Personal 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 the surgical treatment area, we observed trolleys being cleaned after each use and sterile surgical instrumentation being set up using the aseptic non-touch technique, which is a technique used to reduce the risk of healthcare associated infections.
- Infection control training was mandatory. Records showed 5% of staff were outstanding level one training and 30% of staff were outstanding level two training. The one person required to complete level 3 training was compliant.
- At the time of our inspection, we observed syringes containing an induction agent (a rapidly acting sedative drug used for general anaesthesia) in a kidney dish on the anaesthetic machine in the surgical treatment room. The syringes were each covered with a sterile cap to reduce the risk of cross infection.
- We reviewed daily cleaning schedules for the surgical treatment rooms for April 2017 and found these completed.
- The chair covers in the dayroom were made of fabric and each area where the patient sat was covered with a square shaped cover. The chairs were wiped with a disinfection wipe in between patients and square-shaped covers were replaced which we

observed at the time of our inspection. Staff performed a daily check and if the fabric was soiled the cover was changed. A completed checklist for April 2017 showed the chairs had been checked, however, staff were not aware of the maximum timeframe for the covers.

- Staff achieved 100% compliance in the hand hygiene audit in April 2017, we noted that hand gel and sanitizers were readily available on entry to clinical areas; however, we observed staff recording patients' physiological observations, including blood pressure, without decontaminating their hands before moving to the next patient.

Environment and equipment

- There were systems and processes in place to ensure the appropriate maintenance checks were carried out on equipment. There was a planned preventative maintenance schedule in place.
- Routine yearly electrical equipment safety testing was in place. This is a process by which electrical appliances are routinely checked for safety. Records indicated that equipment had been tested appropriately to ensure that it was safe to use.
- Wheelchair access was available to the basement area for patients with mobility difficulties and staff attended this area to provide treatment in these cases.
- The entrance to the clinic was controlled via an intercom system. Key code locks were on the patient changing room door, the surgical treatment room and the staff changing room. At the time of inspection, all patients were escorted by a member of staff when moving through the clinic.
- The resuscitation equipment was stored in the recovery area. It was maintained on a wheeled trolley that could be transported to the other two upper floors if needed as there was no additional emergency equipment stored on other floors in the building.
- Emergency medication was stored in the medicines cabinet in the surgical treatment room, which was left unlocked during surgery for quick access in case of emergency. There was also an emergency tracheostomy kit and anaphylaxis medication in the surgical treatment room.

Termination of pregnancy

- The resuscitation trolley and defibrillator was checked weekly, with additional checks made if the equipment was used. The trolley was sealed with an indicator tag. Information provided post inspection was that this was checked on a daily basis to ensure it remained intact. However, guidance from the Royal College of Anaesthetists (2012) advocate daily checks in all clinical areas.
- There was an additional room that had five chairs in at the time of our inspection. This area did not have staff present, but had a camera in situ and the images were on screen in the dayroom for staff to observe. We found one call bell available in the room for the four beds. We raised this as an area of concern to the registered manager.
- When we returned to the clinic, we found only three chairs in the room and the two patients in the room both had a call bell. We spoke with these two patients, who informed us they had given verbal consent to have a camera in situ, so staff could observe them from the other room. We did not see this consent or discussion recorded in their medical record however there was signage in the room to indicate camera use.

Medicine Management

- There was a policy in place for medicine management, which included the procedure for prescribing, ordering, storage, administration, transport and disposal of medicines.
- Medications were provided via third party arrangements with a local trust and a private pharmaceutical company.
- To review clinical practice and keep in line with medicine management legislations, the provider had introduced a medicines management group in November 2016. The purpose of the group was to review monitor and action any practice that involved handling, storage, prescription and administration of all medications. The group provided accountability for all aspects of medicines management; they worked with external advisors to ensure staff worked to best practice.
- There were no controlled medications stored on site, however, we observed controlled medicine books were used for Oramorph and Midazolam and we were told that these were recorded this way as it was best

practice. We reviewed the controlled medication books for Oramorph and Midazolam and found missing entries and discrepancy with stock. For example, we noted there was a discrepancy with the number of ampoules of Midazolam and found that this was due to an agency anaesthetist using one ampoule for several patients. We raised this as a risk at the time of our inspection. This had not been reported as an incident and staff were unaware of the discrepancy and were made aware of them at the time of inspection by the inspection team. We escalated this to the Registered Manager.

- All other prescription medications were stored appropriately in a locked cabinet, within a locked store cupboard, in one of the consulting rooms and surgical treatment room.
- There was a locked drug cupboard in the day room and we observed staff following policy and performing safety checks when administering medication.
- Daily records of fridge temperatures were completed. Fridge temperature checks showed that the fridges remained within tolerance limits to ensure the medicines were stored at the correct temperature.
- There was clear documentation of information about allergies in the records we reviewed.
- All patients were prescribed antibiotics as prophylaxis treatment for infection and the medication was administered prior to discharge.
- Medicines management pilot training was completed at MSI Manchester on 3 February 2017. This was carried out by the local NHS trust with whom MSUK have a service level agreement for medicines management. Staff told us that they found the session was too generic, but still found it useful. Minutes from the medicines management group evidenced the group discussed the initial feedback. It was decided that improvements to the training package was needed, so that it was bespoke to the medications used by MSI. It was also agreed that there would be a drugs calculation test that all clinical nursing staff would be required to undertake.

Records

- There was a system in place to ensure that records were accurate, secure and complete for every patient who attended the clinic.

Termination of pregnancy

- We reviewed 10 termination of pregnancy patient records. The records were legible, complete and up to date. They all contained a copy of the HSA1 form, with signatures from both doctors and their GMC numbers were visible on the forms we reviewed.
- 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 and the World Health Organisation (WHO) Five Steps to Safer Surgery checklist.
- Records we looked at all contained a scan of the pregnancy to confirm gestational dates.
- The electronic patient 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 no less than three years beginning on the date of the last entry. Patients' details were automatically submitted to the register at the time of treatment.
- MSI Manchester undertook bimonthly medical records audits, the most recent audit (July 2017) at the time of inspection found the clinic to be 100% compliant, 30 records had been reviewed and were all complete. .

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. As part of the consultation, trained nurses or healthcare assistants collected the patient's medical history and any other current relevant information that assisted in assessing the patient's suitability for treatment.
- The organisation's pre-existing conditions guidelines were referenced to ascertain if the patient was suitable for 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.
- VTE assessments were completed in the 21 records we reviewed.
- Patient records were reviewed by the anaesthetist prior to surgery and if they identified any concerns they would see the patient before surgery. Otherwise, patients were first seen by a doctor at the time of surgery. The anaesthetist and doctor both confirmed treatment and verbal consent with the patient before proceeding with treatment.
- The World Health Organisation (WHO) and 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 checklist had been completed in all cases.
- We observed three patients arriving in the treatment room and the surgeon checking details against the World Health Organisation (WHO) and five steps to safer surgery checklist. Adherence to the checklist was audited as part of the medical records audit. We were told that, at the end of every day, the medical notes (including the World Health Organisation (WHO) and 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 the surgical treatment room, which were documented on the patient's record. A set of observations were repeated upon arrival to the day room from the treatment room.
- Prior to reaching the day room, patients were taken to a small recovery area at the side of the surgical treatment room where they were wakened and transferred immediately into a wheelchair, to be taken to the day room. There were two staff present during this transfer.
- The clinic had an up to date transfer policy in place; this stated the pathway staff were required to follow when transferring patients to the local NHS hospital. In the event a patient required an emergency transfer, the transfer policy stated that patients would be transferred

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by a member of clinical personnel. In the root cause analysis (RCA) we reviewed, where a patient required emergency treatment, staff followed protocol, the treatment room list was stopped and staff called for an ambulance.

- At the time of our inspection, we observed the ultrasound scan being used following surgical termination. We were informed by the surgeon that all women were scanned following all surgical terminations from 12 week gestation to reduce the risk of retained products of conception.

Nurse Staffing

- The service had enough staff with the right qualifications, skills, training and experience to keep people safe from avoidable harm and abuse and to provide the right care and treatment.
- Eight registered nurses were employed in the clinic and four district nurses, as of June 2017.
- Senior managers did not use agency or bank staff regularly. Since the last inspection, the clinic had only used one agency operating department practitioner (ODP) in the treatment room. We were told that all agency staff received an induction.
- There were currently no nursing vacancies at the clinic.
- We found that nursing staff worked together across the clinic (for example, treatment room staff and staff providing medical termination of pregnancy treatments). Staff told us that they would informally share information and daily huddles were now in place to disseminate information amongst the wider team.
- At the time of our inspection, there were nominated nursing staff within the surgical treatment room with healthcare assistants and nurses covering the day room.

Medical staffing

- Medical staff worked regularly between the Manchester and Leeds clinics. Medical staff were all 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.

- The remote doctor was based within the centre every Tuesday to provide support to the remote doctor team. 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; this surgeon was appraised by the medical director and was, at the time of inspection, up to date with training and registration.
- There were no vacancies for medical staff and surgeons; if medical staff was needed to cover annual leave or sickness, staff working at other MSI centres provided cover.

Major Incident awareness and training

- The service planned for emergencies and staff understood their roles if one should happen. A business continuity plan was in place. The service planned for emergencies and staff understood their roles if one should happen. A business continuity plan was in place. The plan detailed the responsibilities of individuals and action staff should take in the event of a major event or an emergency situation.
- An emergency backup generator was on site; this was used in case of electricity failure and staff were aware of where the generator was located. The July 2017 Environmental audit had reviewed the condition of the generator and data confirmed it had been tested by an independent specialist who confirmed it was in working order.
- Fire safety checks were completed, as of July 2017 all fire extinguishers were tested, all doors were checked to ensure they had a 4mm gap and all fire detection systems were in working order.

Are termination of pregnancy services effective?

Evidence-based treatment

- The service provided care and treatment based on national guidance and evidence of its effectiveness.
- In accordance to their gestation, patients were offered a choice of procedure within appropriate timeframes. Processes were in place to support patients with

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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 worked within the requirements of Required Standard Operating Procedure (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 contraception methods (LARC) which are the most effective. All patients should be offered testing for chlamydia, offered a risk assessment for other STIs (e.g. HIV, Syphilis etc.), and tested as appropriate. The clinic offered all patients attending MSI Manchester a chlamydia screening test. Patients were also offered testing for other STIs, but this was dependent on the standards agreed with each clinical commissioning group.
- In terms of medical abortions, the service offered four treatment options. Medication could 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 at the same appointment with a 30 minute interval) but had suspended this treatment at the time of our inspection until more outcome data had been collected. The provider planned to reintroduce the treatment, initially as a pilot in another MSI location in August 2017. To ensure the practice was safe and effective, the abortion success rate of patients who opted for this treatment would be reviewed before MSI rolled this method of treatment out nationally. The process for simultaneous administration had been signed off by the MSI executive team, and included staff training and monitoring of patient outcomes and complication rates.
- Patients were offered a choice of early medical termination, medical termination or surgical termination using vacuum aspiration under conscious sedation, or no anaesthetic, if they did not want to receive a general anaesthetic. The method of anaesthesia was according to patient choice and needs.
- Information provided by MSI in February 2017 stated that the uad been reviewed and changes to the policy included clarification about the role of scanning staff. A

training package provided to staff was delivered by a qualified external sonographer in line with the requirements of MSI policy specifically to only date pregnancy.

- Only staff who had completed training and had been assessed against the competency framework could perform scans at Manchester MSI. Staff were supported by a scanning mentor, the mentor worked with staff to complete the required training and assessment, in order to scan patients without supervision. Staff told us that any nurse or health care assistant who had completed training in line with MSI policy could perform ultrasound scans to determine gestational date. Data provided in June 2017 showed, 88% of staff had received ultrasound scanning training, the remaining 22% of staff were new starters and were scheduled to have training.
- During our inspection, we saw that staff who had undertaken the relevant training and assessment performed scans.
- Patients were offered treatment options according to the gestation of pregnancy.
- The MSI website presented all treatment options and information on their website, so that patients were able to read the information in their own time.

Nutrition and hydration

- Patients were given advice and information on restricting diet and fluids prior to attending surgery.
- Patients were given biscuits and offered tea, coffee or water after surgery to aid recovery. There were water fountains available in the general waiting areas. However, the weather was very warm at the time of inspection and we found that the water fountain was empty on the ground floor. This was a waiting area used for partners/family.

Pain relief

- We observed patients in the day room being regularly asked if they were in any discomfort or pain. On entering the day room following surgical treatment, patients were given a heat pack to place on their abdomen to provide comfort.

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- At the time of our inspection, we asked two patients in the additional day room area if they felt their pain was controlled and both did. We observed one of these patients using the call bell, which was responded to by staff immediately.
- We reviewed 10 patient prescription charts and found all patients were prescribed analgesia and all patients had a pain assessment completed.
- We observed patients being administered analgesia at the time of our inspection and on discharge staff gave patients advice on how to manage pain, for example the use of, nonsteroidal anti-inflammatory drug (NSAIDS) which is recommended in the RCOG Guidelines.

Patient outcomes

- MSI Manchester took part in local audits and those arranged by the organisation or external organisations nationally. Senior managers told us that audits were used to identify best practice and areas of improvement.
- We reviewed the annual audit programme, which identified planned audits and actions with time frames. The corporate audit plan included safeguarding, hand hygiene, medical records and infection prevention control.
- MSI Manchester displayed local audits in the staff room, this was so that staff had the opportunity to see where improvements were needed and where the clinic had excelled. For example the LARC uptake audit showed improvements across April – June 2017, however the clinic had not hit their target of 50% across all three months.
- 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.
- LARC data was collected on a monthly basis and was provided to the commissioners on a quarterly basis to demonstrate uptake of LARC (LARC methods included

implants and intrauterine devices or system (IUD/S)). Uptake was poor and did not exceed 29% between April 2017 – June 2017. The clinic did not achieve the internal target of 50% between April 2017 – June 2017.

- The service performed an audit of sexual transmitted infections (STIs) screening. MSI Manchester screened 72% patients in May 2017; this was above the provider's target of 70%. However, STI screening rates dropped to 63% of patients in June 2017; this was lower than the year before, which was 78% and lower than the provider's internal target of 70%.
- Two patients returned to MSI Manchester and were treated with antibiotics. The young people were contacted by the organisation performing the diagnostic test and were given information of how to receive treatment. It was then the preferred provider that monitored if people had received treatment.
- There were six unplanned returns to treatment room during the period 4 January 2017 to 17 March 2017, which were all due to retained clots. One of these cases was transferred out to a nearby hospital and the remaining five were taken back to the surgical treatment room on site. For the period February to May 2017 across eight MSI sites, 0.25% of patients attending Manchester clinic needed to be returned to the treatment room. Manchester was the third highest out of eight sites with unplanned returns to the treatment room.
- If the patient had a health condition that 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.

Competent staff

- Records showed that not all medical staff had an appraisal in the last 12 months. For example, the surgeon on site was scheduled to have an appraisal on the 20 February 2017; however, at the time of inspection, the clinical lead was not able to provide evidence that this had taken place. Information provided after inspection indicated the appraisal had

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taken place. At the time of the inspection we were not provided with the number of nursing staff who had received an appraisal within the 12 months prior to our inspection.

- An induction and training programme was in place for new staff where competencies were assessed with mentor support and supervision. Staff that were new to the organisation confirmed with us at the time of our inspection that they had received an in-depth induction.
- 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. Staff were assessed against these before being allowed to practice unsupervised. Diagnostic ultrasound was used within MSI to confirm gestational age; so that the most appropriate choice of ToP could be offered. Staff were told that they were not expected to diagnose conditions, but should escalate any suspected concerns to the surgeon or doctor.
- Ultrasound scanning was undertaken by staff who received non-accredited training provided by a university. The current training programme had been sent to BMUS (British Medical Ultrasound Society) to consider endorsement.
- 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 and 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. All trained staff must, when required, demonstrate competence to the MSI ultrasound mentor.
- The training matrix provided, showed staff were due refresher training in ultrasound scanning. We were told that staff competence needed to be re-assessed every three years. Data provided by the service on the 27 June 2017 showed there were 14 members of staff who were applicable for ultrasound scanning training, of these, we found 36% had not yet been trained or their training had expired. We found no evidence that those without training were performing or had performed scans.

- 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 nine nursing staff were required anaesthetic and recovery care training and three yearly updates were required. Data provided identified 22% of staff had not been trained nor had an update in the timeframe identified. We did not find any evidence that the 22% of staff who were not trained in anaesthetics and recovery care performed any duties they were not trained in.
- The counselling service was provided by counsellors who were trained to BTEC diploma level 5 and held a graduate certificate in counselling.

Multidisciplinary working

- We observed good team working between all the nurses, healthcare assistants, anaesthetists and consultants. Each day a multidisciplinary huddle took place, which included discussion of any incidents, concerns raised, number of patients expected, staffing and responsibilities.
- 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, staff were clear that the medical consultant/surgeon held the responsibility for patients receiving treatment.
- Discharge letters were generated for the patient's own GP.
- The senior managers at the location were working with other young people's services to increase awareness of the clinic. The aim of working collaboratively was to provide young people's services with an insight to the services MSI provide.

Access to information

- Staff at the clinic had access to paper and electronic patient records. Paper copies of the patient record were kept on site for up to three months and then sent for

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archiving. However, staff were able to request retrieval if needed. Records included documentation in relation to the patient's care, treatment, and medical and social history.

- There were systems in place on both the electronic system and paper records that alerted staff to known risks or concerns about individuals attending the clinic.
- 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". Patients were given letters and were asked if they wanted one sent directly to their doctor.
- Best practice guidelines and MSI Policies were available to staff via the provider's intranet. We also saw paper copies of reports and policies in the manager's office.

Consent, Mental Capacity Act and Deprivation of Liberty

- All staff at the clinic were familiar with the importance of obtaining informed consent from patients before any treatment. We observed nursing and medical staff obtaining consent from patients before clinically assessing them and providing treatment. Staff we observed adhered to RSOP 14 and RCOG Guidelines 'Care of Women Requesting Induced Abortion (2011). A review of records confirmed this. These guidelines highlight that: "".
- We were advised that the consent form was completed at consultation and signed by a 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 patients that were attending for surgical treatment having consent and treatment confirmed by the surgeon before proceeding with treatment.
- 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.
- Staff were aware of the need to complete a pro-forma for patients that were under the age of 18, which was used to identify any safeguarding concerns and to ensure appropriate procedures in obtaining consent.

The proformas assisted staff to document 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 reviewed five records for patients that were 17 years old at the time of treatment and found a pro-forma was completed in all cases. However, we found one case where a risk was identified, but there was no evidence documented that this had been followed up or referred to the safeguarding lead. We raised this with the manager at the time of our inspection to enable follow-up/review.

Are termination of pregnancy services caring?

Compassionate care

- We observed staff interacting with patients; they were attentive to their needs and spoke in a compassionate manner. Staff in the surgical treatment room were supportive and tried to put the patient at ease. This was in line with NICE guidelines that set out the quality standards of patient experience in adult NHS services.
- Comments from the feedback survey from January to March 2017 included: "All the staff on reception were extremely sensitive, compassionate, and helpful".
- 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 to March 2017, 98.2% of 445 respondents stated they were treated with respect.
- 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 day room where patients recovered following surgical treatment at times compromised patients' privacy and dignity.
- Managers and staff told us that the facilities in for surgical services did not always allow patients' privacy and dignity to be maintained. At the time of our

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inspection, we observed one patient in the day room become visibly upset and crying. We observed a member of staff responding to her immediately and gave her a drink of water. We also observed another patient in a lying position on a chair displaying non-verbal signs of pain and who had placed a scarf over her face. There were other patients in the room at the time and their privacy was compromised. We raised this as a concern at our previous inspection, however, there had been little change and the chairs in the dayroom remained located very close to one another with limited privacy.

- When discharge took place, we observed patients asked to sit at the nurses' desk where the nurse would provide medication and prepare the patient for discharge. This was in an attempt to create a more private situation for the patient.

Understanding and involvement of patients and those close to them

- Patients could be accompanied by a friend / relative in the consultation if required.
- Any private patients paying for treatment were taken to a room separate to the reception area to make payment.
- Patients were given impartial, accurate and evidence-based information both verbally and written 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.
- We spoke with 10 patients, who told us that the process had been explained to them prior to the treatment appointment. We reviewed five sets of records and all included a documented discussion about the different termination methods.
- Comments received via the patient feedback survey January to March 2017 included; "anaesthetist was great how he explained anaesthetic options".
- Discussions involving costs were done sensitively. On the unannounced inspection we observed a member of staff discussing cost with an Irish patient; the patient was given the opportunity to come back and pay in Euros or in Sterling.

- It was evident from our observations and records we reviewed that the clinic followed RSOP 12 guidance, ensuring all women were fully informed about treatment options before making a decision. However, they did not inform all patients that their information would be sent to the Department of Health for statistical purposes and that the data published would be anonymised. We reviewed 11 sets of records and found six had evidence of a discussion which referenced the contents of the HSA4 form and what it was used for. At the time of inspection, eight of the patients we spoke with had not been informed about the HSA4 form.

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 and upset.
- 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 at the clinic.
- Staff gave patients written information about accessing help during service opening hours and via the 24-hour telephone service following their procedure.
- Patients were offered counselling sessions, but these were only available on Fridays. At the time of the inspection, a patient listed for treatment had changed their mind and requested to see a counsellor. The clinic immediately made arrangements for the patient to be seen. However, if a patient attended on another treatment day and requested to see a counsellor, they would have to return to the clinic.
- The Department of Health, Required Standard Operating Procedures (RSOP) standard 14 states that: "all women requesting an abortion should be offered the opportunity to discuss their options and choices with, and receive therapeutic support from, a trained pregnancy counsellor and this offer should be repeated at every stage of the care pathway". During our inspection we reviewed the counselling process at MSI Manchester; there were two policies in place, Counselling for patients' policy and counselling for young people aged 15 years and under policy. Counselling was mandatory for patients under the age

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of 16. Young people were given three different options; face to face counselling, webcam counselling or the option for a young person to attend clinic for telephone counselling.

- The policies were stored centrally on the provider's electronic system for staff to access.

Are termination of pregnancy services responsive?

Meeting the needs of local people and individuals

- 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.
- Patients could access information about services on the MSI website/internet page. 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. 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.
- 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.
- Clinics for Vasectomy were ran on a different day to TOP clinics, MSI Manchester ran two to three vasectomy lists each month, which could be flexed depending on need.
- There were admission and exclusion criteria in place and any patients with complex needs that would be placed at risk were referred to the local hospital services for treatment.
- Patients with learning difficulties could have a carer present with them and arrangements could be made for them to be first on the surgical list to allow their carer to stay with them after treatment before other people were in the day room.
- 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 for patients with hearing difficulties.
- 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. If patients were showing signs of uncertainty, they 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 offering a TOP list one day a week at each centre for patients that preferred a female surgeon.
- 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.
- During the discharge process possible complications were explained to the patient as well as advice around

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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.

- The provider had a policy in place for the management of disposal of pregnancy remains following a surgical termination (MSI Management of fetal tissue policy dated May 2016). This incorporated the Human Tissue Authority Code of Practice.
 - We reviewed the process for the storage and labelling of pregnancy remains, which were in line with the MSI policy. To ensure the procedure was complete, pregnancy remains were examined by the surgeon. Staff documented any non-standard disposal option in the patient's record and on a freezer log sheet indicating the reason for storage and date for either collection or disposal of pregnancy remains. For example where remains 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.
 - A patient leaflet was available to patients, detailing the options for disposing of pregnancy remains. Patients were given the option to have pregnancy remains kept separately and this was documented in patient's personal records as part of their consent to treatment.
 - At the time of inspection, we observed two patients attending for surgical termination and found a consent form signed for disposal of pregnancy remains in their record. The form included the options available to the patient or consent for MSI to dispose of the pregnancy remains. This had improved since our last inspection where patients were informed of the options for disposal of pregnancy remains on request.
 - However, we reviewed an additional 11 patient records and found no evidence of discussion in relation to disposal of pregnancy remains documented in six of the records.
- appointments were available to women within three working days. Data provided on waiting times showed between May 2017 – June 2017 all patients received treatment within 3 working days,
- Between May 2017 and June 2017, all patients were offered an appointment in less than five working days from the decision to proceed. This was in line with the Royal College of Obstetricians and Gynaecologists' recommended timeframes. 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 report included; capacity issues and availability of the full range of treatments. The clinic appointment diaries were constantly reviewed and adjusted to ensure full availability. Between December 2016 and May 2017, on average 18% of patients did not proceed for their planned treatment. Patients that do not proceed to treatment can include patients that change their mind on the day, decide to have counselling or after a physical assessment, require treatment within the NHS. This was higher than expected average (15%) for the North area. Managers informed us that they did not follow up patients who did not proceed with their treatment.
 - The dashboard in the staff room displaying data for 1 May 2017 – 1 June 2017 showed surgical lists started on average around 09.49 am and finished around 15:25pm, MSI rated this data nationally, so areas of underperformance and areas of best practice could be seen across all clinics. MSI Manchester surgery start time was rated amber, this meant compared to other clinics start times were later which meant that the treatment room was utilised less. Dashboard data was used for internal monitoring by MSUK to benchmark across locations and allow further analysis into variations.
 - 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

Access and flow

- To provide a responsive service, MSI worked to an internal target, this was set so all treatment options and

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deteriorating, 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.

Learning from concerns and complaints

- 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.
- Where a patient indicated a less than 'very good' response on the patient feedback questionnaire. A record of this was sent to the centre management team as a "Red Alert" and an action plan was put into place (where relevant) to address the issue. The information was then shared with staff during team meetings to promote learning.
- However, this was not always evident at the Manchester MSI clinic. The clinic had received three complaints from 26 January 2017 to April 2017, one related to poor care and two related to complications after treatment. Of these, one complaint was upheld. Whilst reviewing the complaint we found no evidence that staff learnt from complaints.

Are termination of pregnancy services well-led?

Leadership/culture of service related to this core service

- It was evident from discussions that the clinic was working to streamline processes and changes to the local management structure were imminent.
 - When the registered manager was not on site, staff were aware of how to contact senior management. At the time of the unannounced inspection, there was no clinical lead on site; however, staff approached the lead nurse with any issues.
 - We spoke with six members of staff who all felt respected and liked coming in to work. All six members of staff commented on the open and honest culture amongst the local workforce.
- The clinic was registered to carry out termination of pregnancies; it displayed the certificate of approval (as issued by the Department of Health) in the reception area as well as the CQC registration certificate, (as seen as good practice by Department of Health). It also displayed the certificate of employer's liability insurance and the Health and Social care policy statement for patients and visitors to review.
 - The location had two Registered Managers at the time of inspection. On occasions when the registered manager was off site, the Regional Clinical Operations manager shared clinical responsibility and clinical oversight at the clinic. However, we were not assured that the manager had access to the personnel files of medical staff and assurance that all staff on duty were compliant with training. This was supported with our findings of the counsellor, who was not trained to safeguarding level 3 at the time of inspection.
 - We found no evidence of managers at a local level championing staff development. All staff were encouraged to complete mandatory training, but there was no formalised development plan to support staff to complete short courses to improve skill or competencies in different areas.
 - There were no regular team meetings; this meant there was no formal meeting where staff could highlight concerns.

Vision and strategy for services

- The local team followed the corporate Marie Stopes International strategy and vision; this was clearly defined as: "A world in which every birth is wanted".
- The vision was supported by their mission statement, which was: "Children by choice, not chance". The vision set out behaviours and values expected of staff working for the organisation and was displayed for patients and staff to read. Discussions with the local senior management team confirmed there was no local strategy as they followed the corporate MSI vision and strategy. This was because the local management team in Manchester were focusing on patient safety and quality, after the previous inspection highlighted areas of concerns in this area.
- Staff we asked were aware of the mission statement.

Termination of pregnancy

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

- The clinic had locally agreed standards in place, which were audited against performance. Commissioners were cited on quarterly reports; however, the management team recognised there was a lack of dialogue between the commissioner and the clinic. They advised this was something they will look at enhancing in the future.
- The internal corporate programme of audits was dictated by head office. MSI had specific audits to monitor processes and performance across all clinics. We reviewed dashboards that gave a colour coded risk rating to each data set. If the clinic had achieved internal targets, it was rated green, amber for “near to target” and red for underperforming. The dash boards were informative and easy to read. Staff were able to quickly extract data for their clinic and compare their performance against other clinics.
- The regional director was cited on all areas of non-compliance; these were logged on an audit master action plan, which allowed both local and corporate oversight. Any 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 been or was being taken to address the issues identified.
- The HSA1 form was completed, signed and dated by two registered medical practitioners before treatment took place. Clinicians recorded the reason for a patient’s decision for termination of pregnancy; they assessed each individual case against the criteria set out in the Abortion Act 1967. The HSA1 was completed by both practitioners certifying their opinion.
- We reviewed 10 patient notes; all held a completed and signed HSA1 form in line with professional guidelines and the Abortion Act 1967. All the records we reviewed had a certificate of opinion (HSA1), which was signed by two medical practitioners in line with regulatory requirements.
- At the time of inspection, we asked thirteen women prior to treatment and four women post treatment, if they had been informed about the statutory requirement of HSA4 forms. All of the women we spoke with were not informed and did not receive a discussion to explain to them that their details were sent to the Department of Health. This was raised with the senior management team at the time of inspection.
- Patient information was gathered directly from the electronic patient record system and automatically populated the HSA4 forms. Data on the HSA4 form was checked for completeness by staff before it was sent to the Department of Health. Staff told us a hard copy of the form was sent in a DOH envelope by post if the electronic system was not available.
- At the time of the inspection and the unannounced inspection, the registered manager was unable to show us hard copies or electronic personnel files that belonged to doctors who worked at the clinic. The registered manager did not have oversight at a local level of the doctor appraisals and training, as this was handled at provider level. There was no means of formal notification from provider level to suggest that revalidation was complete. This meant registered managers were not assured that surgeons working in their clinic were up to date with training. The registered manager at the time did not have access to these files. Information provided following the inspection indicated this data was stored on the MSUK intranet to enable all managers to check compliance when required.
- A governance framework supported staff to deliver good quality care through the identification and monitoring of risks. As part of the wider corporate organisation, the clinic had a clear governance and committee structure in place including clinical governance, medical advisory and health and safety committees.
- Committees were well represented with non-clinical and clinical attendance; this allowed for oversight of both clinical and operational review at a corporate level.
- The staff noticeboard in the kitchen displayed up to date information on policy, safeguarding, business objectives and information bulletins, such as whistleblowing policy and hand hygiene.
- All staff were clear about their roles and responsibilities and how they fitted within the clinic structure. However, discussions confirmed that they were not involved in decision making processes about the service.

Termination of pregnancy

- MSI had a disclosure of information (whistle-blower) policy. This was available on the staff intranet and set out the procedures to follow with internal disclosures and with disclosures to regulatory bodies.

We observed the surgeon and anaesthetist review the medical records and the surgeon provided the second HSA1 signature.

Public and staff engagement

- Feedback from patients was obtained in a number of ways; this was so they could improve patient care and experience.
- Patients were able to share their story and experience via the 'Share your story' campaign. Patients were also given a paper patient satisfaction questionnaire to complete after their treatment. There was a poster displayed in the waiting area and information on the website of how to do this. At the time of inspection, none of the patients we spoke with had been told about this facility.
- We reviewed the website and found that the experiences were generally positive in nature. Most patients wanted to share their experiences for the benefit of others.
- All patients were given feedback questionnaire prior to discharge; they were asked to complete the short survey at the clinic or later at home. They were anonymous, sealed, and sent to an external organisation for collation and reporting.
- We found no evidence of staff being praised at a local level, for example performance data showed that

activity in the clinic had increased, this meant that staff had improved the service they offered women. We did not see information that showed us staff had been thanked for their support. This was supported by discussions we had with staff at the time of inspection. Since the last inspection there had been no "away" days or staff activities arranged by the provider for staff to build relationships and support each other.

- A staff magazine was distributed across all clinics, 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.

Innovation, improvement and sustainability

- We saw changes to practice at the clinic but these were in the early stages of development and needed time to be embedded in practice. In addition there were changes to the management team, which was still ongoing so we were unable to assess the sustainability or full impact of the improvements.
- The Manchester clinic had recently appointed operations manager who was employed to look at the clinic's operational functions, for example to improve complaints handling, administration processes and overall quality. The clinic still had a clinical operational lead who was based across the North region to look at the clinical functions.
- The Manchester centre had seen continued success in uptake of STI testing and LARC uptake in comparison with other MSI Centres. Staff were keen to increase the uptake.

Outstanding practice and areas for improvement

Areas for improvement

Action the provider **MUST** take to improve

- The provider must ensure that the layout of the day room, where patients recover following surgical treatment, does not compromise patients' privacy and dignity.
- The provider must ensure all staff have received and are up to date with the training and competencies relevant to their role and ensure also that all staff receives regular appraisals.
- Ensure effective medicines management processes are in place and improve recording of controlled drugs to ensure stock levels and doses administered are recorded accurately
- The provider must ensure an effective process for complaints handling, sharing information and taking actions to identify areas for development to improve services.
- Ensure an effective appraisal process is embedded, involving full participation and discussion to enable staff development.
- Ensure improvements in corporate and location level communication and engagement to ensure an effective process for governance, quality and risk oversight of services at local level

Action the provider **SHOULD** take to improve

- The provider should ensure all notifiable incidents are reported to the CQC in a timely manner.
- The provider should ensure that staff at each location appropriately report and record incidents, risks and complaints.
- The provider should ensure that there is evidence of shared learning from incidents and complaints to ensure that lessons are learnt.
- The provider should ensure that all staff complete required mandatory training appropriate to their roles including basic life support and immediate life support training.
- The provider should ensure all patients are made aware of the requirements of HSA4 forms.
- The provider should consider what action can be taken to improve the uptake of LARC.
- The provider should ensure evidence of discussion in relation to disposal pregnancy remains is documented in records.
- The provider should ensure the registered manager has access to and is able monitor the hard copies or electronic personnel files that belong to doctors who work at the clinic under practicing and privilege rights.
- The provider should consider recording of the waiting times every month to monitor variability effectively

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

Termination of pregnancies

Regulation

Regulation 10 HSCA (RA) Regulations 2014 Dignity and respect

The layout of the day room where patients recovered following surgical treatment at times compromised patients' privacy and dignity.

Regulation 10 (1) (2)(a)

Regulated activity

Termination of pregnancies

Regulation

Regulation 12 HSCA (RA) Regulations 2014 Safe care and treatment

The clinic's counsellor was not trained to safeguarding level three.

There was a lack of local oversight for training for surgeons and anaesthetists attending the clinic.

Records showed some staff were not up to date with all competency training.

Records showed not all nursing and medical staff had received an appraisal in 2016.

Regulation 12(1)(2)(c)

Regulated activity

Termination of pregnancies

Regulation

Regulation 17 HSCA (RA) Regulations 2014 Good governance

There was insufficient day-to-day management oversight and insufficient assessment and monitoring of the quality and safety of the service.

This section is primarily information for the provider

Requirement notices

Regulation 17(1)(2)(a)(b)