

Marie Stopes International Maidstone Centre

Quality Report

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

Summary of findings

Letter from the Chief Inspector of Hospitals

The Care Quality Commission (CQC) carried out an announced comprehensive inspection at Marie Stopes Maidstone on 17 May 2016. This service was inspected as part of a wider programme to inspect providers of acute independent healthcare. Our role is to ensure that people receive safe, compassionate and high-quality care. Although we don't currently have the powers to rate these services, we report on whether they are safe, effective, caring, and responsive to people's needs and well led. We highlight areas of good practice and areas of improvement.

MSI Maidstone provides consultations, ultrasound scans, medical and surgical termination of pregnancy, and counselling and support for people who use the service. In addition, long acting reversible contraception and sexually transmitted infection testing and screening are offered.

The centre provides medical termination to nine weeks + four days and surgical termination of pregnancy to 14 weeks. Surgical termination is carried out under conscious sedation.

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.

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

Are services safe at this hospital?

There was an inconsistent approach to action planning and ensuring that lessons learnt from incidents were shared with all relevant staff locally. There was little local ownership of learning from incidents and no clinical oversight.

Staff did not have the appropriate level of safeguarding training to manage safeguarding issues. The policy was not in line with the most recent national guidance. Staff without appropriate safeguarding training were making decisions about the treatment of children attending the clinic. Data provided by the registered manager prior to the inspection showed that only two staff had completed level 3 child safeguarding. Policies did not reflect the most recent national guidance.

Staff did not carry out the five steps to safer surgery checklist, commonly known as the World Health Organisation (WHO) five steps to safer surgery checklist, consistently. Several stages of the checklist were not completed and there was no engagement in the process from the surgeon or anaesthetist.

Infection control systems, processes and practices were not delivered in line with the current national guidance. There was poor hand hygiene, poor use of personal protective equipment and poor pre-surgical preparation.

Staff highlighted long working hours as a frustration at times although they recognised the need for flexibility due to the demands of the job. Heavy workloads, crowded operating and clinic lists and a strict 15 minute consultation time meant best practice was not followed and there were lapses in infection prevention and control procedures and the taking of consent.

However, equipment including surgical equipment, resuscitation and anaesthetic equipment was available, fit for purpose and checked in line with professional guidance.

Are services effective at this hospital?

Whilst policies were accessible for staff and were developed in line with Department of Health Procedures for the approval of independent sector places for the termination of pregnancy services, they were not always updated to reflect practice changes in a timely manner and there was a lack of consultation and engagement of staff to support evidence based care practices.

Summary of findings

Staff were concerned that the registered manager was supporting other clinics and was consequently away much of the time. There was no clinical leader for the service and the arrangements for management support whilst the registered manager was absent were unclear and not known to staff.

We had concerns that consent for surgery and termination of pregnancy was obtained by staff who were not appropriately knowledgeable or trained to do so. The assessment of whether a child was competent to consent was completed using a basic checklist and staff were unable to describe what triggers would suggest a child lacked understanding. The individual patient records did not show that the other conditions for obtaining consent from a child, such as encouraging them to involve a parent, had been considered. Staff spoken to did not have a good understanding of the Fraser guidelines.

Are services caring at this hospital?

Services at MSI Maidstone were very process centric with staff showing limited empathy for how the patients might be feeling. Support from a partner, friend or parent was discouraged and accompanying supporters were asked to leave the premises whilst the patients were being treated.

Staff sometimes failed to consider patient's privacy and walked into the theatre whilst procedures were taking place.

There were complaints about staff being abrupt and blunt towards patients. However, there was good feedback from local surveys that showed individual staff were kind in their approach to individual patients.

Are services responsive at this hospital?

Services were planned and delivered in a way that met the needs of the population. The importance of flexibility, choice and continuity of care was reflected in the services provided both for private and NHS patients.

Patient flow through the centre was managed, although waiting areas could be very crowded at times.

Are services well led at this hospital?

Staff told us they did not feel valued by the organisation although they found the manager on site supportive and approachable. Corporate support was not recognised and staff felt they did not get a response if they tried to seek advice from regional managers.

Whilst Marie Stopes International provided the Maidstone centre with an Integrated Governance Framework in line with the NHS governance agenda and the CQC Essential Standards of Quality and Safety, there were gaps between the governance process at corporate and location level in communication and engagement which should be addressed to ensure evidence based care can be demonstrated at all times.

There was no robust system to ensure action plans were completed, reviewed and audited to improve patient safety and quality of care. We saw several examples of where concerns were identified by the infection prevention and control lead or nominated individual but which had not led to sustained improvement through robust action.

Effective risk management arrangements were not in place to make sure that the certificate(s) of opinion HSA1 were signed by two medical practitioners in line with the requirements of the Abortion Act 1967 and Abortion Regulations 1991.

Staff were able to talk to us about some areas they considered high risk but had not done anything to try and bring about changes. Staff voiced concerns about KPIs, workloads, staffing and management support, facilities and training but did not take ownership for bringing about the necessary improvements.

Staff were not fully aware of the rationale behind a recent practice change for simultaneous administration of the medicines used to effect a medical abortion. There was no evidence based information on site to show this practice was recognised, benchmarked or systems put in place for effective measurement of patient for outcomes.

Summary of findings

The culture was viewed as being top down and corporately led. We found that the staff felt there was little point in voicing concerns or suggesting improvements as they would not be acted upon.

Both patients and staff were encouraged to provide feedback on services provided. Staff contributions and performance were recognised corporately and celebrated which is good practice.

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

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

Importantly, the provider must:

- The provider must ensure that risks to patients are identified, assessed and monitored consistently throughout the treatment and recovery period, and that action plans in assessments and care plans are updated and contain enough detail to enable staff to reduce those risks effectively.
- The provider must take prompt action to address a number of significant concerns identified during the inspection in relation to safeguarding, incident recording and reporting, and the governance of the service.
- The provider must enable all staff to complete training that is necessary for them to fulfil their roles.
- The provider must ensure staffing levels and skills mixes reflect patient needs.
- The provider must ensure that consent is given and recorded in accordance with national guidance. This includes ensuring that the staff recording consent are able to discuss the individual patient's risks of the procedures and the full range of options available to them.
- The provider must display the Secretary of State's approval to carry out abortions.
- The provider must ensure that staff follow MSI Infection Prevention and Control Policies in regards to hand hygiene, staff dress code, decontamination of equipment and premises and preparation of the patient prior to surgery.
- The provider must ensure that staff adhere to MSI medicines management and national guidance on the safe management of medicines.
- The provider must ensure there is appropriate clinical leadership at the centre with clear lines of accountability.
- The provider must review the safe use of sedation medication and practice of individual doctors to reduce the risk of harm involving oversedation.
- The provider must ensure that the care pathways consider the specific needs of children and other emotionally vulnerable patients attending the clinic.
- Statutory Notifications must be submitted to the Commission as required by regulation.

Action the centre SHOULD take to improve;

- Staff should have regular appraisals to establish continual professional development requirements to ensure staff have the right skills to perform their job role.
- The provider should have specific written information in the waiting areas regarding key risks to patients such as domestic abuse, the risk of sexual exploitation, access to support groups and contact numbers if at risk.

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

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

Summary of findings

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

CQC has also undertaken enforcement action for breaches of the following regulations, which are relevant to this location. Regulation 11 Consent Regulation 12 Care and treatment must be provided in a safe way for service users. Regulation 13 Service users must be protected from abuse and improper treatment in accordance with this regulation. Regulation 17 Systems or processes must be established and operated effectively to ensure compliance with the requirements in this Part. (Good governance) Regulation 20 of the Care Quality Commission (Registration) Regulations 2009.

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

Professor Sir Mike Richards
Chief Inspector of Hospitals

Summary of findings

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MSI Maidstone Centre

Services we looked at

Termination of pregnancy

Summary of this inspection

Background to Marie Stopes International Maidstone Centre

Termination of pregnancy (TOP) refers to the treatment of termination of pregnancy, by surgical or medical methods. Marie Stopes UK International (MSI) Maidstone is part of the provider group Marie Stopes International, a not for profit organisation that was founded in 1976, to provide a safe, legal abortion service following the 1967 Abortion Act. MSI believes that everyone should have the right to choose whether and when to have children, no matter where they live. The organisation has expanded from one centre in London to a global network of more than 600 centres across 37 countries.

MSI Maidstone provides consultations, ultrasound scans, medical terminations to nine weeks plus 4 days, and surgical termination to 14 weeks gestation, and counselling and support for people who use the service, referred to as patients. In addition, vasectomy, performed under local anaesthetic, long acting reversible contraception and sexually transmitted infection testing and screening are offered. Surgical termination of pregnancy was carried out under conscious sedation.

The clinic holds a license from the Department of Health (DH) to undertake termination of pregnancy services in accordance with The Abortion Act 1967. Services are provided to both NHS and privately funded patients.

Patients of all ages, including children over 13 years of age are treated at the clinic.

Counselling services are offered to all patients before and after their treatment and are provided face to face or by telephone.

Appointment are made through MSI's One Call service, which is a registered pregnancy advisory service operating 24hrs a day to secure ease of access for patients to MSI services, or alternative services where needed (for example, where a patient would not be suitable for MSI services, they are signposted to an appropriate alternative provide, such as the NHS). The building is not purpose built but modified to provide consulting rooms and an operating theatre. Car parking was available in a nearby public car park.

There was a registered manager, Tammy Jeffrey, in day to day charge of the unit.

Our inspection team

Inspection Manager : Terri Salt, Care Quality Commission

Our inspection team of four included: two CQC inspectors who were also specialist advisors in midwifery and nursing, and a specialist advisor who was a consultant obstetrician and gynaecologist with a particular interest in foetal medicine.

Why we carried out this inspection

This inspection was carried out as part of our planned programme of comprehensive inspections of independent healthcare providers, including termination of pregnancy providers.

Summary of this inspection

How we carried out this inspection

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

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

We have not published a rating for this service as the CQC does not currently have a legal duty to award ratings for services that provide solely or mainly termination of pregnancy. Although we do not currently have the powers

to rate these services, we report on whether they are safe, effective, caring, responsive to people's needs and well-led. We have highlight areas of good practice and areas for improvement.

During our inspection we spoke with staff members including: the registered manager, doctors, registered nurses, health care support workers and administration staff. We looked at the care records of patients including for those aged less than 18 years. We observed interactions and communication with patients and their supporters; however this did not include male patients because there were no vasectomy consultations or procedures taking place. We reviewed performance data submitted by the centre before and after our inspection.

Information about Marie Stopes International Maidstone Centre

Marie Stopes International Maidstone was registered with the CQC in 2010. It provides medical and surgical termination of pregnancy, consultations, ultrasound scans, and counselling and support for people who use the service, referred to as patients. In addition, vasectomy performed under local anaesthetic, long acting reversible contraception. They also provide non registerable services such as well woman screening, well man screening and sexually transmitted infection testing and screening are offered.

MSI Maidstone carried out medical abortion up to nine weeks and four days of pregnancy and surgical abortion up to 14 weeks.

Of the services provided, medical abortion accounted for 2658 (48%) of activity, surgical abortion 2249 (46%). There were no abortions carried out after 14 weeks gestation.

The vasectomy service operates on two days a month. A total of 169 non scalpel vasectomies were performed in the reporting period. Counselling services are offered to all patients before and after their treatment and were provided face to face or by telephone.

What people who use the service say

On the whole, patients were positive about the service they received. There was limited feedback with low respondent rates for the local survey. This was thought by staff to be because the nature of the service meant patients were less willing to engage with the provider.

We did see comments about the staff being kind and supportive throughout the process and people mentioned that they found the theatre nurses reassuring.

People we spoke with were reasonably positive but disliked being kept waiting and lack of toilet facilities whilst waiting.

We also received three negative comments made directly to CQC via our website with all three patients complaining about the attitude of staff, the rushed service and the unpleasant surroundings. We had not received any positive comments made directly to CQC using our 'Share your knowledge' web forms.

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 do not currently have a legal duty to rate termination of pregnancy where these services are provided as an independent healthcare single speciality service.

The safeguarding arrangements at MSI Maidstone were not sufficient to protect patients, particularly children, from the risk of abuse. The MSI policies and processes did not reflect up to date national guidance on sexual exploitation of children and young people, or female genital mutilation.

Staff making decisions about whether a patient was at risk of abuse were not trained to the appropriate level. At the MSI Maidstone clinic there were only two staff trained to level 3 in child safeguarding. The child safeguarding policy for MSI did not meet the requirements of either “Working together to safeguard children (2015)” or the intercollegiate guidance, “Safeguarding Children and Young people: roles and competences for health care staff”. The MSI corporate policy document failed to identify clearly the points of contact where there were safeguarding concerns.

National guidelines for infection prevention and control and cleanliness were not fully adhered to. In particular, ‘The Health and Social Care Act 2008: Code of Practice on the prevention and control of infections and related guidance, 2015’. There were no detailed cleaning schedules or checklists in the theatre. Furniture and fittings were not always easy to clean, disinfect or maintain. Staff did not take adequate infection prevention and control (IPC) precautions with hand hygiene or correct use of protective personal equipment, for example the use of disposable aprons in surgery. We observed a surgeon wearing a large, stoned ring during surgery and not washing their hands between patients. Cleaning schedules and checklists did not meet national requirements. Incidents, including those with a potential to cause harm to patients or staff, were often not reported or acted upon. Staff did not receive prompt feedback from incidents to reduce the risk of recurrence.

The corporate policy of ensuring there was an appropriate adult escort post procedure was not followed at MSI Maidstone and placed patients at significant risk. The senior clinician at MSI Maidstone was unaware of the WHO Five Steps to Safer Surgery checklist and staff did not know the corporate policy on recognising and managing deteriorating patients.

Summary of this inspection

Medicines were safely ordered, supplied, and stored in accordance with manufacturers' instructions, and administered only when they had been prescribed for a named patient. However, there were incomplete systems in place to monitor the medicines stock.

There was inconsistent use of sedative medication such that staff had raised concerns about over sedation with Midazolam. Specific occurrences relating to oversedation were not acted upon or recorded as incidents; instead staff voicing concerns were removed from theatre work.

Nursing staffing levels were not adequate to ensure that patients were cared for by a registered nurse. Unsupervised healthcare assistants (HCAs) were used to supplement and replace trained nurses by completing pre-procedure assessments, scanning patients, taking consent, making decisions regarding safeguarding and providing post-operative care.

Staff reported a very target driven culture with a timed slot for each patient. All the registered nursing staff we spoke with felt patient care and safety were compromised by the need to, "Keep on top of the list".

Staff had received some mandatory training but there were significant shortcomings in the level and breadth of training provided. Safeguarding training was not provided at an appropriate level and not always understood by staff. Training in managing deteriorating patients was not provided to all staff. Infection prevention and control training was not completed by all staff.

Arrangements were in place to manage emergencies and transfer patients to another health care provider.

Records were securely stored, well maintained and usually completed with clear dates, times and designation of the person documenting.

Equipment safety and maintenance checks were carried out in accordance with local and national requirements.

Are services effective?

Care was mostly provided in line with national and statutory guidelines. Nurses offered women appropriate pain relief, prophylactic antibiotics and post-abortion contraceptives. Care for children was not delivered in accordance with intercollegiate guidance, 'Standards for Children's Surgery' (2013) or the Royal College of Anaesthetist standards for the use of conscious sedation of children.

Staff were not always clear about their roles and responsibilities regarding the Mental Capacity Act (2005) (MCA) and Deprivation of

Summary of this inspection

Liberty Safeguards (DoLS). They could identified the need to act in the person's best interest, seeking advice and making joint decisions with others when there were concerns about a person's capacity to understand but were less clear when this might apply.

Consent from adult patients was obtained in line with national best practice guidance and staff followed their corporate policy when obtaining consent from adult patients. This was not the case for obtaining consent for the treatment of children when national guidance was not followed. The ability of a healthcare professional to accept consent from a child was utilised but the wider guidance relating to encouraging parental involvement and ensuring the child was able to understand the risks was not taken into consideration. Consent was routinely accepted from children without proper assessment of their ability to understand the risks.

The organisation performed some audits recommended by The Royal College of Obstetricians and Gynaecology (RCOG) such as infection control, consent to treatment, discussions about options for abortion and contraception, confirmation of gestation and medical assessments audits. However, there was limited evidence that the programme of audits had led to improvements in the safe delivery of the service.

The two certifying doctors had not usually seen the patient prior to a termination. Doctors relied on the health care assistant (HCA) or nurse's summary of the facts of the patient's case, and the grounds on which she was seeking an abortion to make a decision.

The provider participated in the Under 25's screening programme. Young people were encouraged to access testing for Chlamydia and advice on other sexually transmitted diseases.

Information provided by MSI Maidstone showed that 100% of medical, nursing staff and administrative staff had completed an appraisal as of December 2015.

A telephone advice line for patients was available 24 hours a day.

The centre adhered to the RCOG guidelines for the treatment of patients with specific conditions, such as ectopic pregnancy.

Policies were accessible for staff however there was no effective process to ensure that they had been updated in accordance with professional guidance.

Are services caring?

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

Summary of this inspection

Staff spoke about their commitment to providing good care and said the patients were the reason they did the job but this was not always translated into practice. Individual staff were kind and gentle with individual patients but staff failed to understand their more complex emotional needs.

Time pressure and a very inflexible pathway led to patients being rushed and staff failing to see where their needs were not being met.

Staff sometimes failed to consider the need for privacy and walked into the theatre whilst procedures were taking place.

Partners, parents and other supporters were seen as an inconvenience and their presence was discouraged.

There was good feedback from local surveys that showed individual staff were kind in their approach to individual patients. However, there were also a few complaints about staff being abrupt and blunt towards patients.

Are services responsive?

- The needs of children having treatment were not considered either corporately or locally. There was no differentiation of pathways and parental involvement was discouraged. This is contrary to the guidance from the royal colleges.
- Facilities whilst waiting were poor and partners, parents or other supporters were expected to leave the premises whilst the patient was receiving treatment. There were no lavatories for male visitors to the premises.
- A professional interpreter service was available to enable staff to communicate with patients for whom English was not their first language, although this was not permitted in theatre. There were also translation facilities on the MSI website where leaflets could be downloaded in 20 languages
- routine local practice on the disposal of pregnancy remains was not consistent with the corporate policy.
- Staff told us that discussions around disposal of pregnancy remains took place when requested by the patient. Information was provided to women on their options and they could choose to discuss their options with staff. Though staff respected the reality that not all women wished to discuss this.
- Patients could book appointments through the MSI UK telephone booking service, One Call, which was open 24 hours a day throughout the year. This provided patients with prompt access to appointments. It also enabled patients to choose the location they attended.
- There was a fast track appointment system for patients with a higher gestational age or complex needs.

Summary of this inspection

- There was a clearly defined specialist referral process for patients who had additional medical needs making them unsuitable for treatment at the centre.
- The service monitored its performance against the waiting time guidelines set by the Department of Health (DH). Between January 2015 and December 2015, all patients had their treatment within seven working days from decision to proceed to termination of pregnancy, which is within the DH recommendations.
- Support was available for patients with a learning disability or other complex needs.
- Complaints were managed centrally in accordance with MSI policies but there was little local learning from complaints.

Are services well-led?

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

We found:

- There was poor leadership of the service with a manager who was frequently absent and who had no clinical leadership support.
- Corporate support was not recognised and staff felt they did not get a response if they tried to seek advice from regional managers. Staff told us they did not feel valued by the organisation although they found the manager on site supportive and approachable.
- The organisational culture was not open and transparent. We heard staff being highly critical of each other in conversations, complaints about unequal voices and preferential treatment.
- The Key Performance Indicators (KPIs) and time constraints worked against staff providing high quality person centred care.
- Poor practice was accepted and continued, even where staff had voiced safety concerns.
- Governance arrangements were insufficiently robust with poor oversight of clinical practice.
- Doctors were bulk signing HSA1 forms and did not have sufficient time to review the individual circumstances of patients.
- The Department of Health Licence authorising the provider to carry out abortions on the premises was not displayed.

Detailed findings from this inspection

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's provided as a core service by an independent hospital.

Incidents and safety monitoring

- The MSI Serious Incident Management Policy set out the procedure for reporting and responding to incidents, categorising them and the investigative process.
- There were 147 incidents reported between April 2015 and April 2016.
- There were no Never Events reported. Never Events are serious incidents that are wholly preventable as guidance or safety recommendations that provide strong systemic protective barriers are available at a national level and should have been implemented by all healthcare providers. We asked staff (including the clinical lead) how they learned from incidents, near misses and never events. They were not familiar with the term "Never event" but indicated learning about safety incidents took place through staff meetings, verbal handovers and email communications. Some staff said that staff meetings had only really happened since the CQC inspection was announced.
- Staff told us that not all incidents were reported or recorded on an incident log, for example failed abortions. Managers and staff acknowledged there was under reporting of incidents.
- Team members who are involved in or carry out part of the investigation process were required to document

evidence of their attendance at root cause analysis (RCA) training. Managers advised us that they had not completed any RCA training but there were low numbers of such investigations.

- There was no clinical oversight of incident reporting and investigations at local level.
- Serious incidents (SIs) were reported and investigated centrally, rather than at clinic level. This meant that there potentially no timely escalation of incidents which would delay the cascade of learning and any actions that may be required to be taken.
- Staff showed us how they completed a paper record for incidents. This was then sent to the centre manager, who uploaded the information to the electronic incident database held centrally at head office.
- We noted the incident form provided staff sections covering date, time and location and by type. Staff were required to describe the incident and any immediate actions taken.
- We saw minutes of recent team meetings and could not see that this forum was used to share learning about incidents.
- Staff reported hearing about things through, "gossip" rather than through formal channels.
- Staff could not describe any learning or changes to practice as a result of an incident that had occurred, either locally or from other centres.

Duty of Candour

- The duty of candour is a regulatory duty that relates to openness and transparency and requires providers of health and social care services to notify patients (or other relevant persons) of certain 'notifiable safety incidents' and provide reasonable support to that person.
- The registered manager told us there had been discussion about the duty of candour at team meetings: Records seen confirmed this had been discussed.

Termination of pregnancy

- Nursing staff were not aware when asked what the duty of candour was, despite the registered manager indicating they would have awareness. There was a degree of understanding about being open and honest when an error occurred, but nursing staff were not aware of the finer details, such as formally apologising in writing. Staff could not provide us with any examples of when candour had been applied or confirm any training in this area.

Mandatory training.

- Staff told us they were required to complete mandatory safety training in a range of subjects. This included manual handling, safeguarding, infection prevention and control, health and safety, fire, information governance and basic or intermediate life support.
- Mandatory training was provided face to face and online. Staff told us they were unable to undertake the online training because of time constraints. However staff training records we saw indicated the majority of safety subjects had been completed by 100% of staff. The organisational target for mandatory training was 100%.
- The registered manager told us the unit closed four times per year and on such days staff were expected to complete mandatory training, such as basic and intermediate life support. However, staff we spoke with told us that, "The closure days did not always happen." They could not recall when the last closure day had occurred.
- Staff had no training in meeting the needs of children undergoing surgery.
- Staff had not had any training in caring for patients during the perioperative period, including training in the management of difficult airways for theatre staff.
- The intercollegiate guidance, "Safeguarding children and young people: roles and competences for health care staff" (2015) gives clear guidance that staff working in clinical roles where they see children should be trained to level 3 in child safeguarding.
- The MSI Corporate training strategy referenced this document but only required clinical staff to be trained at child safeguarding level two and non-clinical staff to be trained to level one.
- There were only two staff at MSI Maidstone trained to level 3 in child safeguarding. One of these was the safeguarding lead and registered manager who did not provide direct patient care. This meant staff without the appropriate level of safeguarding training were making decisions about the level of risk to children and whether or not to make referrals.
- One HCA told us that they had completed online level 1 and level 2 child safeguarding training and additional training about Female Genital Mutilation. They last had face to face training about five years previously. Their understanding was limited; they could talk about some of the triggers on the pro-forma used at MSI but nothing outside of this.
- One of the registered nurses told us they had not yet completed any safeguarding training through MSI but felt their training from a previous job still counted. They were unable to describe potential indicators of abuse.
- Another registered nurse said that they had completed level 2 child safeguarding training three years previously but hadn't been offered a certificate. This nurse described a recent situation that they felt, "Wasn't actually a safeguarding issue but was FGM". FGM is female genital mutilation and is potentially a serious safeguarding concern.
- All patients were either seen in a one to one consultation with a nurse or healthcare assistant or had a telephone consultation. Staff told us they did not routinely take the opportunity to ask women about domestic abuse in line with NICE guidelines. This guidance is for everyone working in health and social care whose work brings them into contact with people who experience domestic violence and abuse.
- The MSI policies and processes did not reflect up to date national guidance on sexual exploitation of children and young people, or female genital mutilation.

Safeguarding

- The registered manager was the designated member of staff (safeguarding lead) responsible for acting upon adult or child safeguarding concerns locally and for ensuring staff were adequately trained on issues relating to safeguarding.
- A corporate Safeguarding Forum report dated 21 January 2015 showed that safeguarding leads for individual clinics did not attend this meeting.

Termination of pregnancy

- The centres did not treat any young person under the age of 13 in line with their organisational policy. Children under the age of 13 would be referred to the NHS.
- Between January 2015 and December 2015 the centre had treated 54 young people who were aged between 13 and 16 years old.
- Staff told us it was the organisational policy that if a girl under 13 years of age used the service then a safeguarding referral would automatically be made in line with national guidance. We saw that for those aged 13 to 16 years, a very basic safeguarding checklist was completed.
- In the period January – April 2016, across all MSI clinics, 230 children less than 16 years of age were seen but no safeguarding referrals were made. Thirteen children under 16 years of age were treated at the Maidstone clinic.
- The Safeguarding Adults at Risk policy was updated in April 2016 and included sections on forced marriage, FGM and domestic abuse.
- **Cleanliness, infection control and hygiene**
- Staff we spoke with were able to access a range of infection prevention and control (IPC) policies to guide their practice. However, staff could not recall any recent training to support the policies.
- There were no alcohol hand gel dispensers at the entrance to the theatre. We did not see any evidence that hand gel was used by staff entering the theatre. There was hand gel in the recovery area.
- There was no permanent hand washing sink in the recovery area, however; a portable handwashing unit was in place to mitigate any associated risks.
- Staff were not consistently following good IPC practice in line with national and local standards and policies. We brought this to the attention of the registered manager at the end of the inspection.
- We saw one nurse who was not bare below the elbow, which is best practice to allow for effective hand washing.
- We also noted that the sink in the theatre was not used by any member of staff throughout the entire list of 21 patients. We saw a surgeon wore sterile gloves but kept their large, stoned costume rings on when undertaking surgical procedures. This surgeon did not wash their hands or use alcohol gel between patients and failed to follow good hand hygiene practice. Other theatre staff changed their gloves but did not wash their hands or use hand gel between patients.
- We saw staff were carrying out good hand hygiene in the consulting rooms and recovery area.
- Nursing staff in the theatre followed recommended dress code practices, as outlined by The Association for Perioperative Practice. Staff wore theatre attire, also known as ‘scrubs’ which is the sanitary clothing worn by staff where clothing may come into contact with infectious agents, and theatre clogs. Personal protective equipment (PPE) was provided to reduce the risk of cross contamination.
- The surgeon did not wear an apron to protect their theatre clothing from potential contamination and to reduce the risk of cross contamination during surgical procedures.
- We observed that poor practice in the theatre meant that the sterile gloves were contaminated by being removed from the outer wrapper with unwashed hands. The contaminated gloves were dropped by the surgeon from unwashed hands onto the trolley, which contaminated the sterile field.
- We observed poor practice in pre-operative preparation of the genitalia. This posed a risk of introducing an infection.
- Minutes of the corporate Infection Prevention and Control Committee dated 21st October 2015 showed that there was a concern about staff wearing their own clothes in the theatre. There was no evidence that any action had been taken in respect of this.
- An infection prevention and control (IPC) strategy was in place for 2014/16 and was displayed on a staff noticeboard. This set out the roles and responsibilities for all staff, arrangements for the IPC committee, and monitoring of the strategy and reporting to the board.
- In accordance with national requirements, a director of infection prevention and control (DIPC), based at MSI head office was responsible for leading the organisation’s infection prevention team. The DIPC was part of the organisation’s clinical governance and patient safety teams and structures.
- An infection prevention and control link nurse was appointed at the centre in 2015 to promote good infection control practice in their work area with colleagues, patients and relatives. They were responsible for undertaking infection control audits

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where required within their work area, for disseminating new infection control information to colleagues, and to act as a role model. However they had not completed any training for this role and had not participated in any infection control committee meetings or forums. They were also not able to provide examples of any information shared with colleagues, other than results of the audits they had undertaken on a quarterly basis.

- The most recent audit was reported in April 2016. The audit failed to identify areas of poor practice.
- All of the areas we inspected were visibly clean. Staff confirmed that cleaning was carried out by clinical staff and an external cleaning company.
- Within opening times nursing staff would clean equipment and the environment with approved cleaning materials and mop up any spillages, using a spillage kit for that purpose. Staff knew where to locate the spillage kit and correctly described the procedure for managing spillages in accordance with local policy.
- Staff we spoke with said that the 15 minutes allotted to each consultation was insufficient to allow proper cleaning of the room and equipment, which they did whilst the patient was still signing consent forms.
- We observed that in the theatre, a member of staff used a single antiseptic wipe to clean all equipment, the couch and the floor between patients.
- The reclining chairs in the recovery area had a fabric cover that prevented adequate cleaning between patients.
- We asked to see the cleaning schedules and checklists used to monitor cleaning and were told these were not available as they remained under development. This meant that staff were not able to confirm when cleaning last took place.
- There was appropriate segregation of clean and dirty waste, and safe disposal of clinical waste including sharp objects. An external contract was set up for the collection of all clinical waste, and staff reported they were satisfied with the service.
- There were separate areas for storing and dealing with clean and dirty surgical items. However, there was no direct access from the theatre to the room containing the locked specimen freezer used to store pregnancy remains, which was on another floor within the centre. Staff had to carry an unsealed bucket of pregnancy

remains through a patient waiting area, upstairs to a records cupboard where the fridge was sited. This was poor infection prevention and control practice as well as potentially being offensive to patients waiting.

Environment and equipment

- Health and safety checks, such as fire certification and waste management audits were completed with no outstanding actions.
- All electrical items were tested for electrical safety to the requirements of the electricity at work regulations.
- Staff took responsibility for checking equipment and we saw records that demonstrated checking processes had taken place regularly.
- There was access to emergency equipment, including a resuscitation kit bag, and oxygen and suction. Medicines to be used in emergencies, including the management of anaphylaxis, were easily accessible. However, we noticed a discrepancy between the list and the stock of two medicines provided and brought this to the immediate attention of the manager, who told us corrective action would be taken.
- The registered manager told us there was a service level agreement with an external provider for the cleaning of sterile surgical equipment.
- The service had access to an on-site maintenance person, who was responsible for portable appliance testing, fire safety checks and technical equipment. In addition there were external arrangements for legionella water testing and fire certification. These were all up to date with no outstanding actions.

Medicine Management

- We were told that medicines used in the treatment of abortion (abortifacient medicines) were only prescribed and administered once the legal requirements for obtaining the opinions of two doctors that the abortion could go ahead were met. Medicines were either prescribed by an on-site doctor, or prescribed remotely by a doctor at other premises.
- Abortifacient medicines were administered following the certification of two doctors for the legal grounds for abortion. They were either administered over a two day period, where patients returned to a treatment centre the following day, or both the medicines could be administered within six hours of each other. Staff were heard to provide women with a choice and indicate the success rate with both methods.

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- Medicines were obtained via the MSI central procurement arrangements. A designated staff member was responsible for stock checks and for ordering top up supplies. However, there were no local stock controls in evidence. Staff told us there were more formal arrangements in place in the past but that these were no longer used. This meant stock may run out or be diverted without being noticed.
- A corporate service level agreement, dated 4 April 2016, was in use for the supply of prescription-only medicines, with appropriate dispensing labels.
- We saw medicines safety alerts were sent to all centres by MSI central office, received, and acted upon. Staff we spoke with were able to locate these and understood the significance of acting upon them.
- There was no local pharmacist input into monitoring medicines optimisation or audit processes. We were told a pharmacist would be appointed in the near future. Staff could not recall seeking pharmacist advice or completing any medicines management training.
- Medicines were stored safely within locked secured cupboards. Keys to these cupboards were only accessible via a secure coded storage container, attached to an internal wall. However, we also saw three ampoules of medicines were not stored in their original packaging in a cupboard in the theatre and brought this to the attention of the registered manager.
- The minimum and maximum temperature of fridges were monitored and recorded to ensure that medicines were kept at the required temperature. We reviewed the records for fridge temperature monitoring and saw that these were complete and that the temperatures were all consistently within the required range.
- Staff told us medicines were usually drawn up in advance for surgical treatments which is contrary to good medicines management practice.
- Conscious sedation is defined as, 'a technique in which the use of a drug or drugs produces a state of depression of the central nervous system enabling treatment to be carried out, but during which verbal contact with the patient is maintained throughout the period of sedation. The drugs and techniques used should carry a margin of safety wide enough to render loss of consciousness unlikely'. Staff were concerned that some patients are over sedated and anaesthetists are not using an appropriate dose of sedation.
- Nursing staff reported to us that they had tried to discuss two recent cases of oversedation with the

anaesthetist but they wouldn't listen. They felt there was inadequate support to address concerns about anaesthetists not following the corporate sedation policy and no senior back up in case of an emergency.

Records

- Patient records were paper and electronic and only accessed by relevant staff.
- Guidance on the disposal of pregnancy remains indicates the inclusion of a clearly recorded entry in the woman's medical notes that she has been given appropriate information about the options for disposal and what, if any, decision she has made. It should also be recorded if a woman declines the offer of information and chooses not to make a decision.
- Of the 15 sets of records we reviewed on site, none contained documented evidence of discussion about pregnancy remains disposal. However, staff told us that these discussions only occurred when patients raised this issue.
- All the records we looked at were well maintained and completed with legible dates, times and signature of the person completing the record.

Assessing and responding to patient risk

- A pre-existing conditions list formed part of the risk assessment for suitability for medical or surgical termination. Staff were alerted to specific risks, such as clotting disorders, severe unstable asthma and cardiac disease. In such cases the individual would be referred to the NHS. Staff could not recall any recent referrals of this nature.
- Patients were not routinely seen by the surgeon or anaesthetist pre-operatively, unless a specific request was made to do so by the nurse. Instead, patients having surgical termination of pregnancy were initially assessed by telephone.
- Prior to surgery there was a further assessment of their medical and obstetric history, measurement of temperature and blood pressure. An ultrasound scan confirming pregnancy dates and viability and number of gestations was carried out in all cases by either an HCA or a registered nurse.
- Relevant laboratory testing was also carried out where appropriate, for example haemoglobin levels. Testing for Rhesus factor and also for sexually transmitted infections was carried out and acted upon.

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- We spoke with one registered nurse in the theatre who had not heard of the WHO five steps to safer surgery checklist and was unclear about MSI policy around this.
- We observed and heard the completion of a modified pre-operative check list with the patient in the waiting area, prior to surgery. This was completed by the non-clinical co-ordinator and then again by the nurse in the theatre. Checks included when the patient last ate and drank, any allergies, the completion of a consent form and the type of anaesthetic consented for. The surgeon and anaesthetist were not involved in the checking of patients.
- There was no team brief or de-brief at either the start or the end of the operating list to discuss safety concerns in a timely manner. These should be part of the process for completion of the WHO five steps to safer surgery checklist.
- Staff told us the five steps to safer surgery checklist was not used for any patients undergoing vasectomy but we were unable to observe this during the inspection.
- Patients who had a surgical procedure were monitored in the immediate post-operative period by nursing staff to assess their recovery and fitness for discharge. All patients were able to be observed by the nurse from a central communication base (nurses' station).
- We asked staff if there was a formal process used to monitor for signs of deterioration in patients who had surgery. We were told that the recovery staff monitored and recorded the patient's vital signs. Staff increased the frequency of observations of individuals where a change was noted. Nursing staff were unclear about whether or not they used a Modified Early Warning Scoring tool (MEWS) to identify patients at risk of a sudden deterioration in their condition. One staff member said they were around but only used if a patient became ill, and as patients were never ill, they never used them.
- A registered nurse in the theatre said they took two sets of observations, one when the patient came from the theatre to the recovery area and another when they were discharged back to reception. These were usually done by a healthcare assistant. This nurse was not aware of the use of MEWS charts and could not describe the MSI policy on deteriorating patients.
- Post-operative observations were recorded on the electronic patient record system. If staff were concerned about a patient, they would request a medical review.
- A formal arrangement was established for transferring deteriorating patients to a local hospital. There was a clear referral pathway to follow. Staff contacted patients to follow up on the outcome.
- We were told antibiotics were given to prevent uterine infection and chlamydia. Patient records seen confirmed this happened routinely.
- Patients attending the service were encouraged to have screening for chlamydia as part of their treatment, but had the choice to decline this. Where such screening took place, negative results were sent by text message. Positive results were managed by phoning the person directly. They were asked at this point if they had taken the preventive antibiotics and advised that their partner would need to be screened and treated before they resumed sexual activity.
- The service reported 100% for risk assessment of women who attended for a surgical abortion with respect to venous thromboembolism, (VTE) which is the term given to blood clots. This was in accordance with national guidance.
- A HCA we spoke with thought there was a grab bag for anaphylaxis, used when people have an allergic reaction to a drug, but was not sure. Other staff were also uncertain as to whether the anaphylaxis kit mentioned in the team meeting minutes of 12 May 2016 had arrived in time for the inspection.
- Staff had not had training in managing anaphylactic reactions.
- Patients could travel home after surgical treatment with conscious sedation without a responsible adult to accompany them. We were told by several nursing staff that this included children travelling by public transport on long journeys.
- The corporate policy on surgical terminations under conscious sedation required staff to ensure that a responsible adult accompanied patients home. This policy was not being followed in practice. Direct observation showed that staff discharging patients did not check whether they had an accompanying adult. Patient records did not show whether patients were accompanied post procedure. Staff we spoke with confirmed that they were not adhering to this policy.
- The Medical Royal Colleges' publication "Safe Sedation Practice for Healthcare Procedures Standards and

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Guidance” (2013) state “Patients meeting discharge criteria following sedation who go on to be discharged home should be discharged into the care of a suitable third party”.

- Staff were concerned about this practice and one said they worried about young girls getting buses and trains without anyone with them for journeys of up to two hours. Another said, “It’s their choice we can’t make them have someone.” We were told that nursing staff discharging patients from the theatre to the reception area to go home would not know whether they had someone with them or not.
- There were no set discharge criteria for patients post surgery in use at MSI Maidstone.

Nursing staffing

- A corporate representative told us that MSI operated a centralised rota function in London which enabled the organisation to centrally plan resourcing to ensure they constantly had clinical management in each site. They told us all clinics had a clinical team leader in post and an additional clinical team leader in development post to provide an additional layer of clinical support.
- There was a clinical team leader in development but not a clinical team leader at the Maidstone clinic. The clinical team leader in development did not provide clinical support or leadership to the team. The provider supplied an organisational chart that showed this nurse as the clinical lead for the centre but this was not borne out in practice. Nurses had to contact the centre manager at MSI London with clinical issues. However, we were told by several nurses that they rarely got a reply.
- There was one HCA and two registered nurses on duty on the day of our inspection. The HCA admitted and assessed surgical patients and nurses ran two early medical abortion (EMA) lists.
- There were four registered nurses employed by the service (three whole time equivalents) and no vacancies at the time of our inspection. There was no agency nursing staff used in the last three months
- Staffing arrangements for clinical services were based on activity, with flexibility in the workforce to rotate staff into consultation or the theatre.

- Working hours for nurses were 8:00am to 4:00pm, with some staff starting at 7.30am and finishing at 3.30pm or 8.30am until 4.30pm, depending on service needs. Nursing staff confirmed they stayed later pending patients’ fitness for discharge.
- Staff reported heavy workloads and unreasonable expectations of seeing each patient in an allotted 15 minute time slot. We were told that this compromised their ability to give personalised care and respond to the needs of the patients. We were told by all the nursing staff that we spoke with that in these 15 minutes the staff member needed to perform an ultrasound scan, offer STI testing, discuss the options available and obtain consent as well as clean the room between patients.
- Nursing staff were supported by four administrative staff (2.6 whole time equivalents).
- There was no senior children’s nurse corporately from whom staff could seek advice about the care of children.

Medical staffing

- Appropriate medical practitioners were available for surgical treatment including a surgeon and an anaesthetist.
- Doctors were engaged under practising privileges. Practising privileges means doctors are authorised to provide a service as an independent practitioner, not directly employed by the service.
- There were no vacancies for medical staff and no agency staff had been used in the last three months.
- We were informed that suitable checks were carried out centrally to enable medical staff to practice at the treatment unit: for example professional registration, qualifications, insurance, disclosure and barring and revalidation.

Major Incident awareness and training

- The centre’s major incident and business continuity plans provided guidance on actions to be taken in the event of a major incident or emergency. Emergency plans and evacuation procedures were in place. Staff we spoke with were aware of how to respond to major incidents, however; they could not recall a situation when this was required, or any specific training provided.

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Are termination of pregnancy services effective?

Evidence-based treatment

- Policies were accessible for staff. However they were not always updated in line with national professional guidance.
- MSI Maidstone offered surgical abortion up to 14 weeks gestation of pregnancy and medical abortion up to 9 weeks and 4 days gestation of pregnancy. All patients underwent an ultrasound scan at the treatment centre to determine gestation of the pregnancy. This was in line with the MSI guidelines for all abortions.
- Choice was offered in line with RCOG Evidence-based Clinical Guideline Number 7: The Care of Clients Requesting Induced Abortion. Patients could choose to have early medical abortion (EMA), medical abortion or surgical treatment under conscious sedation.
- Mifepristone and misoprostol are the medicines used to bring about abortion. Mifepristone is a drug that blocks a hormone called progesterone that is needed for pregnancy to continue. Mifepristone, when used together with another medicine called misoprostol, is used to end an early pregnancy. Misoprostol causes contractions of the womb. As a consequence, the womb expels the pregnancy.
- Misoprostol tablets are licensed in the UK to treat ulcers of the stomach and gut (small intestine) and to prevent ulcers associated with taking certain anti-inflammatory pain medication in adults. Misoprostol does not have a UK licence to induce abortion, so its use in this way is described as 'off-label'. The use of 'off label medicines' must be fully explained to patients before they take them.
- We saw that patients were provided with information about this and that they consented to taking the medicine:
 - Six hour interval - where the patients had a six hour gap period between administration of the stage one and stage two medicines.
 - 24 to 48 hour interval where the patients had a longer gap period between administration of the stage one and stage two medicines.
- The six hour method of inducing abortion is not compliant with RCOG recommendations in 2015. These state 'Medical abortion at or below 63 days gestation'

which recommends 24 – 48 hours between the administration of the medicines used to bring about abortion. This treatment is also not compliant with RSOP10: Professional Guidelines which requires providers to have regard to relevant and professional guidance. The provider was unable to supply the CQC with any mitigating evidence as to the effectiveness of this practice.

- Ultrasound was used in surgical procedures to reduce the risk of surgical complications, such as perforation of the uterus, in accordance with RCOG guidance.
- Cervical preparation to reduce the risk of damage to the cervix was only offered to children less than 16 years of age and over 12 weeks of pregnancy. The national guidance from the RCOG is that cervical preparation should be considered on a case by case basis; there was no evidence that this was happening.
- The centre adhered to the RCOG guidelines for the treatment of patients with specific conditions, such as ectopic pregnancy.
- RCOG guideline No. 7 and RSOP 13 recommends that screening for sexually transmitted infections (STI) should be made available. All patients, who gave consent, were tested for sexually transmitted infections, including chlamydia, HIV, gonorrhoea and syphilis. Patients with positive test results were treated or referred to other sexual health services.
- Patients undergoing medical abortion were asked to ensure that a pregnancy test was completed after four weeks to ensure that the procedure had been successful. Patients were advised that they could telephone One Call and were invited to attend a centre if they had any concerns.
- All patients were treated with prophylactic antibiotics to prevent infection in accordance with national and local guidelines.

Nutrition and hydration

- The centre did not proceed with surgical treatment if the patient had a drink within six hours of treatment. This is not in accordance with national guidance on fasting prior to operative procedures under sedation or anaesthetic which suggests patients may have clear fluids up to two hours prior to the procedure. The MSI corporate policy was to allow surgery to proceed where the patient had no solid food for at least six hours and clear fluids up to two hours pre-operatively.

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Pain relief

- Pre and post procedural pain relief was prescribed by registered medical practitioners and its administration was recorded on patients' records. Patients undergoing medical abortion were given advice on the use of painkillers and the appropriate dosage, should they require it during their stay and after leaving the centre. If the patient was nauseous further medication was provided to resolve this.
- Best practice was followed as non-steroidal anti-inflammatory drugs (NSAIDs) were usually prescribed. These are recognized as being effective for the pain experienced during the termination of pregnancy.
- Staff we spoke with were clear about which medication would be offered and in which order. For example for a medical abortion procedure NSAIDs would be administered first, if this was not effective paracetamol would then be offered.
- The post-surgical information provided to patients included space to record when their pain relief was next due, this ensured that patients would be informed about the correct time interval between taking the medication.

Patient outcomes

- The service treated patients for abortion only where pregnancy was confirmed by ultrasound scan to be 14 weeks gestation and under. Medical abortion was offered up to nine weeks and four days gestation of pregnancy and surgical abortion was offered up to 14 weeks gestation of pregnancy.
- Between January 2015 and December 2015 MSI Maidstone carried out 2249 surgical abortions, 2658 medical abortions, and 169 vasectomies.
- There were 64 or 2.4% of treatments that resulted in failed medical abortions recorded between April 2015 and March 2016. Patients could choose to have further medical treatment or have surgery: 12 patients had surgical treatment.
- There were 15 failed surgical abortions recorded between April 2015 and March 2016 that resulted in continuing pregnancy.
- The organisation set key performance indicators (KPIs) for the centre and individual staff. These were

- monitored and reported upon as part of an ongoing audit plan and performance review (appraisal) and any variance from the norm was discussed with individual staff.
- Staff expressed concern that they were assessed and bonuses were paid based on performance against Key Performance Indicators (KPIs) for patients leaving the centre with long acting reversible contraception and "Did not proceed". Staff felt that this corporate focus on achieving KPIs worked against the concept of patient choice.
- The team meeting minutes dated 14 April showed that staff had raised concerns with the manager about the KPIs and the pressure this put staff under to rush consultations.
- Minutes dated 15 July 2015 recorded a company wide focus on 'Do not proceeds'. Where a patient of less than 5 weeks and three days gestation had decided not to go ahead with the termination they were being called and offered a later appointment.
- Key performance indicators (KPIs) at the centre between January and April 2016 that met targets were: 100% of HAS1 forms were correctly completed and 100% of patients were screened for sexually transmitted infection. Outcomes that did not meet the KPI targets were: lower than expected rates (39% compared to target of 55%) of people leaving the centre with LARC, and lower than expected rates of patient who did not proceed with treatment (96% compared to target of 98-100%).
- Patients undergoing medical abortion were asked to ensure that a pregnancy test was completed four weeks after they passed the products of conception to ensure that the procedure had been successful. Follow up was undertaken through a method agreed with the patients. This was usually by telephone and women were invited back to the centre if there were any concerns.
- Patients who had undergone a surgical procedure were offered a follow up appointment, however; nursing staff told us that women did not tend to routinely take up this option.
- The centre manager told us that in order to monitor outcomes they relied on other staff reporting back to them or patients contacting One Call telephone service. If the clinic was informed that there had been a complication an incident form would be completed and it would be documented in patients' notes to ensure that the information was captured. This was monitored

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by the quality leads and cascaded through the two staff meetings. There had been 80 reported cases in the last 12 months; there was no evidence of a trend that needed to be investigated further.

- In common with all centres providing termination of pregnancy, the Maidstone centre would not be aware of all complications and incidents that occurred once the patient had left the centre.

Competent staff

- All staff had a job description issued by the central office which set out their function, responsibilities and expected behaviours.
- Nurses and health care assistants (HCAs) undertook the same roles with the exception that HCAs could not administer medicines. There was no oversight of the clinical performance of the healthcare assistants.
- Staff were not supported through a formal induction process; instead they 'shadowed' another member of staff for six weeks. This was contrary to the corporate policy that there should be a formal induction with a competency based assessment as part of the process and allowed for poor practice to spread.
- An online module was available for training on the Abortion Act 1967 but some longer serving staff had not completed it.
- External scanning training was provided which staff reported as very useful. Scanning was carried out by HCAs and registered nurses.
- Staff reported contraception training was not available. A course for insertion of implants was withdrawn without explanation. However, staff said they had been asked to carry on inserting implants. At MSI Maidstone the registered nurses decided to stop providing this service.
- Staff told us they had annual appraisals. Records stated 100% of medical staff, nursing staff and administrative staff had completed an appraisal in the last 12 months.
- One member of staff told us that they had an appraisal this year but hadn't had one previously. They said they hadn't actually seen their appraisal papers but knew it had been done and sent off to head office.
- Staff requested support for revalidation from the clinical lead at another centre but had not received a reply.
- Staff reported that they did not have regular clinical supervision as there was a lack of clinical team leader.
- There was no oversight or monitoring of medical practice at the centre.

Multidisciplinary working

- Staff gave examples of working with other agencies and services such as the local sexual health services and early pregnancy units at the local hospitals.
- The service referred women with suspected ectopic pregnancy or other complications to a private imaging diagnostic service for second opinion and confirmation.

Seven-day services

- The Maidstone centre was open five days a week. Medical treatment was carried out five days a week. There were two lists with 40 appointments on each day.
- Surgical procedures were carried out on two days a week. Up to 40 surgical procedures were undertaken on each list.
- A counsellor was available at the centre on Monday and Friday. Telephone counselling was available at other times.
- The Required Standard Operating Procedures set by the Department of Health state that patients should have access to a 24-hour advice line which specialises in post abortion support and care. One Call, the MSI telephone advice line, provided 24 hours a day and seven days a week. Callers to the One Call Line could speak to registered nurses or midwives who performed triage to help prioritise treatment and who gave advice. They could also contact counsellors through this number.

Access to information

- MSI used an electronic central information management system that was accessible across the UK. Staff had access to specific systems relevant to their role. For example only the prescribing doctor could enter medicines on the prescription page. This system ensured that patient care records were instantly available if a woman was referred to a different MSI centre for further treatment.
- A patient's consent was required for any communication to be shared with their general practitioner (GP), even if the GP had made the initial referral. Patients were asked if they wanted their GP to be informed by letter about the care and treatment they received. Patients' decisions were recorded and their wishes were respected.
- An information leaflet was given to patients on discharge providing sufficient information to enable other practitioners to manage any complications in line

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with DH RSOP 3: Post procedure. The leaflet provided details of the MSI UK 24 hour telephone helpline arrangements. This leaflet was discreet and designed to fit into a purse to help protect privacy.

Consent, Mental Capacity Act and Deprivation of Liberty

- Consent was obtained at the initial assessment and confirmed on the day of treatment. We spent time in the theatre but did not see the surgeon or anaesthetist review the consent form or the patient record. We did not see the surgeon or anaesthetist taking part in the review of consent as part of the WHO five steps to safer surgery checklist.
- The Royal College of Surgeons guidance on seeking consent is that in addition to completing the consent form, there should be a record in writing in the patient notes about the details of the consent discussion with your patient. There was no evidence of this happening.
- Staff we spoke with talked about a lack of time and need to keep the appointment on track. One member of staff said about the information provided, "They can't take it all in, it's so fast". This presented a risk that consent was not fully informed.
- We observed a member of staff passing the consent form to the patient to read and sign whilst they cleaned the room. There was no opportunity given for discussion or questions and when questioned the member of staff felt this was because of a lack of time.
- The GMC guidance states that the task of seeking consent may be delegated to another person, as long as they are suitably trained and qualified. In particular, they must have sufficient knowledge of the proposed investigation or treatment, and understand the risks involved, in order to be able to provide any information the patient may require.
- At MSI, consent was taken by registered nurses and healthcare assistants who had not completed training in obtaining consent. We had concerns that staff taking consent did not have the detailed knowledge to answer complex questions about medical risks. This was demonstrated during an interview where one member of staff was unable to explain the risks of the procedure and what fully informed consent meant to members of the inspection team.
- The MSI policy dated April 2014 was that this must be undertaken by a Medical Doctor a Registered Nurse or Healthcare Assistant trained and signed off as competent in accordance with MSI "Obtaining Informed Consent Competency Framework" to take consent. Training records supplied by the provider showed that staff at MSI Maidstone centre had not completed the training and had not been signed off as competent.
- Patients were seen alone to ensure that they were voluntarily presenting for treatment.
- All care records we reviewed contained signed consent from patients.
- A trained pregnancy counsellor offered patients the opportunity to discuss their options and choices in line with Department of Health RSOP 14 discussion as part of the consent process.
- All children aged 15 years and under were required to discuss their options with a counsellor prior to giving their consent. This might be via a telephone consultation. The Informed Consent Policy dated April 2014 does not mention that children are required to discuss their options with a counsellor.
- Nurses or a healthcare assistant completing the pre-termination assessment did complete a basic checklist to assess whether aged 15 years and under was competent to give consent. The staff, including the registered manager, had an inconsistent understanding of the Fraser guidelines. They were not able to discuss thresholds for capacity to consent except as a vague "If the member of staff had some concerns".
- We were told, by nursing staff and the registered manager that the doctors prescribing any medication or performing surgery would assume the nurses had checked this and that they did not look at the assessment forms.
- Discussion about consent and providing the opportunity for the child to involve a parent were not recorded in the child's record. Any recording relating to consent was minimal in nature and failed to demonstrate that an effective assessment of capacity to consent and encouragement of parental involvement had taken place in line with RSOP7, GMC guidance and the Fraser guidelines. Fraser guidelines are used specifically to decide if a child can consent to contraceptive or sexual health advice and treatment.
- Staff we spoke to, including the registered manager, could not provide examples of what might make them consider a child lacked capacity to consent or thresholds where there would be concerned about this.
- The registered manager said, "The counsellor would pick it up". The counsellor was not responsible for or

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qualified to obtain consent. Other staff also said they would ask the counsellor if they weren't certain and ask them, "To help the child make the decision". Most consultations with the counsellor were made by telephone, the counsellor did not see the child and had no way of knowing whether the person they were speaking with was the child presenting for an abortion.

- Staff were clear that they felt parental involvement was not a good thing. One said, "The trouble is parents might not react as you think and might be disappointed" and "Parents get upset, we don't involve them".
- Staff were concerned that 'Did Not Proceed', the term used when women decided not to proceed with treatment, was measured as a KPI and linked to their performance bonus. They felt that this encouraged staff to ensure that patients underwent procedures.
- Staff were also concerned that the pressurised environment and linking of KPIs to performance bonuses meant that there was a culture that worked against patient choice. They talked about implants being fitted whilst the patient was sedated (at the same time as the operation) and the limited time available to discuss the choices prior to this. One staff member describe it as "feeling like a hamster in a wheel" and said the word, "Cattle market" came up quite a lot.
- The team meeting minutes dated 15 July 2015 showed that there was a company wide focus on 'DNPs' and that if a patient had a gestational age of 5 weeks three days or less and had not proceed there was to be a follow up call and offer of a later appointment.
- Staff understanding of the Mental Capacity Act 2005 and how it affected their roles was limited. Whilst they could not describe the specific legislative requirements, they talked about not treating people who couldn't understand and referring back to the doctors or discussing with the registered manager.
- Staff identified the need to act in the person's best interest, seeking advice, if needed, and making joint decisions with others if there were concerns about a person's capacity to understand. They were less clear about who had a legal right to make a best interest decision.

Are termination of pregnancy services caring?

Compassionate care

- We observed that some nursing staff were compassionate in their interactions with patients in the recovery area. Attention was paid to ensure each patient understood what was to take place and information and reassurance was offered.
- Staff were seen to support each patient throughout their surgical procedure, providing physical contact and appropriate use of verbal interaction.
- However, we also observed that in the theatre staff attitude was acceptable rather than warm. The anaesthetist did not engage with the patients whilst we were observing in the theatre; their conversation was restricted to specific instructions about care. They did not smile or provide reassurance.
- In interviews with nursing staff we heard an attitude and value base that failed to empathise and understand the patients' perspective. This was particularly true when they spoke about patients who were children. They talked about it being quickest to see the person alone with one staff member saying, "I don't think they partners or friends should even come through the door".
- Of child patients, one nurse said, "They are only here for three hours after cervical preparation. They have a nurse keeping an eye on them so they don't need a parent".
- Staff felt they wanted to stop partners and parents coming into the building blaming a lack of space.
- Staff failed to consider the privacy and dignity of patients. Staff walked into the theatre whilst a list was in progress and a patient was being treated. There were no curtains in the recovery area and no way to protect the patient's privacy whilst providing care.
- The team meeting minutes dated 12 May 2016 showed complaints had been received about staff being blunt and abrupt. This was shared at the team meeting but there was no recorded action relating to this.
- Feedback was obtained through a patient satisfaction survey, Patient comments in the most recent report (January to March 2016) included: "Thank you for understanding and being there and for holding my hand. I really appreciate it" and "Nurse in surgical procedure extremely friendly and comforting. Procedure and care absolutely faultless, no pain throughout".

Termination of pregnancy

Understanding and involvement of patients and those close to them

- Nursing staff explained the available methods of termination of pregnancy that were appropriate and safe to patients. The staff considered gestational age (measure of pregnancy in weeks) and other clinical needs whilst explaining the options.
- There were mixed views in the patient satisfaction survey about whether patients and those close to them were kept informed. In the most recent report made available to us (January to March 2016), 70% of respondents stated they were kept informed of delays and 84% stated that staff clearly explained what was going to happen. Both of these indicators scored over 10% below the MSI targets.
- One patient commented: "It would have been nice to have been told at the booking that my husband would not be allowed to come in for my consultation. He was left waiting in the waiting room not knowing what was happening".

Emotional support

- Counselling services were available to patients using the service and were offered to all patients pre and post treatment.
- Where a child aged 15 years and under they were required to have a counselling appointment on a day prior to their treatment. This could be either face to face counselling or via video calling.

Are termination of pregnancy services responsive?

Service planning and delivery to meet the needs of local people

- The corporate business development team planned the service in discussion with clinical commissioning groups (CCGs). This was in accordance with RCOG Evidence-based Guideline Number 7: The Care of Clients Requesting Induced Abortion which states that commissioners and providers of abortion services should have local strategies in place for providing information for patients and healthcare professionals on routes of access including self-referral.
- The services were operational five days per week, Monday to Saturday inclusive, and were accessible to

the local population and those from further afield. A range of treatment options were available, including medical termination up to nine weeks, plus four days gestation and surgical termination of pregnancy up to 14 weeks gestation. Contraception, including long-acting reversible contraception (LARC) and sexually transmitted infection (STI) screening was available.

- MSI Maidstone was the only stand-alone termination of pregnancy provider in Kent. However, patients could choose to be cared for at another centre to protect their privacy depending upon the treatment they chose.
- Evening and weekend appointments were not available which could limit access to the centre for some patients.
- A fast track appointment system was available for patients with a higher gestation period or those with complex needs.
- Service level agreements were in place with local laboratories for tests relating to sexually transmitted infections and following vasectomy.

Access and flow

- Initial contact for any of the services provided by MSI UK was made through One Call, the national contact centre, which was open 24 hours a day throughout the year. GPs and other services such as local genito-urinary clinics could refer patients directly to MSI.
- At the initial phone contact an individual patient assessment was undertaken to determine the most suitable location for treatment at an MSI UK centre. For example, patients who were more than 14 weeks pregnant were directed to another MSI UK centre.
- Patients could specify their preference for an appointment at a particular centre, and would also be told of possible appointments at other MSI UK centres so they could attend the most suitable appointment for their needs and as early as possible.
- The Business Development Team (located in the national support office) provided daily reports on wait times and worked with the centre team to ensure a full range of treatments was offered within 3 working days.
- Appointment times were designed to ensure short waiting times and access to the full range of services. There was flexibility to re-arrange appointments at very short notice to meet the needs of the patients.

Termination of pregnancy

- Appointments were 15 minutes long. Heavy workloads, crowded operating and clinic lists and a strict 15 minute consultation time led to best practice not being adhered to.
- There were 40 appointment slots on three lists each day. Up to 40 surgical treatments could be carried out on each operation day.
- On the day of our inspection there were 21 patients on the morning surgical list. There were also patients attending for medical abortions.
- Department of Health Required Standard Operating Procedures state that patients should be offered an appointment within five working days of referral and they should be offered the abortion procedure within five working days of the decision to proceed with termination of pregnancy. MSI UK monitored the average number of days patients waited from initial contact to consultation, from consultation to treatment and the whole pathway from contact to treatment. Between January 2015 and December 2015 no patients waited longer than 10 days from decision to proceed up to treatment being carried out.
- We followed one patient who underwent the first part of a medical abortion. Her attendance at the centre took 50 minutes and followed a telephone consultation. There were some positive aspects of her experience, including information provision and adherence with safe practices but the consultation felt very rushed to the inspector. The nurse was doing other tasks such as cleaning rather than paying attention to the patient.
- Staff were concerned that 'Did Not Proceed', the term used when women decided not to proceed with treatment, was measured as a KPI and linked to their performance bonus. They felt that this encouraged staff to ensure that patients underwent procedures.
- Staff were also concerned that the pressurised environment and linking of KPIs to performance bonuses meant that there was a culture that worked against patient choice. They talked about implants being fitted whilst the patient was sedated (at the same time as the operation) and the limited time available to discuss the choices prior to this. One staff member described it as "feeling like a hamster in a wheel" and said the word, "Cattle market" came up quite a lot.
- The team meeting minutes dated 15 July 2015 showed that there was a company wide focus on 'DNPs' and that if a patient had a gestational age of 5 weeks three days or less and had decided not to proceed there was to be a follow up call and offer of a later appointment.
- Medical staff were challenged by nursing staff on occasions when they stopped for a break before the end of a list (when there may be only one or two patients waiting for treatment). This made the morning list run late and impacted on the afternoon session.
- There was limited space in the waiting rooms. At one time during the day there were 15 people in the waiting room, with four standing due to lack of available seating. Staff told us that this was the usual situation and that the clinic was a bit quieter because of the inspection.

Meeting the needs of local people and individuals

- The pathways at MSI Maidstone were not patient focused.
- The attitudes of staff were a barrier to good care of children. Staff felt that all patients should be treated the same regardless of their age. Staff told us that they actively discouraged parental involvement.
- Staff were unaware of MSI policy about parental presence during consultations but one said they let parents in sometimes, "as an exception".
- All patients received a 15-minute private consultation without anyone else present. Partners were not invited into the consultation or theatre to offer support. Staff told us this used to happen but had stopped. They could not tell us why. Some staff told us they didn't think partners or other supporters should be on the premises until the patient was ready to be collected.
- A professional interpreter service was available to enable staff to communicate with patients for whom English was not their first language. However, staff reported that extra time with patients was not allocated when working with an interpreter, which impacted on waiting times.
- Interpreters were allowed in the consultation but were not allowed in the theatre which limited the ability of patients to understand and give continued consent throughout the process.
- Patients with learning disabilities were required to be accompanied by a responsible person.

Termination of pregnancy

- To maintain confidentiality, patients were provided with a pin number for staff to use to confirm their identity. This pin number was also required for supporters seeking access to the centres.
- An information leaflet titled 'Your treatment information' was available for patients attending any MSI centre. This leaflet contained information about different options available for termination of pregnancy including what to expect when undergoing a surgical termination. This also included any potential risks.
- There was a clearly defined referral process for patients who required a specialist service. MSI Maidstone treated clinically fit and healthy patients whose pregnancy was 14 weeks gestation or below. Patients with unstable medical conditions who did not meet these criteria were referred to the most appropriate NHS provider to ensure that they received safe and timely treatment. Patients with pregnancies above 14 weeks gestation were referred to other MSI centres.
- The Maidstone centre was inaccessible to wheelchair users or people with limited mobility.
- There was only one toilet in the waiting room for patients and no toilet facilities for men.
- Leaflets were given to patients to inform them what to expect after the procedure. This included a 24 hour telephone number which patients could call to seek advice if they had any concerns.
- The Human Tissue Authority published guidance about the sensitive handling of pregnancy remains following pregnancy loss or termination in England, Wales and Northern Ireland in March 2015. This was followed by Royal College of Nursing Guidance for staff to follow where the pregnancy, including medically or surgically induced termination of pregnancy ended before the 24th week of gestation. In the case of termination of pregnancy, the mode of disposal may have a bearing on the way the remains are collected. The guidance indicates that where a patient prefers not to make a decision about disposal, they should be informed what method of disposal will be used. Where a patient does not want to engage in any discussion about disposal, their position should be respected but they should be made aware that information is available to access should she so wish.
- We saw that these processes were included in a corporate policy. Information provided to us in advance of the inspection suggested that women were informed of the options for disposal of pregnancy remains on request.
- However, we were told by nursing staff at the Maidstone centre that limited discussions took place with patients around making informed choice about pregnancy remains. Relevant information about pregnancy remains was not included in any patient information leaflets that we saw. Staff we spoke with told us they discussed options on an individual basis but only if a woman raised this issue.
- All pregnancy remains went into a bucket after being signed and checked. There was no recording of which ID number was in which bag so a late decision to take the remains for personal disposal was not possible. If a patient had made it clear prior to the operation that they wanted to dispose of their own remains, they were put into an opaque pot and a release form signed.
- Information about local and national support organisations was available. For example, the contact details for Victim Support, NSPCC, Frank, MIND, Samaritans, Choices (domestic violence) and Headstart Kent (an organisation promoting emotional resilience for young people).
- Nurses undertaking pre-abortion assessments had a range of information available to them that they could give to patients as required. This included advice on contraception, sexually transmitted infections, miscarriage and how to access sexual health clinics.
- Abortion protesters were occasionally outside the Maidstone centre. One Call informed patients of this prior to arrival at the centre so they were prepared. Staff told us that the protestors were mostly peaceful but they would contact the police for assistance when necessary.
- Patients had access to a 24 hour aftercare telephone line provided by registered nurses. Nurses were trained to assess and provide advice over the telephone. Individuals could be booked back into MSI centres for further assessment if required.
- A range of information leaflets was available, covering such topics as sexually transmitted infection, contraception, and Anti-D treatment for rhesus negative, reporting abuse and how to access other services.

Learning from concerns and complaints

Termination of pregnancy

- Information was displayed to advise patients how to raise a concern or complaint informally or formally.
- A record of complaints was maintained. Between January 2015 and December 2015, there were four formal complaints; three were not upheld and one had not been followed up by the patient.
- Formal complaints were managed nationally by the Head of Customer and Quality Services. A full investigation of all complaints was carried out and feedback was provided to the centre managers who informed the staff of any learning points and changes in policy.
- Review of the four complaints demonstrated that duty of candour had been observed and written apologies were offered to the complainants.
- There were three complaints raised to the Care Quality Commission during the reporting period. All raised similar concerns of staff attitude, poor facilities and environment and a rushed service.

Are termination of pregnancy services well-led?

Leadership/culture of service related to this core service

- The centre manager (who was the registered manager) was covering a regional post that required frequent travel to Norfolk. This left the centre without a manager in day to day control of the service.
- The registered manager had limited understanding of some of the key requirements of the role, including the Abortion Act 1967 and child safeguarding (despite being the safeguarding lead). They had no clinical qualifications or experience and had no oversight of the clinical practice at the centre outside of the KPIs.
- The registered manager explained how aspects of leadership were managed at a corporate level through business support. This included medical staffing rotas, registration checks with professional regulatory bodies, insurance, doctors training, appraisals and revalidation. Information was communicated to the registered manager with respect to those who could prescribe medicines.
- Staff were unclear about who was in charge in the manager's absence. Team meeting minutes from April

2016 showed that staff asked for clarity about who was in charge when the manager was away. They also asked who the clinical lead was. There was no answer recorded.

- There was no clinical leadership at the centre. There had been a recent appointment of a clinical team leader in development but they did not assume any responsibility for clinical leadership, oversight of clinical performance by nursing staff or line management of the nursing team.
- A coordinator managed the clinic to ensure that it ran smoothly. We were told that keeping everyone happy was a challenge. For example keeping the patients informed of waiting times.
- Communication with regional nurses and head office relating to changes in policy and professional advice for nurses was difficult to access on occasions. Staff and managers told us there was little contact with other MSI centres, other than by email or at training events.
- Nursing staff we spoke with were unclear about the arrangements that the organisation had put in place to support the process of revalidation. We saw that clarity had been asked for at regional meetings but that this remained unresolved.
- There was no designated children's lead within the service or a recognition that a service was provided to children at the provider level.

Vision and strategy for services

- The organisation had clearly defined corporate objectives to support its aim to deliver the highest quality care for patients. Senior managers had a clear vision and strategy for this service and staff were able to demonstrate common aims with us during individual interviews.
- The registered manager advised us there was no local service related vision or formal strategy, but stated there was "healthy" competition between other MSI providers with regard to the key performance indicators and financial targets.
- Overall we found staff were aware of the vision and strategy in place for MSI. The values and objectives had been shared with staff from the point of induction, and each had a general understanding of the overall strategy in place.

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

Termination of pregnancy

- A current public liability insurance certificate was seen in reception.
- We asked the registered manager how they were assured the staff were undertaking their duties and responsibilities in accordance with professional practices and local protocols. They told us there were internal systems in place to monitor how the centre complied with national guidance and regulations. This included an MSI 'Nominated individual self-assessment tool' audit carried out by members of the corporate management team. This last happened on 29 February and 1 March 2016.
- As a result of the most recent nominated individual audit a number of required actions were identified. These included: displaying the certificate for approval (the licence for termination of pregnancy) issued by the Department of Health, and the introduction and completion of checklists to monitor standards in both infection prevention and control and regulatory compliance. At the time of our inspection these actions were not implemented, without any explanation offered.
- The approach to anticipating and managing day-to-day risks to people was reactive rather than pro-active, and tended to be led at a regional or corporate level. This meant that opportunities to prevent or minimise harm could be missed.
- Legislation and regulations require that in non-NHS locations, a certificate of approval (licence) for termination of pregnancy issued by the Department of Health must display a certificate of approval (licence) issued by the Department of Health. The certificate of approval was not on display when we arrived. We asked to see the certificate and once we had explained what the certificate looked like, the registered manager was able to find it.
- MSI had a corporate annual audit programme. Hand hygiene, infection prevention and control and safeguarding were audited twice a year and were 78% compliant in March 2016, 93% compliant in April 2016 and 92% compliant respectively. Medicines management and protective personal equipment were audited quarterly and were 96% compliant in March 2016 and 79% compliant in April 2016 respectively. Medical records were audited six times per year and were 99% compliant in March 2016.
- The Abortion Act 1967 clearly outlines that a termination can take place only if two registered medical practitioners are of the opinion, formed in good faith, that at least one and the same grounds for a termination is met, within the terms of the Act. The following notifications are a legal requirement under the Abortion Act: HSA1: two doctors are required to sign the HSA1 form, which is the certificate of opinion before a termination is performed. HSA2: to be completed by the doctor within 24 hours of an emergency termination and HSA4: notification to the Department of Health, either manually or electronically, within 14 days of the termination taking place.
- The Required Standard Operating Procedure (RSOP) standard one requires the provider to ensure that the completion of legal paperwork (HSA1 and HSA4 forms) is undertaken in a timely manner. Concerns were raised regarding bulk signing of HSA1 forms.
- Effective risk management arrangements were not in place to make sure that the certificate(s) of opinion HSA1 were signed by two medical practitioners in line with the requirements of the Abortion Act 1967 and Abortion Regulations 1991. We found some evidence that doctors were being requested to sign HSA1 forms in bulk without the opportunity to have full access to patient information. We saw one doctor sign 26 forms in two minutes.
- If two doctors were not onsite, MSI UK employed doctors who used an electronic approval system to provide HSA1 signatures, and medical prescriptions for abortions under 12 weeks if required. They relied on the information provided on the form for the reason given for termination being requested.
- MSI governance systems had failed to identify concerns with the signing of HSA1 forms. Internal audits showed high levels of compliance.
- No Statutory Notifications had been made to the Commission since April 2011. The regulations require the provider to notify the Commission of any event where a patient suffers or is put at risk of serious and enduring physical or psychological harm or suffers or is at risk of abuse. This had not happened and the MSI governance systems had failed to identify this as a concern.
- Staff told us two staff meetings had been held in the past month, the two previous to those had been cancelled and before that there were none. We saw records of a few staff meetings but there was no regularity to when they were held.

Termination of pregnancy

- The Department of Health requires every provider undertaking termination of pregnancy to submit data following every procedure (HSA4 form). This information had been correctly submitted.

Culture within the service

- Staff had mixed views on the culture at MSI Maidstone and gave conflicting messages.
- Staff told us that they were often told that someone was coming to help but this did not usually happen. Several said that they just got on with their own job.
- The culture within the wider organisation was perceived by staff to be top-down and directive with service development led by the executive management team with minimal opportunities for staff engagement. This meant that the direction and leadership approach was not always clear.
- Staff told us they were not always comfortable reporting incidents and raising concerns. We were told that a member of nursing staff had been moved from the theatre following their request to the surgeon to not have medicines drawn up in advance. Other staff told us that they did feel comfortable raising concerns but they couldn't recall issues they had raised that had been actioned. They told us it may have been dealt with but that they wouldn't know.
- Another staff member said they would raise concerns but it depends who you are raising them with as to whether they listen or not.
- Nursing staff talked about surgeons being more important than anyone else and being "Pandered to" such that you couldn't say anything about them.
- We were told, "It's a blame game". Staff said they felt listened to but reported concerns were not always acted upon. This, apparently, led to staff asking "What's the point". One said, "It's the mantra around here".
- Staff also said, "It's a nice place to work and the manager is supportive of staff needs around social and family commitments. She wouldn't ask you to do anything she wouldn't do herself".

- Several staff talked to us about their discomfort and concern about letting patients leave the centre after surgery alone and travelling by public transport. However we were not assured that this was raised with the management team.
- Reporting of KPIs against individual staff was felt to be unfair and divisive. We were told that some of the outcomes were logged against the wrong staff and didn't reflect who had actually done the work.

Public and staff engagement

- An external company was used to receive and interpreted feedback from members of the public who had used the service. An anonymised Patient Feedback Questionnaire (CFQ) with postage paid was given to each person who attended the service. These were either sent directly to the external company or left within the centre to be sent to the external organisation.
- Completed CFQs were sent daily to the external company for analysis and urgent issues reported to the Governance team and Regional Manager within 24 hours. Reports were generated quarterly and the findings were discussed in team meetings. However there had only been two meetings at the time of our inspection.
- Patients attending the centre were given feedback forms which asked for their opinion of the service. However; staff, told us that due to the sensitivity of the procedure and the emotional experience for the patients, response rates were low and it was sometimes a challenge to engage with patients in this way.
- A regional conference was held in December 2015 where staff met with colleagues from other MSI UK centres, and were given the opportunity to engage and feedback on practices. Staff told us they had received an update by the Director of Commercial operations which included actions being taken to address issues raised such as revision of the induction training programme for new staff and a new electronic system to produce rotas in a timelier manner.

Outstanding practice and areas for improvement

Areas for improvement

Action the provider **MUST** take to improve

- The provider must ensure that risks to patients are identified, assessed and monitored consistently throughout the treatment and recovery period, and that action plans in assessments and care plans are updated and contain enough detail to enable staff to reduce those risks effectively.
- The provider must take prompt action to address a number of significant concerns identified during the inspection in relation to safeguarding, incident recording and reporting, and the governance of the service.
- The provider must enable all staff to complete training that is necessary for them to fulfil their roles.
- The provider must ensure staffing levels and skills mixes reflect patient needs.
- The provider must ensure that consent is given and recorded in accordance with national guidance. This includes ensuring that the staff recording consent are able to discuss the individual patient's risks of the procedures and the full range of options available to them.
- The provider must display the Secretary of State's approval to carry out abortions.
- The provider must ensure that staff follow MSI Infection Prevention and Control Policies in regards to hand hygiene, staff dress code, decontamination of equipment and premises and preparation of the patient prior to surgery.

- The provider must ensure that staff adhere to MSI medicines management and national guidance on the safe management of medicines.
- The provider must ensure there is appropriate clinical leadership at the centre with clear lines of accountability.
- The provider must review the safe use of sedation medication and practice of individual doctors to reduce the risk of harm involving oversedation.
- The provider must ensure that the care pathways consider the specific needs of children and other emotionally vulnerable patients attending the clinic.
- Statutory Notifications must be submitted to the Commission as required by regulation.

Action the provider **SHOULD** take to improve

- Staff should have regular appraisals to establish continual professional development requirements to ensure staff have the right skills to perform their job role.
- The provider should have specific written information in the waiting areas regarding key risks to patients such as domestic abuse, the risk of sexual exploitation, access to support groups and contact numbers if at risk.

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 11 HSCA (RA) Regulations 2014 Need for consent

The provider had not ensured that medical staff were obtaining consent prior to carrying out procedures in line with national guidance and the GMC code.

The matters above have been addresses nationally with MSI at provider level by CQC issuing a warning notice.

Regulated activity

Termination of pregnancies

Regulation

Regulation 9 HSCA (RA) Regulations 2014 Person-centred care

The provider had not ensured that regulated activities were provided in a person-centred way, particularly in relation to children under 18 years of age.

Regulated activity

Regulation

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

The provider had not ensure that patients received safe care and treatment at MSI Maidstone Centre.

Staff understanding of corporate policies and national guidance on deteriorating patients and WHO surgical safety checklists was very limited..

Patients, including children, were allowed to leave the premises unescorted after treatment.

Medicines management practice was not always safe.

This section is primarily information for the provider

Requirement notices

The matters above have been addresses nationally with MSI at provider level by CQC issuing a warning notice.

The following requires a local response.

The staff had poor infection prevention and control practices

Regulated activity

Regulation

Termination of pregnancies

Regulation 17 HSCA (RA) Regulations 2014 Good governance

The registered provider had not got sufficiently robust governance systems in place to monitor care practices at MSI Maidstone centre effectively. Risks were not identified and concerns were not acted upon.

HSA1 forms were signed by doctors who did not have sufficient information to make a decision in good faith about the individual circumstances of each patient. Where the information was available they lacked the time to review it. Audits of HSA1 forms were inadequate and failed to recognise concerns because they only recorded the patient number, the doctors names and the dates of signing and procedure.

The matters above have been addresses nationally with MSI at provider level by CQC issuing a warning notice.

The following breach of regulation needs to be addresses locally.

Leadership was poor with no clinical leadership at the clinic, inaccessible corporate clinical leadership and a registered manager who was frequently absent and who lacked the knowledge and skills to carry out the role effectively.

Regulated activity

Regulation

This section is primarily information for the provider

Requirement notices

Termination of pregnancies

Regulation 18 HSCA (RA) Regulations 2014 Staffing

The provider had failed to ensure there were sufficient staff with the appropriate skills and qualifications to meet the needs of the patients.

Regulated activity

Regulation

Termination of pregnancies

Regulation 13 HSCA (RA) Regulations 2014 Safeguarding service users from abuse and improper treatment

The provider had insufficiently robust systems in place to ensure that people were protected from the risk of abuse. The corporate policy did not follow the guidance contained in Working together to safeguard children (2014).

The corporate training strategy meant that staff who were not trained to the appropriate level were making decisions about whether a child should be referred to the local safeguarding children team.

The matters above have been addresses nationally with MSI at provider level by CQC issuing a warning notice.

Regulated activity

Regulation

Termination of pregnancies

Regulation 10 HSCA (RA) Regulations 2014 Dignity and respect

The registered provider was not ensuring that people were treated with respect and that their dignity was protected.

Partners, parents and other supportive adults were actively discouraged from providing support to the patient throughout the process.

Interpreters were not allowed in the theatre.

Staff entered the theatre to speak to the theatre team and ask them to sign HSA1 forms.

This section is primarily information for the provider

Requirement notices

Regulated activity

Surgical procedures
Termination of pregnancies

Regulation

Regulation 18 CQC (Registration) Regulations 2009
Notification of other incidents

The registered person must notify the Commission without delay of the incidents specified in paragraph (2) which occur whilst services are being provided in the carrying on of a regulated activity, or as a consequence of the carrying on of a regulated activity.

The provider had failed to submit any statutory notifications to the Care Quality Commission between April 2011 and the date of the inspection visit.

This section is primarily information for the provider

Enforcement actions

Action we have told the provider to take

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

Regulated activity	Regulation
Termination of pregnancies	<p>Regulation 13 HSCA (RA) Regulations 2014 Safeguarding service users from abuse and improper treatment</p> <p>Staff who were not trained to the required level in child safeguarding were making decisions about the treatment of children.</p> <p>There was poor oversight of the safeguarding arrangements.</p> <p>13.—(1) Service users must be protected from abuse and improper treatment in accordance with this regulation.</p> <p>(2) Systems and processes must be established and operated effectively to prevent abuse of service users.</p> <p>(3) Systems and processes must be established and operated effectively to investigate, immediately upon becoming aware of, any allegation or evidence of such abuse.</p>