Marie Stopes International Essex 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 International Essex centre on 12 April 2016. This inspection was part of a wider programme to inspect providers of acute independent healthcare.

MSI Essex 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. MSI Essex also provides services via seven early medical abortion units (EMU) known as satellite units.

The centre provides medical termination to nine weeks + three days and surgical termination of pregnancy to 23 weeks + six days. Surgical termination is carried out either under general anaesthetic, conscious sedation, by vacuum aspiration or dilatation and evacuation or no anaesthetic according to patient choice and needs.

At the time of inspection there was no registered manager in place. There was a newly appointed clinical operations manager in post but they were yet to apply as registered manager. They were responsible for the day-to-day management at MSI Essex and they were being supported by the regional manager.

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

Are services safe at this service?

There was an inconsistent approach to categorising incidents, action planning and ensuring that lessons learnt from incidents were shared with all relevant staff locally and across the organisation.

There was no effective process to review incidents and undertake trend analysis to reduce the risk to patients subsequent to an incident.

Incidents were not a standard agenda item on staff meetings to heighten awareness and enable shared learning. A duty of candour policy was introduced in April 2016 however there was no training for staff on the duty of candour regulation

There were no staff on site that were trained and competent to assist the anaesthetist to administer anaesthesia and monitor patients undergoing conscious sedation or general anaesthesia. Marie Stopes International provides a two-day introduction to anaesthetic course however at the time of inspection no member of staff at MSI Essex had undertaken this course. We had further concerns that a two day course would not be sufficient to fully equip nursing staff with the knowledge and skills to assist in an emergency situation if a patient with a difficult airway

Staff did not carry out the World Health Organisation (WHO) 'Five Steps to Safer Surgery' checklist appropriately. Staff were completing all sections of the hard copy of the checklist, without any verbal checks, before the procedure had taken place. Local audit was not effective as it was a quantative check that the paperwork had been completed. No observational audit was undertaken to ensure compliance was in line with best practice.

Not all infection prevention and control process followed standard practice. Handwashing practices audit results in February 2016 had been poor. The appointed lead for infection prevention and control (IPC) had not received MSI infection control training. Staff were observed to rinse surgical instruments prior to decontamination in a sluice area adjacent to the theatre. This was not documented standard practice within the MSI decontamination policy.

Not all staff had the appropriate level of safeguarding training to manage safeguarding issues. Training data provided did not distinguish between adult and children safeguarding training. 52% of staff had completed level 2 training. The clinical operations manager had received level three training however records showed that they had not received level 2 training.

Summary of findings

There was no finalised emergency patient transfer agreement in place at the time of inspection. There were no lone working safety processes in place for staff at the satellite units and staff had not received any training on dealing with violence and aggression.

However staff were confident to report serious incidents, whistle blow or challenge if they suspected poor practice. The centre had a planned preventative maintenance programme in place for equipment. Equipment was serviced and labelled appropriately to identify review dates for maintenance.

Staff were knowledgeable about what constitutes a safeguarding concern and were confident to raise incidents when there were concerns of sexual violence, poor social support, or where there was evidence of coercion.

Are services effective at this service?

Policies were not always updated to reflect practice changes in a timely manner. There was a lack of consultation and engagement of staff to support evidence based care practices. Minutes from the corporate clinical governance meetings did not consistently demonstrate effective reporting on patient outcomes to demonstrate effective practices. Quality dashboards with key performance indicators (KPI) to improve quality measurements were being introduced.

Staff were unable to provide us with an explanation or evidence of the decision making process behind the introduction of simultaneous drug administration. Staff could not assure us that the treatment was evidence–based.

Only 40% of the centre staff had received consent training and as none of the staff had received safeguarding training at level 3 we were not assured that staff taking consent had the appropriate knowledge, skills and competence to support patients who may be vulnerable or lack capacity to make a decision.

However there was evidence that when concerns around consent were recognised, that related to a safeguarding issue, incidents were reported and there was appropriate collaborative working with external agencies such as the police, social services and staff at the local NHS hospital.

Are services caring at this service?

Patients were positive about the care provided, which they noted was individually patient centred. Staff were helpful, caring and treated patients with dignity and respect.

Staff adopted a non-directive, non-judgemental and supportive approach to women receiving treatment for termination.

MSI Essex scored above the national average for rating the overall service at 96% very good or excellent. Comments were overwhelmingly positive in the 61 comments cards received in the week prior to inspection.

RSOP standard three requires that there are protocols in place to support women following a termination, including access to counselling and support services. Staff we spoke with stated that all women requesting a termination were offered the opportunity for emotionally support from a trained pregnancy counsellor. This would be offered at any time pre or post termination. This was completed either face to face or by telephone by staff at the One Call centre.

Staff could describe the range of emotional responses that women may experience during and following an abortion

Are services responsive at this service?

Service planning and delivery met the needs of the population. The services provided reflected the importance of flexibility, choice for patients. Commissioners and stakeholders were involved in service planning.

Between January and December 2015, no patients waited longer than 10 days from first appointment to termination of pregnancy unless they requested a delay. Staff managed patient flow through the centre well and in November 2015 the average patient time spent in the centre was 106 minutes (against a target of 110 minutes). 95.9% of patients were satisfied with the process for booking appointments and comparative analysis indicated a year on year improvement.

Summary of findings

Translation services were available for patients who did not have English as a first language and notices were displayed in the reception areas informing patients this service was available.

There was a complaints procedure in place. Complaints advice was given in the back of the patient literature and also displayed in the patient information folder in waiting areas. The service had made changes regarding the process in place for patients arriving late in response to a number of complaints.

Are services well led at this service?

Marie Stopes International provided MSI Essex with an Integrated Governance Framework which was not being measured against the most up to date standards. The framework made reference to the CQC Essential Standards of Quality and Safety however these were replaced by the Fundamental standards in 2014.

There were gaps between the governance processes at corporate and location level in communication and engagement. 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.

There was no effective system to ensure action plans arising from incidents, local audit or "nominated Individual visits" (NI) visits were completed, reviewed and re-audited to improve patient safety and quality of care.

Risk management arrangements were not effective to ensure 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.

Local audit process to ensure completion of HSA1 forms only included a check that the form was completed and signed. It was not a qualative check of the process.

There was no process or monitoring system in place at MSI Essex to ensure that the submission of HSA 4 forms to the Department of Health had been undertaken within the legal timeframe.

The culture was viewed as being top down and corporately led. Senior staff did not always feel they had a strong voice at corporate level.

However, the service had a vision, core values and strategy of which the staff had a general understanding.

Staff were complimentary about the current leadership team at MSI Essex. They stated they were visible and approachable and were open to new ideas and changes.

We saw areas of good practice including:

- Staff were described and observed as being non-judgemental

However, there were also areas of poor practice where the provider needs to make improvements.

Importantly, the provider must:

- Ensure that there is an effective process for incident reporting and that recording is consistent to enable analysis of data to highlight areas of improvement.
- Ensure a consistent approach to action planning and ensuring lessons learnt from incidents are shared with all relevant staff locally.
- Ensure that senior staff involved in the investigations have access to formal training in root cause analysis to support the risk management process.

Summary of findings

- Ensure that hard copy documentation in relation to the World Health Organisation (WHO) 'Five Steps to Safer Surgery' checklist is completed accurately and used appropriately at each phase of the surgical procedure.
- Undertake improvements in corporate and location level communication and engagement to ensure evidence based care can be demonstrated at all times.
- Ensure that there are competent and appropriately trained staff on site with sufficient airway knowledge to enable prompt and competent support to the anaesthetist.
- Establish an effective system to ensure and demonstrate that staff are competent and qualified to carry out their roles safely and effectively in line with best practice.
- Ensure an effective system is in place for risk management and quality improvement. Including effective local audit process to ensure care is provided in accordance with legislation and best practice guidelines.
- Ensure that there are effective processes in place to ensure that the certificate(s) of opinion HSA1 form are signed by two medical practitioners in line with the requirements of the Abortion Act 1967 and Abortion Regulations 1991.
- Ensure that there is an effective process for submission of HSA 4 forms to the Department of Health within the legal timeframe of 14 days.
- Ensure that there are effective infection prevention controls and systems in place to lower the risk of infection and drive improvement.
- Review the practice of open storage of multiple surgical termination products in a single container and amend policy and guideline to ensure good infection control practice.

In addition the provider should:

- Ensure that specific lone worker staff safety risk assessments are in place for the satellite units. Staff should receive training on violence and aggression to safeguard them.
- 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

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

Summary of findings

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

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Background to Marie Stopes International Essex Centre

Termination of pregnancy (TOP) refers to the treatment of termination of pregnancy, by surgical or medical methods. The centre provides medical termination to nine weeks + three days and surgical termination of pregnancy to 23 weeks + six days. Surgical termination is carried out either under general anaesthetic, conscious sedation, by vacuum aspiration or dilatation and evacuation or no anaesthetic according to patient choice and needs.

Marie Stopes UK International (MSI) Essex is part of the provider group Marie Stopes International. MSI Essex opened on 6 August 1992 and provides consultations, ultrasound scans, medical and surgical termination of pregnancy, and counselling and support for people who use the service. In addition, vasectomy, performed under local anaesthetic, long acting reversible contraception (LARC) and sexually transmitted infection (STI) testing and screening are offered.

MSI Essex also provides services via seven early medical abortion units (EMU) known as satellite units. These are located in the community where medical termination and consultations in the early stages of pregnancy are provided in a private consulting room. All locations hold a licence 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 those aged less than 18 years are seen and medically treated at all of the locations however surgical termination of pregnancy (SToP) only takes place at MSI Essex. Counselling services are offered to all patients before and after their treatment and are provided face to face or by telephone. Appointments are made through a 24 hour registered pregnancy advisory centre (MSI One call centre).

The building at MSI Essex is not purpose built but modified to provide four consulting rooms, one theatre, one screening room and 14 day couches. A small car park is available on site and there are facilities in place to support people with a physical disability.

Our inspection team

A CQC lead inspector led our inspection team**.** The team included a specialist adviser and an inspection manager.

How we carried out this inspection

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

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

We inspected the clinic as part of our schedule of independent hospitals.

An announced inspection took place at MSI Essex on 12 April 2016. During our inspection we visited the main location only. Before visiting, we reviewed a range of information we hold about the centre and asked other organisations to share what they knew. We also viewed information provided by the centre which included feedback from people using the service about their experiences.

We spoke with 20 staff members including managers, doctors, registered nurses, health care support workers and administration staff. We reviewed the care records of 10 patients, five of which had undergone surgical termination of pregnancy, and five had undergone

Summary of this inspection

medical termination of pregnancy. We observed interactions and communication with patients and those close to them during our inspection; however this did not include male patients as there were no vasectomy consultations or procedures taking place during the inspection.

This service was inspected but not rated.

We have not rated this service because we do not currently have a legal duty to rate this type of service or the regulated activities which it provides. Although we do not currently have the powers to rate these services, we report on whether they are safe, effective, caring, responsive to people's needs and well-led. We highlight areas of good practice and areas for improvement.

Information about Marie Stopes International Essex Centre

MSI Essex centre is a clinic that provides termination of pregnancy and family planning services to private and NHS patients. In addition, vasectomy, performed under local anesthetic, long acting reversible contraception (LARC) and sexually transmitted infection (STI) testing and screening are offered.

It has one operating theatre where day case procedures are undertaken. The clinic has 14 day-couches available, no overnight accommodation is provided. The clinic is registered to provide the regulated activities:

- Diagnostic and screening procedures
- Surgical procedures
- Treatment of disease, disorder or injury
- Family Planning
- Termination of Pregnancy.

Between January and December 2015 the centre performed 2354 early medical abortions and 5651 surgical abortions. 117 terminations during this period were above 20 weeks gestation.

No children under the age of 13 were treated at MSI Essex however there had been children treated between 13 and 15 years between January and December 2015, exact numbers were not provided.

MSI Essex is open Monday to Saturday, with Wednesdays closed alternately. The centre provides surgical termination of pregnancy to 23 weeks + six days and medical termination to nine weeks + three days. Vasectomy lists are performed once a fortnight.

At MSI Essex surgical termination is carried out either under general anaesthetic, conscious sedation, by vacuum aspiration or dilatation and evacuation, or no anaesthetic according to patient choice and needs..

At the time of inspection there was no registered manager in place. There was a newly appointed clinical operations manager in post. They were responsible for the day-to-day management at MSI Essex and they were being supported by the regional manager. It had been identified as part of the “nominated Individual visits” (NI) in October 2015 that the clinical operations managers were in the process of applying to be registered managers however CQC records could not establish that this had taken place. At the time of inspection the new clinical operations manager was yet to apply as registered manager.

Staff employed consisted of one medical doctors (wte 1.0), eleven registered nurses (wte 10.24) and 13 administration staff (wte 10.8). There was one vacancy for a registered nurse at the time of inspection. The total number of shifts of agency cover for registered Nurses in the three months prior to inspection had been 17.

Termination of pregnancy

Safe	
Effective	
Caring	
Responsive	
Well-led	

Summary of findings

There was an inconsistent approach to categorising incidents, action planning and ensuring that lessons learnt from incidents were shared with all relevant staff locally and across the organisation.

There was no effective process to review incidents and undertake trend analysis to reduce the risk to patients. Incidents were not a standard agenda item on staff meetings to heighten awareness and enable shared learning. A duty of candour policy was introduced in April 2016 however there was no training for staff on the duty of candour regulation.

Staff did not carry out the World Health Organisation (WHO) 'Five Steps to Safer Surgery' checklist appropriately. Staff were completing all sections of the hard copy of the checklist, without any verbal checks, before the procedure had taken place. Local audit was not effective as it was a quantative check that the paperwork had been completed. No observational audit was undertaken to ensure compliance was in line with best practice.

Not all infection prevention and control process followed standard practice. Handwashing practices audit results in February 2016 had been poor. The appointed lead for infection prevention and control (IPC) had not received MSI infection control training. Staff were observed to rinse surgical instruments prior to decontamination in a sluice area adjacent to the theatre. This was not documented standard practice within the MSI decontamination policy.

Not all staff had the appropriate level of safeguarding training to manage safeguarding issues. There was no finalised emergency patient transfer agreement in place at the time of inspection.

There were no lone working safety processes in place for staff at the satellite units and staff had not received any training on dealing with violence and aggression.

Policies were not always updated to reflect practice changes in a timely manner. There was a lack of consultation and engagement of staff to support evidence based care practices.

Staff we spoke with were unable to provide us with an explanation or evidence of the decision making process behind the introduction of simultaneous drug administration. Staff could not assure us that the treatment was evidence–based.

There were no staff on site who were trained and competent to assist the anaesthetist to administer anaesthesia and monitor patients undergoing conscious sedation or general anaesthesia.

Only 40% of the centre staff had received consent training and as none of the staff had received safeguarding training at level 3 we were not assured that staff taking consent had the appropriate knowledge, skills and competence to support patients who may be vulnerable or lack capacity to make a decision.

There were gaps between the governance processes at corporate and location level in communication and engagement. There was no effective system to ensure action plans arising from incidents, local audit or “nominated Individual visits” (NI) visits were completed, reviewed and re-audited to improve patient safety and quality of care.

Risk management arrangements were not effective to ensure 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

Termination of pregnancy

Regulations 1991. There was no process for monitoring submission of HSA 4 forms to the Department of Health to ensure this had been undertaken within the legal timeframe.

The culture was viewed as being top down and corporately led. Senior staff did not always feel they had a strong voice at corporate level.

However we also found that;

Staff were confident to report serious incidents, whistle blow or challenge if they suspected poor practice.

Staff were knowledgeable about what constitutes a safeguarding concern and were confident to raise incidents when there were concerns of sexual violence, poor social support, or where there was evidence of coercion. There was appropriate collaborative working with external agencies such as the police, social services and staff at the local NHS hospital.

The centre had a planned preventative maintenance programme in place for equipment. Equipment was serviced and labelled appropriately to identify review dates for maintenance.

MSI Essex scored above the national average for rating the overall service at 96% very good or excellent. Comments were overwhelmingly positive in the 61 comments cards received in the week prior to inspection. Patients said that staff were helpful, caring and treated patients with dignity and respect.

Staff adopted a non-directive, non-judgemental and supportive approach to women receiving treatment for termination. Staff could describe the range of emotional responses that women may experience during and following an abortion.

There was a complaints procedure in place. Complaints advice was given in the back of the patient literature and also displayed in the patient information folder in waiting areas.

Service planning and delivery met the needs of the population. Between January and December 2015, no patients waited longer than 10 days from first appointment to termination of pregnancy unless they requested a delay. Staff managed patient flow through the centre well and in November 2015 the average patient time spent in the centre was 106 minutes (against a target of 110 minutes). 95.9% of patients were satisfied with the process for booking appointments and comparative analysis indicated a year on year improvement.

Translation services were available for patients who did not have English as a first language and notices were displayed in the reception areas informing patients this service was available.

The service had a vision, core values and strategy of which the staff had a general understanding.

Staff were complimentary about the current leadership team at MSI Essex. They stated they were visible and approachable and were open to new ideas and changes.

Termination of pregnancy

Are termination of pregnancy services safe?

Our key findings for safety were:

- Senior managers did not have a consistent approach to ensuring that all staff received information regarding lessons learnt.
- Review of incidents was not a standard agenda item at team meetings.
- There was no effective process to review incidents and undertake trend analysis to reduce the risk to patients.
- Senior staff involved in incident investigations had not had any formal training in root cause analysis which they felt would be beneficial to the risk management process.
- There was no training for staff on the duty of candour regulation.
- Handwashing practices audit in February 2016 had scored 43%.
- The appointed lead for infection prevention and control (IPC) had not received MSI infection control training.
- Staff rinsed surgical instruments prior to sending off site for decontamination in a sluice area adjacent to the theatre. This was not documented standard practice within the decontamination policy.
- Not all staff had the appropriate level of safeguarding training to manage safeguarding issues. Training data provided did not distinguish between adult and children safeguarding training. 52% of staff had completed level 2 training.
- There were no staff at MSI Essex with additional training to enable prompt and competent support to the anaesthetist should a general anaesthetic be required.
- Staff did not carry out the World Health Organisation (WHO)'Five Steps to Safer Surgery' checklist appropriately and the format of local audit was not effective to ensure compliance.
- There was no finalised emergency patient transfer agreement in place at the time of inspection.
- There were no lone working safety risk assessments in place for the satellite units and staff had not received any training on dealing with violence and aggression.

However:

- Staff we spoke with were confident to report serious incidents, whistle blow or challenge if they suspected poor practice.
- The centre had a planned preventative maintenance programme in place for equipment. Equipment was serviced and labelled appropriately to identify review dates for maintenance.
- Staff were knowledgeable about what constitutes a safeguarding concern and were confident to raise incidents when there were concerns of sexual violence, poor social support, or where there was evidence of coercion.

Incidents

- Staff reported incidents in hard copy format to the manager who raised an incident report through an electronic incident reporting system. Staff we spoke with could provide examples of previous incident reports such as patients leaving before being fit for discharge.
- Staff we spoke with felt confident about reporting serious incidents, whistle blowing or challenges if they suspected poor practice. However there was an inconsistent approach to categorising incidents, action planning and ensuring that lessons learnt from incidents were shared with all relevant staff locally and across the organisation.
- Staff we spoke with said that senior staff provided feedback to the reporter on actions taken but it was not clear how all relevant staff locally, and across the organisation, received appropriate information on lessons learnt to help improve patient safety.
- Review of incidents was not a standard agenda item at team meetings. Minutes did not include incidents and practice changes to heighten awareness and prevent reoccurrence.
- The process for incident management and trend analysis was not effective. Data provided prior to the inspection demonstrated that there had been 254 incidents reported in the period between 24 March 2015 and 23 March 2016. Of these 28 had been reported as clinical incidents under the main incident type, four as pre-existing condition, three had been reported as non-clinical, one as personal accident, seven as safeguarding and three as security or violence/abuse/harassment. This meant that 81% (208 out of 254) had

not been categorised under the main incident type heading. There were four incidents reported of haemorrhaging none of which were categorised as clinical incidents.

- The clinical operations manager and regional manager stated that an incident log was held on site and that the local team were required to provide an incident response to the corporate team within a week of an incident occurring, following which a review of incidents to identify themes and trends would occur at the corporate level at integrated governance committee meetings (IGC). We reviewed the IGC minutes submitted from February, August, November 2015 and January 2016. In February 2015 it was noted that, along with three other sites, "Essex have the highest number of reported incidents". The head of projects was to investigate and feedback at the next meeting however the August IGC minutes were vague and did not stipulate any specific information or analysis other than "confirmation received that a list of what is considered an incident needing to be recorded was sent to centres ". Therefore we were not assured that any analysis of incidents was effective in identifying risk and actions to prevent reoccurrence.
- There had been one serious incident (SIRI) reported between January and December 2015, which we reviewed, regarding a delayed procedure due to an intubation risk. An investigation, root cause analysis (RCA) and action plan had been undertaken. The investigation had identified appropriate actions for example the importance of engagement between the "did not proceed" (DNP) team and the patient, via a dedicated phone line. However senior staff involved in the investigations had not had any formal training in root cause analysis which they felt would be beneficial.
- 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 provider carried out a series of "nominated Individual visits" (NI visits) that comprised of two days of assessment at individual locations. These visits were undertaken by the UK Head of Facilities and Health and Safety Adviser and the Governance Assistant. MSI Essex had a NI visit 20-22 October 2015. It had been noted at the NI visit that duty of candour required improvement. Actions included review of the standard by the clinical operations managers, monthly reflection sheets to be introduced and duty of candour to be discussed with the team. When questioned the clinical operations manager and regional manager were aware of the requirements under duty of candour. A duty of candour policy was introduced in April 2016 to provide staff with a process to follow when they were dealing with serious incidents. There had been no training for staff on the requirements of the regulation.

Cleanliness, infection control and hygiene

- There was an infection control policy in place and 92% of staff (25 out of 27) had received up-to-date training as per MSI policy. Bi-annual infection control audits were undertaken and practices reviewed, such as hand washing practices which scored 43% compliance in February 2016. A training session on hand washing technique and hygiene was actioned with all staff. Staff planned to undertake random checks and a repeat audit in the next few months to monitor and measure improvements in practices.
- There was a colour-coded system for segregation of waste. Cleaning schedules and checklists were in place and staff were familiar with the daily weekly and monthly checks required.
- Cleaning schedules, daily checklists and appointment of an infection prevention and control (IPC) lead were identified and included in the local action plan devised following the NI visit. At time of inspection these three actions had been completed however the appointed lead for IPC was one of the two members of staff that had not received MSI Infection control training.
- Staff prepared instrument trays using a non-touch aseptic technique. The majority of medical devices used in theatre were single use items, decontamination and sterilisation of any reusable items occurred off site. Collection and delivery was three times a week and there was a process to enable tracking of instruments trays sent for processing.
- One member of staff was allocated to work in the sluice area to help prevent potential cross infection concerns. Staff wore the appropriate protective clothing for cleaning equipment; however, we observed staff rinsing instruments prior to decontamination in a sluice area adjacent to the theatre. This was not documented standard practice within the decontamination policy.

Staff sprayed instruments with a pre-treatment foam spray prior to transportation. The foam is a recommended pre-treatment when there is a delay between instrument usage and decontamination.

- Multiple surgical termination products were individually bagged and left in a single open hazardous waste bin in a sluice room next to theatres for the whole day. This was not removed between cases. At the end of the list the container was then sealed and taken to the freezer before collection. Segregation of fetal tissue only occurred if there were specific requirements to do so (either on patient request, requirements for DNA identification or criminal investigation). Staff wore appropriate personal protective clothing such as gloves, aprons and goggles.
- There is no information or guidance regarding multiple storage of products during an operating list in either the MSI UK Management of fetal tissue policy dated June 2014 or the Safe Management, Handling and Disposal of Waste Policy and Procedures, June 2014.

Environment and equipment

- The centre had a planned preventative maintenance programme in place. All the equipment reviewed during the inspection had been maintained by a contracted company and maintenance dates were visible on the equipment. Equipment had also undergone portable appliance testing (PAT).
- Staff we spoke with stated that the contracted company were able to respond to the needs of the clinic should a piece of equipment require repair. The equipment for the satellite clinics were part of the equipment log and serviced on site.
- There was a spare ultrasound machine in case of failure to prevent delays for patients booked for scans.
- There was access to resuscitation equipment including an automated external defibrillator (AED). These devices are able to diagnose life threatening cardiac conditions in a patient, and enable treatment through defibrillation. MSI UK Resuscitation policy, dated August 2015, stated that any sealed bags / trolleys should have seals checked daily for integrity and then a full check monthly. Any unsealed equipment should be checked daily. Current guidance from the British Heart Foundation and Resuscitation Council states checks for AED should be undertaken regularly, (ideally daily).
- Monthly checks of this machine had been undertaken and an annual maintenance check completed.
- The theatre environment was visibly clean. Staff cleaned appropriately between patients and all equipment seen during the inspection was checked, serviced and readily available for use. The nominated individual self assessment (NISA) local action plan that was produced from the NI visit in October 2015 included a visual inspection of the premises. 84 recommendations were recorded that ranged from items such as a "broken towel rail" and "bin propping door open" to a "noncompliant theatre light". Data provided demonstrated that 61 of the tasks had been completed (72%) with the other 23 being marked as in progress where orders had been placed for items requiring replacement.

Medicines

- There were systems in place for medicine management. These included obtaining, recording, handling, storing and security of medicines. Daily monitoring and recording of the medication fridge temperatures, and ambient room temperatures where medications were stored, were in place and clearly checked and within normal limit range.
- The Clinical Operations Manager was responsible for medicine management. There was a medicines management policy in place however this was out of date having been due for review in March 2016.
- There were no controlled drugs stored or given in the clinic at the time of inspection. Doctors could prescribe medications remotely via an electronic system. Medication was given as per prescription and signed for electronically. Patients were prescribed antibiotics in accordance with local antibiotic formularies.
- Medications were stored securely in a locked cupboard within the recovery area. Registered nurses held the keys. There had been one incident reported on 25 January 2016 that "58 tabs of codeine missing". No actions, investigation or outcomes were recorded and therefore we could not be assured that steps had been taken to address this.
- We reviewed ten sets of patients' records. Staff had recorded patients' allergies clearly in the records and patients wore red wristbands to indicate a sensitivity or allergy.
- The last medicine audit overall compliance score was 94.7%. An action plan to improve compliance included topics such as instructing staff in rotation stock control

practices. Clinical staff received an update in medicines administration and controlled drug management on 2 February 2016. Staff evaluation of the standard of the training was positive and practices observed during inspection were in line with MSI policy.

- Staff we spoke with were aware of medicine management procedures and monitoring systems were in place to identify medication errors. There had been 17 medication errors reported as incidents between 24 March 2015 and 23 March 2016. Nine of the 17 related to missed medication, three related to dose not documented, four related to antibiotic prescription or delivery and one related to over dosage of paracetamol. Two of the missed medications related to the non-administration of Anti-D. Rhesus disease can largely be prevented by having an injection of a medication called Anti-D immunoglobulin (Anti-D ig). National guidance states that Anti**-**D Ig should be given to all non-sensitised RhD-negative women having a therapeutic termination of pregnancy.

Records

- Patient records were a combination of paper records and electronic records. Storage of paper records was secure behind the reception area or in locked boxes. Electronic records were password protected and access was limited to those staff with a right to access them.
- Staff stated that Marie Stopes International were investing in a new patient record system to provide more accurate data and support quality-monitoring practices for safe patient outcomes.
- The service provided staff with information governance and data protection practices training. Records showed that 96% of staff were trained in information governance and data protection practices.
- An electronic system was used for documenting patients' care during the operative phase. This included staff members, procedure performed, swab and instrument counts and implant details. Staff were observed to complete swab counts at the end of the operative procedure and record this appropriately on the electronic system.
- There was no hard copy theatre register or implant register. Best practice guidelines state that accurate recording is essential, including serial numbers and expiry dates of any implanted products. A member of staff stated that there had previously been diaries used as implant registers however this had lapsed and currently the stickers from implants were kept in a clear plastic bag, with the date and patient initials written on each sticker. This meant that should there be any errors with the computer system it would be very labour intensive to be able to track details of implants to patients.
- Staff undertook bi-monthly audits of 30 sets of notes. The audit included six sections: One Call booking, central records system (CRS) workflow, ultrasound scans, pre-operative, procedure and post-operative. Results for the last six months showed a compliance rate of 97%.
- We reviewed ten sets of patient's notes which staff had completed fully with appropriate patient risk assessments. Records included completed treatment decision flow charts, signed and dated consent forms for treatment and two independent signatures obtained to authorise the termination procedures.

Safeguarding

- Safeguarding policies and procedures were in place using the relevant guidance and legislation to underpin duty. However these had not been updated; for example the Working Together to Safeguard Children, which is a guide to interagency working, 2010 version was in use but this guidance was updated in 2015. The policy set out how health professionals working within Marie Stopes International worked together to safeguard and promote the welfare of vulnerable people and those at risk, and protected them from abuse.
- There was a corporate safeguarding adviser for additional support. Staff we spoke with at MSI Essex were aware of the need for appropriate reporting of FGM concerns including police and social services involvement to safeguard vulnerable women and children.
- Between 24 March 2015 and 23 March 2016 there had been 28 incidents resulting in safeguarding referrals. Five of the 28 related to FGM. Appropriate notifications were made and information provided to the patients and GPs where consent had been obtained. Following one incident relating to FGM in November 2015, an action identified was "staff to be informed of the new FGM policy" however we found no evidence of this policy in place.
- Not all staff had the appropriate level of safeguarding training to manage safeguarding issues. Training data provided did not distinguish between adult and children

safeguarding training. Data provided showed that six out of twenty seven staff had not received level 1 safeguarding training. Out of 17 clinical nursing staff (registered nurses and health care assistants) nine had not received level 2 safeguarding training (52%). The clinical operations manager had received level three training however records showed that they had not received level 2 training.

- The Intercollegiate Document for Healthcare Staff (2014) advises that "all clinical staff working with children, young people and/or their parents/carers and who could potentially contribute to assessing, planning, intervening and evaluating the needs of children and young people and parenting capacity where there are safeguarding/child protection concerns" should be trained to level three. This meant that there were insufficient numbers of appropriately trained staff to appropriately assess, plan, intervene and evaluate the needs of children and young people attending the service.
- Senior staff stated that safeguarding was discussed at every team meeting although this was not minuted. Staff we spoke with were confident to discuss concerns and said that peer involvement was encouraged where there was any doubt.
- The assessment for all patients under the age of 18 included a safeguarding proforma which had questions around relationships, contraception and safety. Staff gave examples of safeguarding concerns raised resulting from these initial assessments and the support mechanisms for vulnerable children. Children less than 13 years of age were not treated at the centre however staff were aware that if they requested treatment, given the fact that a child under 13 years of age is not considered in law to be able to consent to sexual activity safeguarding principles would be actioned including police and social services involvement. Staff knew about safeguarding practices for young women with a pre-existing mental health condition, those who were subject to sexual violence or poor social support, or where there was evidence of coercion. Thirteen of the 28 safeguarding incidents reported on the incident log related to vulnerable patients where concerns of abuse or possible coercion were identified.

Mandatory training

- There were four closure days per year to support staff to complete mandatory training and other activities such as reflection on practice. Topics for mandatory training included scanning, health and safety, fire safety, display screen equipment, COSHH, manual handling, infection control, safeguarding Level 1, safeguarding Level 2, intermediate and basic life support, information Governance and anaesthetic training.
- Staff we spoke with were clear about mandatory training and were positive about the last closure day in February 2016 which provided refreshers in medicine management, infection control, current practice updates and revalidation requirements.
- Simulation exercises had been actioned in February 2016 in line with the management of the deteriorating patient and response times were good.
- Data provided stated an overall mandatory training attendance for MSI Essex staff of 95% however this was not accurate. On review of the data, the totalled number of staff trained was incorrect and therefore the overall percentage arising from the totals was inaccurate.
- Training data provided demonstrated that 17 out of 27 (62%) staff had received life support training in 2015. The data did not clarify whether this was basic life support of intermediate life support. Five staff, including the clinical operations manager, had no date recorded for life support training. Three front of house staff had not applicable recorded against this training however this was not consistent, as five other front of house staff had received training.
- There was no information available locally to confirm that medical staff had undergone mandatory training. All medical staff were required to complete their mandatory training as for the other clinical staff. There was no evidence available to confirm that this occurred. No local checks of competency and training of clinicians were undertaken.

Assessing and responding to patient risk

- The majority of patients receive treatment under local anaesthetic or conscious sedation however on occasion a general anaesthetic may be necessary. Marie Stopes International provided a two-day introduction to anaesthetic course. We were concerned that a two day course would not be sufficient to fully equip nursing staff with the knowledge and skills to assist in an emergency situation of a patient with a difficult airway.
- At the time of inspection no member of staff at MSI Essex had undertaken the MSI anaesthetic course. Two

trained staff had previously been in place but had recently left MSI employment. We were not assured that there were staff on site with sufficient airway knowledge to enable prompt and competent support to the anaesthetist should a general anaesthetic be required and we raised our concerns to the senior managers on site. The clinic provided information that two members of staff were due to undertake the two-day course by the end of April 2016.

- There was a process in place to determine the level of patient risk and appropriateness for patients to receive treatment at MSI centres. Patients may either opt to have a telephone consultation carried out by a separate MSI team at the One Call centre, or face-to-face consultation at any MSI centre. A treatment decision flow chart was utilised to determine treatment options, and a pre-existing conditions (PEC) guideline was utilised to determine clinical risk.
- The PEC guideline clearly outlined referral options. If patients had any contributing pre-existing conditions, such as a high body mass index or ectopic pregnancy, they were referred to an NHS provider of termination services. If further information was required to complete the assessment, a referral was made to the patient's GP to request this information with the patient's consent. There was a dedicated team at the MSI One Call centre who would process these referrals and inform MSI Essex if the patient could be treated safely at the centre.
- Staff did not carry out the World Health Organisation (WHO) 'Five Steps to Safer Surgery' checklist appropriately. We reviewed ten records, spoke with staff and reviewed audit practices. All ten records reviewed had a completed hard copy checklist. However staff in the operating theatre were observed completing all aspects of the WHO 'Five Steps to Safer Surgery' checklist before the surgery had started. This included the 'sign out' and recovery sections. These sections are designed to record the correct number of swabs and instruments after a procedure had been conducted to ensure none were retained and also record any concerns in the recovery phase. Staff when questioned stated this was due to the speed of throughput of patients.
- The risk to patients of retained swabs was partially mitigated as staff were observed to complete swab counts at the end of the operative procedure and record this appropriately on the electronic system.
- The medical records' audit did not identify this practice. The audit entry stated "WHO Surgical checklist completed and signed" and we noted that this was included in the preoperative section of the records audit and not the procedure section. This was a quantitive audit only and as such did not identify any risk to patients. There were no observational quality audits to ensure that the check was completed appropriately. We raised this as a concern to managers on site.
- Patient records contained venous thromboembolism risk assessments (VTE) which staff completed prior to patients receiving surgery. The risk assessments informed staff if prophylactic treatments were required. Audits of pre-admission checks showed that VTE assessments were routinely completed. 5651 patients who underwent surgical abortion were risk assessed for VTE in last 12 months. 95% patients surveyed in December 2015 had VTE risks explained prior to procedure.
- We observed that all patients treated on the day of inspection had observations of pulse, respiration and blood pressure performed in theatre. A set of observations were then again performed postoperatively. The discharge policy was in draft, dated, April 2016, and had not been ratified. The appendix of this new policy included a discharge checklist. Staff we spoke with stated that patients were only considered for discharge once they had ate and drank, passed urine, if observations were stable and they were fully alert and orientated.
- The provider confirmed that anaesthetists left the MSI premises once the theatre list was finished and they had completed a final ward round. This meant nursing and healthcare assistant staff were left to monitor patients until discharge. There was no policy in place with regard to the management of deteriorating patients, in order to instruct staff about what process to follow when caring for patients post-surgery.
- There was a national early warning score (NEWS) chart in use to record patient observations during the medication phase of a late (staged) termination. A staged termination is a two-stage termination and is performed between 19 and 23 weeks + 6 days gestation. The first stage involves softening the cervix and the second stage is surgical removal of the fetus under

general anaesthetic. This meant that closer observation was in place during the presurgical stage of the termination. The NEWS chart had clear escalation steps to escalate any patient deterioration.
- There had been four emergency transfers to a local NHS hospital between 8 May 2015 and 29 December 2015. Two related to patients in excessive pain, one to haemorrhage and one for an ectopic pregnancy.
- The centre were currently reviewing and finalising the updated emergency patient transfer agreement with the local NHS hospital. The lack of a transfer agreement had been identified as part of the NI visit in October 2015 however this had not yet been finalised at the time of inspection. Once in place the agreement would include a direct line through to the admitting doctor to ensure a timely response when needed.

Nursing staffing

- Adequate staffing levels were in place at time of inspection. There was only one nurse vacancy at the time of inspection and staff turnover was low. All staff rotated from consultation to working in the theatre in order for them to have an understanding of the service provided and enable some flexibility in providing cover in the event of staff sickness.
- The total number of shifts of agency cover for registered Nurses in the three months prior to inspection had been 17.
- Staff highlighted long working hours as a frustration at times although they recognised the need for flexibility due to the demands of the job.
- Staff at the satellite clinics were working alone at times. A general lone worker policy was in place; however, further considerations on staff safety should be in place such as panic alarms and buddy systems as staff can be physically isolated with vulnerable women and their partners. Staff had not received any training on violence and aggression which should be in place to safeguard them.
- There had been nine incidents reported between 24 March 2015 and 23 March 2016 of incidents where patients or partners had become violent and aggressive, with one physical assault on a member of staff. A health and safety audit in April 2016 highlighted the need for this training to support the clinical staff.

Medical staffing

- Medical staffing was provided by doctors working both remotely and within the centre. The remote doctors were employed by Marie Stopes International (MSI); their role was to review patients' case notes and medical histories prior to signing the HSA1 forms and prescribing medications.
- Surgical lists occurred at the centre five days per week and an anaesthetist was always present. The anaesthetists work at other local trusts and MSI employs them on a sessional basis. Consultant urologists were also employed on a sessional basis to perform vasectomies.

Major incident awareness and training

- There was a contingency business plan in place in the event of an emergency. The centre had a backup emergency battery should the power fail and was classed as a priority for restoring failure with the power company should the need arise. There was no major incident policy in place.

Are termination of pregnancy services effective?

Our findings for effective were:

- Policies were not always updated to reflect practice changes in a timely manner. There was a lack of consultation and engagement of staff to support evidence based care practices.
- Staff were unable to provide us with an explanation or evidence of the decision making process behind the introduction of simultaneous drug administration for medical abortions. Staff could not assure us that the treatment was evidence–based.
- Minutes from the corporate clinical governance meetings did not consistently demonstrate effective reporting on patient outcomes to demonstrate effective practices. Quality dashboards with key performance indicators (KPI) to improve quality measurements were being introduced.
- We were not assured that staff taking consent had the appropriate knowledge, skills and competence to support patients who may be vulnerable or lack capacity to make a decision.

However:

- There was good collaborative working with external agencies such as the police, social services and staff at the local NHS hospital.

Evidence-based care and treatment

- Policies were accessible for staff however several policies were out of date for review. There was a lack of consultation and engagement of staff to support evidence based care practices.
- Staff we spoke with stated that senior staff utilised team meetings and closure training days to reemphasis the importance of keeping updated for effective practice.
- The service treated patients for early medical abortion (EMA) where pregnancy was confirmed by abdominal or transvaginal scan to be under nine weeks and three day's gestation. There were varied treatment options available for patients undergoing EMA. The option of simultaneous administration of medicines for EMA was introduced at the centre in March 2016, which was outside of the Royal College of Obstetricians and Gynaecologists (RCOG) guidelines 2011.
- If services offer treatment options that are not in line with the RCOG guidance then the provider should make sure that:
- The treatment / administration interval is evidence based
- The staff are informing patients of the most up to date information about risks and benefits so that they can make an informed decision.
- The provider is monitoring and auditing outcomes.
- MSI had started to offer simultaneous administration, with the patient taking both tablets at one appointment. Corporate emails and consent forms were circulated across the service locations regarding these practice changes, however the MSI EMA policy dated October 2015 had not been updated to reflect the introduction of simultaneous administration of medicines.
- Staff locally had not participated in the development and implementation of simultaneous administration of medicines which was a new treatment at the centre. They were unable to provide us with an explanation or evidence of the decision making process behind the introduction of the new treatment. Staff could not assure us that treatment was evidence–based.
- The regional manager and clinical operations manager were also unaware of the evidence behind this corporate decision. We could not locate, and staff could not direct us to, risk assessments, action plans for the evaluation of this treatment, or any evidence of outcome monitoring since the practice had changed. We raised this as a concern at the time of inspection.
- Marie Stopes International reached the corporate decision three days after the inspection, on 15 April 2016, to suspend the practice of simultaneous drug administration to enable a substantiating review to ensure best practice and support both patients and staff.

Pain relief

- Medical staff prescribed pre and post procedural pain relief on medication records. Non-steroidal anti-inflammatory medication and intravenous paracetamol was administered during the procedure. Non-steroidal anti-inflammatory medication is recognised as being effective for the pain experienced during termination of pregnancy. In addition, there were other medications that could be administered if patients still experienced pain.
- Staff measured the effectiveness of pain relief through a scoring system in the patient's notes and through questionnaires to patients following their surgery. Patients' comments did not highlight pain as a problem and the medical records audits we reviewed did not indicate a trend or poor pain management.
- However included in the vasectomy survey was a system for "red alerts". If a problem was identified the survey was red alerted and sent to the centre for investigation. In Q3 MSI Essex had one red alert out of 19 responses, results demonstrated a score of 37% for pain during procedure and 42% for how the procedure matched the patients' expectation. There were no red alerts for MSI Essex in Q4.
- There had been two incidents recorded on the electronic system, one in August 2015 and one in September 2015, where a transfer to a NHS trust had occurred due to a patient having prolonged pain. The incident log recorded that a low level investigation took place but no other specific details were recorded.
- Staff provided patients advice on discharge regarding the type of pain relief to take should they require it.

Patient outcomes

- The centre benchmarked itself against the Department of Health Abortion statistics produced annually. The centre performed 2354 early medical terminations and

5651 surgical terminations between January and December 2015 and the key performance indicators and monitoring systems showed effective outcomes for the vast majority of patients. However monitoring was not in line with the Required Standard Operating Procedures (RSOP) 16: performance standards and audits.

- Senior staff stated that on a quarterly basis, clinical reports were produced, for example, the failure rate by surgery and medical treatments, infection rates and patient transfers, including reasons. These numbers were converted into rates which allowed trend analysis against previous results centrally. However we reviewed minutes from the corporate clinical governance meetings which did not consistently demonstrate effective reporting on patient outcomes to demonstrate effective practices.
- Quality dashboards with key performance indicators (KPI) to improve quality measurements were being introduced. Staff we spoke with were familiar with these monitoring practices although they stated they were not reported consistently for comparison. For example two KPI results for November 2015 were displayed, patients that did not proceed (DNP) result was 18%, against a target of 14%, and patient flow, 106 minutes against a target of 110 minutes. However there was no other data which meant staff could not see whether there was an improving or worsening picture.
- The clinical commissioning groups (CCG) set MSI Essex targets. Key performance indicators included the take-up of long acting reversible contraception (LARC) and screening or risk assessment for sexual transmitted infection testing (STIs). The centre performed well in both areas achieving 52% LARC against a target of 50% and STIs 80% against a target of 70% in December 2015.
- There was an annual audit schedule for MSI Essex and the NI visit on 20-22 October 2015 was utilised to monitor compliance and produce action plans to improve effectiveness. Out of 63 identified recommendations from the Nominated individual self assessment (NISA) local action plan 29 had been marked as completed (46%). However some actions lacked detail including nominating designated owners for tasks and timeframes.
- Some actions that had been identified were additional guidance on the Mental Capacity Act in the form of pocket guides and face-to-face training in violence and aggression to be sourced.
- Senior staff stated that the team held regular discussions to ensure patients' care and treatment was coordinated to achieve the expected outcomes..

Competent staff

- Staff we spoke with stated there was a procedure in place for the recruitment and induction of new staff. A recent employee explained that the induction programme covered such topics as policies, treatment types, fire safety, health and safety and confidentiality. Shadowing provided support to new starters and encouraged integration and all staff were required to rotate and work in all areas.
- It was reported that all clinical staff received a welcome pack on induction which included a training framework, however, there was minimal training competency framework information available on site.
- Data provided on the training matrix included some competency data however this was vague, with just a "Y" or "N" indicated against and individuals name with topics such as scanning, ward, theatre, MA1st and MA 2nd. Staff we spoke with stated that experienced staff assessed new staff competency and provided additional one to one training if necessary. However there was no evidence provided of competency documentation, when and how competency was achieved or that those staff acting as mentor were appropriately trained to do so.
- Nursing staff we spoke with confirmed that there was a system of appraisal where they could identify learning needs. Registered staff stated that the introduction of monthly reflections of their practice was to support the revalidation process.
- Information provided prior to inspection stated that 100% of medical staff, 80% of nursing staff and 80% of administrative staff had undergone appraisal between January and December 2015.
- There was no information available locally to confirm that medical staff had undergone clinical appraisal. Anaesthetists were employed on a sessional basis. Anaesthetists' revalidation should be undertaken in the NHS hospital where they had main employment. This was then reviewed by the corporate health systems director of MSI to ensure it was complete. Surgeons were employed by MSI. Appraisals and competency assessments were carried out by the lead clinician for

Marie Stopes International. Whilst this was the process, there was no evidence available to confirm that this occurred and no local checks of competency of clinicians were undertaken.

Multidisciplinary working (related to this core service)

- Staff stated that there was good liaison with allied health professionals (AHP) to support an integrated care pathway for patients. They said medical input was good and liaison with GPs was satisfactory. Care pathways were in place to ensure that following a termination procedure women were only discharged once any necessary requirements for ongoing post procedural care was in place such as counselling follow up appointments and future contraception.
- Staff gave examples of collaborative working with external agencies such as the police, and staff at the local NHS hospital to support emergency transfers and referrals for safeguarding vulnerable adults and children. The incident log also gave examples of interactions and collaborative working with social services to safeguard vulnerable women who were at risk of domestic abuse or sexual exploitation.

Seven-day services

- The centre did not operate seven days per week; however patients had access to the MSI 24 hour helpline. If necessary, the call centre could access appointments at the centre for the patient to be assessed, including ultrasound investigation.

Access to information

- RCOG guidance sets out in recommendation 8.2 that "On discharge, all women should be given a letter providing sufficient information about the procedure to allow another practitioner elsewhere to manage any complications."
- Staff we spoke with stated that patients' consent was sought to inform their GP following the procedure. If consent was denied patients were given a letter to give to a health care professional in case of complications, but we did not see this in practice.

Consent, Mental Capacity Act and Deprivation of Liberty Safeguards

- MSI provided consent training to both registered nurses and health care assistants. Data provided in the training matrix demonstrated that six out of 15 staff (40%) had completed MSI training for consent, three were in process and six had not received the training. None of the staff had received safeguarding training at level 3 this meant that we were not assured that staff taking consent had the appropriate knowledge, skills and competence to support patients who may be vulnerable or lack capacity to make a decision.
- Bi annual medical records audits monitored compliance with consent practices. The audit encompassed a quantative check of 30 patient records and included:
  - All consents are signed, logged and noted
  - Consent reaffirmed
  - Anaesthetic choice has been logged and noted

However there was no section included in the records audit to consider either consent for children and young people, assessment of capacity to consent.

- Staff we spoke with said that if females under the age of 16 years attended, they were encouraged to involve a parent or guardian and that staff applied the Fraser guidelines for checking rationale and understanding when obtaining consent from girls under the age of 16. Fraser guidelines are used specifically to decide if a child can consent to contraceptive or sexual health advice and treatment.
- Incidents were reported when concerns around consent where recognised. There had been two incidents reported between 24 March 2015 and 23 March 2016 where terminations did not take place. "Did not proceed" due to cultural influences was recorded and appropriate referrals had been made. There were also two further incidents where it had been recorded that the patient was uncertain of their decision and counselling, support and appropriate referrals had been put in place.
- There were consent forms in place for contraception options and the supply of chosen method and testing for sexually transmitted infections.
- The ten care records we reviewed contained signed consent forms from patients for the procedures and in some cases where women had agreed to contraception implants. Possible side effects and complications were recorded.
- Pocket sized Mental Capacity Act guidance had been distributed to all staff at the time of inspection for information

Termination of pregnancy

Are termination of pregnancy services caring?

Our findings for caring were:

- Patients were positive about the care provided, which they noted was patient centred.
- Staff offered a good service and were helpful, caring and treated patients with dignity and respect.
- Staff adopted a non-directive, non-judgemental and supportive approach to women receiving treatment for termination.
- MSI Essex scored 96% for the overall service rating of very good or excellent in patient satisfaction surveys.
- Staff knew of the range of emotional responses that women could experience during and following an abortion.

Compassionate care

- Staff were polite and helpful to patients both in person, attending at the reception desk, and on the telephone. We observed that staff treated patients and partners with dignity and respect. Reception staff were careful when speaking on the telephone not to repeat any personal information. If patients wanted to discuss sensitive issues or appeared distressed they could offer them a private room to discuss their needs.
- Marie Stopes UK action quarterly patient satisfaction surveys, to establish whether they are meeting the individual needs of people who use the service. The surveys included comparative analysis to measure improvements month on month but also to compare the performance across the different Marie Stopes centres. MSI Essex scored 96% for rating the overall service at very good or excellent in both Q3 (July to September 2015) and Q4 (October to December 2015) which was slightly above the national average of 95%. The patient comments supported this finding.
- Patient comments and the satisfaction surveys were mainly positive such as:

- 96% patients satisfied with information provision.
- 95% patients were satisfied with how well the service understood their needs
- 96% patients were satisfied with the overall quality of care they received.
- There were improvements seen in the comparative data, of the patient satisfaction survey, where scores had been below target. For example In Quarter 2 (April to June 2015) the result for the amount of time and attention given to patients was 82%, this had increased to 91% in Q3 and 93% in Q4. Similarly the way patients were greeted on arrival had been 88% in Q2, 89% in Q3 and 93% in Q4.

- MSI actioned separate quarterly patient satisfaction surveys for vasectomy patients. In Q4 98% of patients were completely satisfied with the service they received and100% would recommend MSI Essex to others. The recent patient comments cards supported this finding.

- Patients commented that the doctors and staff were professional and compassionate.
- Relatives, partners or friends were able to accompany patients during consultations and treatments; however they were unable to accompany during the surgical procedure to protect others privacy and dignity.

Understanding and involvement of patients and those close to them

- We reviewed 61 patient comments cards submitted the week prior to inspection. There were positive views from all the patients about the care provided, comments noted that care was patient centred. Comments also included that staff were helpful, caring and treated patients with dignity and respect.
- Patients, including those undergoing vasectomy, also commented that they were satisfied with information provision and felt involved in the decision making process. Patients noted that staff adopted a non-directive, non-judgemental and supportive approach to women receiving treatment for abortion.
- During inspection we observed that staff introduced themselves to patients. In theatre patients were introduced to all healthcare professionals involved in their care, and were made aware of their roles and responsibilities within the theatre environment.
- One patient told us they were fully informed regarding the different options and that the staff were very supportive.

Emotional support

- RSOP standard three requires that there are protocols in place to support women following a termination, including access to counselling and support services.

Staff we spoke with stated that all women requesting a termination would be offered the opportunity for emotionally support from a trained pregnancy counsellor. This would be offered at any time pre or post termination. This was completed either face to face or by telephone by staff at the One Call centre. Staff could describe the range of emotional responses that women may experience during and following an abortion.

- Data provided prior to the inspection stated that "client's aged under 16 are required to have a counselling appointment on a day prior to their treatment"..
- Following an incident where a patient was indecisive regarding treatment, records demonstrated that three counselling sessions within MSI were provided and then additional support was sought from an external crisis centre.

Are termination of pregnancy services responsive?

Our key findings for responsive were:

- Services were planned and delivered in a way that met the needs of the population
- The service reflected the importance of flexibility and choice for patients.
- Commissioners and stakeholders were involved in service planning.
- Between January and December 2015, no patients waited longer than 10 days from first appointment to termination of pregnancy unless they requested a delay.
- Staff managed patient flow through the centre well and in November 2015 the average patient time spent in the centre was 106 minutes (against a target of 110 minutes)
- 95.9% of patients were satisfied with the process for booking appointments and comparative analysis indicated a year on year improvement
- Translation services were available for patients who did not have English as a first language.

However

- Data from Q4 (October to December 2015) patient satisfaction survey showed that only 68% patients felt informed about delays during their visit.

Service planning and delivery to meet the needs of local people

- Services were planned and delivered in a way that met the needs of the local population. The importance of flexibility, choice and continuity of care was reflected in the services provided.
- MSI provides a service 24 hours a day, 365 days a year. There was a contact 0345 number which was included in free call packages from landline and mobiles. Women could also access the service by email, text and by a website enquiry form which provided patients with timely access to appointments.
- Clinical commissioning groups (CCG) fund the majority of patients. Commissioners and stakeholders were involved in service planning. The growth of the "Early Medical Units" (EMU) in the community had seen a slight reduction of medical terminations within the Essex main centre.
- Senior staff at MSI Essex said that future service planning included a revised structure to include district nurse teams with a designated manager providing leadership and support to manage the satellite EMUs and the increasing demand for earlier terminations.

Access and flow

- Marie Stopes International had a dedicated team who monitored and managed capacity on a daily basis via the wait times monitoring systems. The business support team (located in the main MSI support office) provided daily reports on wait times and worked with the centre team to ensure patients were offered a range of treatments within three working days.
- The opening days and times of MSI Essex were designed to ensure short wait times and allow access to the full range of services. Between January and December 2015, no patients waited longer than 10 days from first appointment to termination of pregnancy unless they requested a delay. The vasectomy service occurred on a separate day to the termination of pregnancy services; this ensured that males and females did not meet during their treatments.
- Front line staff were aware of the importance of flexibility to enable appointments to be re-arranged at very short notice to meet the needs of the patient. There were instances of staff sickness that resulted in satellite clinics being cancelled. Staff stated that when this occurred the patients were offered alternative sites and

appointments straight away. 95.9% of patients were satisfied with the process for booking appointments and comparative analysis indicated a year on year improvement.

- Staff managed patient flow through the centre well and in November 2015 the average patient time spent in the centre was 106 minutes (against a target of 110 minutes). However patient satisfaction survey results remained below target in Q3 and Q4 in relation to how satisfied patients were with the total length of time spent at the centre. Results for Q3 were 79% and 87% in Q4 against a target of 90%.
- Another aspect of the patient satisfaction survey that rated red in both Q3 (64%) and Q4 (68%), against a target of 90%, related to how informed the patient was about delays during their visit. When questioned senior staff stated they were looking at possible improvements such as electronic sign posting in the waiting areas and heightening staff awareness at meetings.

Meeting people's individual needs

- MSI Essex was equipped with a small private room where young people and vulnerable adults could be taken ensuring a discreet service and the room was purposefully 'non-clinical'.
- Staff we spoke with said that if a health condition related to mental health and capacity issues the centre would work with the relevant agencies and principle care workers to ensure that the patient experience and care pathway fulfilled the physical and mental health needs. Treatment options were presented to the patient determined by their specific needs and requirements. For example domestic abuse or drug abuse etc. would be referred or sign posted. However there was a lack of 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.
- Patients were informed of the options for the disposal of pregnancy remains on request, however very few patients requested the information. A patient information leaflet was provided which details the options available.
- Staff we spoke with said that patients were advised what documentation was required in order to procure a cremation or burial. Where possible (and with the patients permission) the centre liaised with the funeral directors to facilitate as smooth a process as possible to alleviate stress.
- There was a policy and procedure in place for the disposal of fetal remains (MSI UK Management of fetal tissue policy dated June 2014) which complied with the Human Tissue Authority Code of Practice. Inspectors observed the storage and labelling processes on site which complied with MSI policy. Staff documented any non-standard disposal option in the patient's record and on a freezer log sheet indicating the reason for storage and date for either collection or disposal. Products were only released to the patient or the police once stringent checks had taken place. Where products remained uncollected, staff would contact the patient, if appropriate to do so, to ask for further instruction. If not senior staff would make a decision to dispose of products after three months.
- There was written information for patients and partners explaining what to expect during and after the abortion (to include potential side effects, complications and any clinical implications).
- Translation services were available for patients who did not have English as a first language. Notices were displayed in the reception areas informing patients this service was available.

Learning from complaints and concerns

- There was a complaints procedure in place. Complaints advice was given in the back of the patient literature and also displayed in the patient information folder in waiting areas. The Regional Managers contact details were available in reception, along with CQC information leaflets on 'how to make a complaint' if patients were not satisfied with the centres response.
- MSI Essex had received 12 complaints between January and December 2015 which were benchmarked for trends with other centres via the incident reporting system. There were very few complaints about the service or staff members. One of the regular complaints was about the waiting times at the centre which resulted in the removal of the standard "20 minute late rule" which allowed patients to be 20 minutes late, as this was impacting on patients who turned up on time and would cause delays. Following the change any patient arriving late was managed on an individual basis and accommodated on the day where possible.

- Issues could also be raised via the patient feedback questionnaires and would prompt a "red alert" for individual locations. Senior staff reported that positive and negative feedback was communicated at team meetings and the feedback reports received quarterly were shared with the team although this was not evident in the meeting minutes seen.

Are termination of pregnancy services well-led?

Our key findings for well led were:

- Marie Stopes International provided MSI Essex with an Integrated Governance Framework which was not being measured against the most up to date standards.
- There were gaps between the governance processes at corporate and location level in communication and engagement.
- 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.
- There was no effective system to ensure action plans arising from incidents, local audit or NI visits were completed, reviewed and re-audited to improve patient safety and quality of care.
- 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.
- Local audit process to ensure completion of HSA1 forms only included a check that the form was completed and signed. It was not a qualative check of the process.
- There was no process for monitoring submission of HSA 4 forms to the Department of Health to ensure this had been undertaken within the legal timeframe.
- The culture was viewed as being top down and corporately led. Senior staff did not always feel they had a strong voice at corporate level.

However;

- The service had a vision; core values and strategy.
- Staff knew the values and each had a general understanding of the overall strategy in place.
- Staff were complimentary about the current leadership team at MSI Essex. They stated they were visible and approachable and were open to new ideas and changes.

Vision and strategy for this this core service

- The vision and strategy of MSI Essex was to deliver high quality care promote good outcomes for patients and encompass key elements such as compassion, dignity and equality.
- The service had shared the values and objectives with staff and overall staff knew of the vision and strategy in place for the centre. Each member of staff had a general understanding of the overall strategy in place.

Governance, risk management and quality measurement for this core service

- Marie Stopes International provide the Essex centre with an Integrated Governance Framework in line with the NHS governance agenda and the CQC Essential Standards of Quality and Safety. However the CQC Essential Standards of Quality and Safety were replaced by the fundamental standards in 2014, this meant that provider was not measuring performance or quality against the most recent standards.
- Data provided prior to the inspection stated that the corporate Integrated Governance Committee (IGC) meets three times a year and reports directly to the MSI Board. Local IGCs meet four times a year. On a quarterly basis MSI UK Governance Support Team produces and shares national clinical governance reports with the Essex Centre to support governance, risk management and quality measurement practices. However no local IGC minutes were provided. We reviewed the corporate ICG minutes of meetings between February 2015 and January 2016 and found there was no consistent joined up approach to reporting and monitoring.
- There were gaps between the governance processes at corporate and location level in communication and engagement. For example, 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. Whilst there had been email

exchanges and updates to the consent form, the guidelines and protocols had not been amended and the research was not referenced accordingly to justify the practice change. Staff had not been formally engaged or involved prior to implementation and written information provision for women regarding this new treatment option was lacking. There were no audit outcomes or evidence based information on site to show this practice was recognised or benchmarks set so that improvements in practice could take place. There was no evidence in the minutes submitted corporately that this new practice had been discussed and approved formally prior to implementation.

- Standardised Integrated governance meeting templates were being introduced. It had been minuted in the corporate IGC meeting in January 2016 that it would be the last meeting using the old format.
- The provider carried out a series of "nominated Individual visits" (NI) that comprised of two days of assessment at individual locations. The individual locations then utilise a nominated individual self-assessment tool (NISA) following the NI visit to action and monitor recommendations for improvement. MSI Essex NI visit occurred on 20-22 October 2015 and a local (NISA) action plan had been created to address non-conformances, however there was no effective management process in place to ensure action plans were completed, reviewed and audited. For example it had been highlighted that a revised transfer agreement with a local NHS hospital required review and sign off however this was still in the process of being actioned during the inspection nearly six months later.
- 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. Medical staff were being asked to sign between 30 and 60 HSA1 forms at a time, some for the next day, or two to three days or a week in advance. Surgeons and anaesthetists were requested to do this as the demand was too great for remote doctors.
- Five medical staff were interviewed and we were informed by them that HSA1 forms were being signed based on the 'reason for termination' information only, which was printed or handwritten on the back of the form. We were not assured clinicians had access to all relevant information to enable a decision of opinion in good faith. Only one out of the five doctors stated that they reviewed the patients' medical history on the computer system prior to signing the HSA1 form.
- We reviewed seven job role descriptions which were limited in content. Completion of HSA1 forms was mentioned specifically in job plans for remote doctors, surgeons and anaesthetists. We noted that there was no allowance for time taken to review medical history and other information, as relevant, within these specific job plans.
- Medical staff rotate around various MSI centres and stated that this was common practice. Two doctors stated they had raised concerns with MSI centrally and were assured by the medical director in post at the time that this was acceptable practice.
- Medical record audits were completed biannually and included the measure of "HSA 1 complete and legible and complete with two signatures". However this did not identify any of the concerns raised by medical staff as it was an audit of the completed forms rather than the process. We were also concerned that there was a lack of assurance that two signatories had been obtained before the abortifacient medication was prescribed and again the audit was not effective in providing assurance in this regard.
- There was no process or monitoring system in place at MSI Essex to ensure that the submission of HSA 4 forms to the Department of Health had been undertaken within the legal timeframe.

Leadership / culture of service

- It had been identified as part of the NI visit in October 2015 that the clinical operations managers in post at that time were in the process of applying to be registered managers however CQC records could not

establish that this had taken place. At the time of inspection there was a newly appointed clinical operations manager who was yet to apply as registered manager. They were being supported by the previous manager who had just recently been promoted to regional manager.

- Staff we spoke with viewed the culture as being top down and corporately led. Staff did not always feel the centre had a strong voice at corporate level. However staff were complimentary about the current management team on site. They stated they were visible and approachable and were open to new ideas and changes. Staff felt they could raise concerns and that these would be acted on.
- There was evidence of recent efforts to improve communication. Individual staff pigeonholes and engagement groups had been introduced.
- Staff talked about their commitment to ensuring patients were looked after in a safe and caring manner and clinical staff were proud of the service provided at the centre.
- The clinical operations manager and regional manager recognised that the seven satellite (EMU) sites required stronger leadership and staff support to manage increasing demands, maintain stability and consistency. They were hopeful that this would improve with the new structure which was planned for May 2016.

Public and staff engagement

- All patients including those undergoing a vasectomy were given a questionnaire during their stay and quarterly reports were produced by an external company. October to December 2015 showed MSI Essex scored between very good and excellent overall, with the majority of scores in line with other MSI centres.
- Staff felt valued by the current management team and listened too. An internal staff magazine had been introduced in winter 2015 which included feedback from the communications and engagement corporate committee which had staff representatives to raise issues such as lone worker policy and expenses. There were also staff awards where staff could nominate someone who embodied the key values and behaviours of the organisation.
- There had been a regional conference in December 2015 where staff had the opportunity to engage and feedback on practices. Staff had received an update by the director of commercial operations which included actions being taken to address issues raised such as a new rota system to produce rotas in a timelier manner.

Innovation, improvement and sustainability

- Senior staff at MSI Essex recognised the challenges in the future such as, insufficient clinic space, increasing patient demand and a more flexible approach needed for EMUS in the local communities. They stated that the plan was for continuous improvement through increased leadership support and staff development to manage increasing demands for the services going forward.

Outstanding practice and areas for improvement

Areas for improvement

Action the provider MUST take to improve

- Ensure that there is an effective process for incident reporting and that recording is consistent to enable analysis of data to highlight areas of improvement.
- Ensure a consistent approach to action planning and ensuring lessons learnt from incidents are shared with all relevant staff locally.
- Ensure that senior staff involved in the investigations have access to formal training in root cause analysis to support the risk management process.
- Ensure that hard copy documentation in relation to the World Health Organisation (WHO) 'Five Steps to Safer Surgery' checklist is completed accurately and used appropriately at each phase of the surgical procedure.
- Undertake improvements in corporate and location level communication and engagement to ensure evidence based care can be demonstrated at all times.
- Ensure that there are competent and appropriately trained staff on site with sufficient airway knowledge to enable prompt and competent support to the anaesthetist.
- Establish an effective system to ensure and demonstrate that staff are competent and qualified to carry out their roles safely and effectively in line with best practice.
- Ensure an effective system is in place for risk management and quality improvement. Including effective local audit process to ensure care is provided in accordance with legislation and best practice guidelines.
- Ensure that there are effective processes in place to ensure that the certificate(s) of opinion HSA1 form are signed by two medical practitioners in line with the requirements of the Abortion Act 1967 and Abortion Regulations 1991.
- Ensure that there is an effective process for submission of HSA 4 forms to the Department of Health within the legal timeframe of 14 days.
- Ensure that there are effective infection prevention controls and systems in place to lower the risk of infection and drive improvement.
- Review the practice of open storage of multiple surgical termination products in a single container and amend policy and guideline to ensure good infection control practice.

Action the provider SHOULD take to improve

- Ensure that specific lone worker staff safety risk assessments are in place for the satellite units. Staff should receive training on violence and aggression to safeguard them.
- 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	Regulation
Surgical procedures Termination of pregnancies Treatment of disease, disorder or injury	Regulation 12 HSCA (RA) Regulations 2014 Safe care and treatment (1) Care and treatment must be provided in a safe way for service users. (h) assessing the risk of, and preventing, detecting and controlling the spread of infections, including those that are health care associated. Not all infection prevention and control process followed standard practice. Handwashing practices audit results in February 2016 had been poor (43%) The appointed lead for infection prevention and control (IPC) had not received MSI infection control training. Staff were observed to rinse surgical instruments prior to decontamination in a sluice area adjacent to the theatre. This was not documented standard practice within the MSI decontamination policy.