Marie Stopes International Norwich 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 Norwich on 6 May 2016. This service was inspected as part of a wider programme to inspect providers of acute independent healthcare.

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

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

Are services safe at this service?

There was an inconsistent approach to action planning and ensuring that lessons learnt from incidents were shared with all relevant staff locally. There were no effective systems to monitor and manage risks. Incidents were not a standard agenda item on staff meetings to heighten awareness and enable shared learning.

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, and 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.

Staff did not have the appropriate level of safeguarding training to manage safeguarding issues. There were no staff trained at level three working at the centre which 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.

Satellite units had no processes in place to ensure the safety of staff. Staff had not received any training for dealing with situations of violence and aggression.

Regional staff from other Marie Stopes centres made up approximately 50% of the workforce. Staff we spoke with highlighted long working hours as a frustration at times although they recognised the need for flexibility due to the clinical demands of the service. The managers recognised that recruiting more local staff for continuity and stability would be beneficial and were currently advertising.

Infection control audit results were poor and there was no clear action plan available to improve scores and lower the risk of infection.

Staff were not trained to recognise and respond to a deteriorating patient. The resuscitation policy stated that resuscitation drills, delivered by an external company, should be carried out every three months. A simulation had taken place in MSI Norwich on the 25 February 2016 and the result had been significantly poor, with a score of 14 out of 34. This indicated a high risk with urgent action required. It was recommended that a repeat scenario take place in two weeks however, this was not undertaken until May 2016.

There were no effective systems in place for equipment maintenance. There were no visible labels on equipment to identify service dates and no records were held of any equipment checks at the satellite units.

There were systems in place for medicine management that included obtaining, recording, handling, storing and security of medicines.

Are services effective at this service?

Summary of findings

Policies were accessible for staff but were not 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.

There was limited accessible evidence on site or from requests to the corporate HR department to show how competent and qualified the centre staff and regional staff working at the centre were to carry out their roles effectively in line with best practice.

The number of staff receiving continual professional development was unclear because mangers could not access information from the corporate system and there was no data provided regarding clinical appraisal rates.

Only 40% of the centre staff had received consent 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.

The centre benchmarked itself against the Department of Health Abortion statistics produced annually. The centre performed 535 early medical terminations and 723 surgical terminations in the last year 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.

Are services caring at this service?

Patients were positive about the care provided by staff and those we spoke with felt that care was individually centred. Staff were observed to be 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.

Marie Stopes Norwich scored the national average for rating the overall service at 95% very good or excellent in patient satisfaction surveys.

RSOP standard three requires that there are protocols in place to support women following a termination. This includes the provision of sufficient information, counselling and support services and consent to share information with their GP and the Department of Health. Staff we spoke with stated that women would be offered access to a counsellor should they require it, however this was not seen in practice during the inspection. Staff were aware of the range of emotional responses that may be experienced during and following a termination of pregnancy.

Are services responsive at this service?

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

Patient flow through the centre was compromised at times. There were periods of extended waiting times due to the lack of recovery space causing theatre backlogs. The average patient time spent in the centre was 107 minutes in March 2016 (against a target of 95 minutes).

Senior staff stated that future service planning included consideration of a second weekly surgical list to reduce waiting times and improve capacity management and patient flow through the centre.

Translation services were available for patients who did not have English as a first language.

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

Are services well led at this service?

Summary of findings

Marie Stopes International provided the Norwich centre with an Integrated Governance Framework which they stated was in line with the NHS governance agenda and the CQC Essential Standards of Quality and Safety. There were gaps between the governance process at corporate and location level in communication and engagement which needed to be addressed to ensure evidence based care can be demonstrated at all times. The CQC Essential Standards of Quality and Safety were replaced by the fundamental standards in 2014.

There was no effective system in place to ensure action plans were completed, reviewed and audited to improve patient safety and quality of care.

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. The local audit process was not specific enough to identify the practice. The audit results were based on a quantative measure only that HSA1 forms had two signatures.

We were informed by clinicians that bulk signing of HSA1 forms, of between 30 to 60 forms at a time, was undertaken. Surgeons and anaesthetists were requested to do this as the demand was too great for remote doctors and we were informed by doctors that HSA1 forms were being signed on the basis of 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.

There was no process in place for assurance that HSA 4 forms were submitted to the Department of Health within the legal timeframe of 14 days.

Leadership had been inconsistent with six different managers at MSI Norwich in the last three years. Staff stated that this had affected continuity and stability for the clinical teams. The culture was viewed as being top down and corporately led. Teambuilding was difficult due to approximately 50% of the staff, at times, coming from other centres and the lack of leadership on site had reduced staff morale. There was evidence that this was being addressed with the introduction of new managers, attempts to recruit local staff and through communication and engagement groups. Staff told us they did not feel valued by the organisation although they found the new managers on site supportive and approachable.

Marie Stopes Norwich did not have a formal strategy although staff were clear about supporting the patients to deliver high quality care, promote good outcomes for patients, and encompass key elements such as compassion, dignity and equality.

We saw several 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.
- 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.
- Ensure that all equipment at MSI Norwich and the EMU has been serviced and is in good working order.
- Ensure there is an effective system in place to record and monitor servicing and maintenance of equipment.

Summary of findings

- Improvements in corporate and location level communication and engagement, should be addressed to ensure evidence based care can be demonstrated at all times.
- Establish a robust 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 staff have regular appraisals to establish continual professional development requirements to ensure staff have the right skills to perform their job role.
- Ensure a robust 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.
- Ensure the quality of photocopied templates (flow charts) is improved to enable clarity of patient records.

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

Summary of findings

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Background to Marie Stopes International Norwich Centre

Termination of pregnancy (TOP) refers to the treatment of termination of pregnancy, by surgical or medical methods. Marie Stopes UK International (MSI) Norwich is part of the provider group Marie Stopes International. MSI Norwich was commissioned and commenced services on the 1 October 2013 in line with a tender award for Norwich clinical commissioning group (CCG), North Norfolk CCG, South Norfolk CCG and West Norfolk CCG.

MSI Norwich 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 Norwich also provides services via three early medical abortion units (EMU) known as satellite units situated in Cambridge, Kings Lynn and Thetford. 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 license from the Department of Health (DH) to undertake termination of pregnancy services in accordance with The Abortion Act 1967. Services are provided to both NHS and privately funded patients. An additional EMU unit in Peterborough is planned and due to open in June 2016 to provide a vasectomy service bi–monthly, a further EMU in Cambridge is licenced but is not currently being utilised.

Patients of all ages, including those aged less than 18 years are seen and medically treated at all of the locations, however surgical intervention only takes place at MSI Norwich, with one surgical list a week. Counselling services are offered to all patients, before and after treatment, and are provided face to face or by telephone. Appointments are made through a 24hour registered pregnancy advisory centre (MSI One call centre).

The building is based in Norwich community hospital and the premises was originally shared with Norfolk foot surgery service. MSI currently have sole use of the building, however this may change in the future. They currently have two consulting rooms, one theatre, one screening room and nine 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

Our inspection team was led by a CQC Lead Inspector and included an additional inspector.

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 Norwich on 6 May 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.

Summary of this inspection

We spoke with 12 staff members including managers, doctors, registered nurses, health care support workers and administration staff. We reviewed the care records of two patients undergoing surgical termination of pregnancy. We observed interactions and communication with patients and those close to them and spoke with seven patients during our 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 Norwich Centre

MSI Norwich is a clinic that provides termination of pregnancy and family planning services to private and NHS patients. It has two consulting rooms, one operating theatre and nine day care 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 1 March 2015 and 29 February 2016 the centre performed 535 medical terminations (42%) and 723 surgical terminations (58%) and 677 medical terminations at the EMUs. 17 terminations during this period were above 20 weeks gestation.

No children under the age of 13 were treated at MSI Norwich however there had been children treated between 13 and 15 years between March 2015 and February 2016, exact numbers were not provided.

The centre operates two days per week (Thursday and Friday) and provides surgical termination of pregnancy to 23 weeks + six days and medical termination to nine weeks + four days. At MSI Norwich surgical termination is carried out either under general anaesthetic, conscious sedation, by vacuum aspiration or dilatation and evacuation.

At the time of inspection there was no registered manager in place. An application had been submitted to CQC in April 2016 for the regional manager to become the registered manager; this application was approved on 15 July 2016. This individual is also registered manager at MSI Maidstone.

There was a newly appointed clinical operations manager in post. They were responsible for the day to day management at MSI Norwich and they were being supported by the regional manager.

Information provided by MSI Norwich prior to the inspection indicated that the new clinical operations manager would be applying in the future as a second registered manager but this had not yet taken place.

Staff employed consisted of two medical doctors (wte 0.2), two registered nurses (wte 1.6) and one administration staff (wte 0.6).

Termination of pregnancy

Safe	
Effective	
Caring	
Responsive	
Well-led	

Summary of findings

There was an inconsistent approach to action planning and ensuring that lessons learnt from incidents were shared with all relevant staff locally. There were no effective systems to monitor and manage risks. Incidents were not a standard agenda item on staff meetings to heighten awareness and enable shared learning.

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, and 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.

Staff did not have the appropriate level of safeguarding training to manage safeguarding issues. There were no staff trained at level three working at the centre which 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. At the time of inspection the clinical operations manager was only trained to level one safeguarding.

Regional staff from other Marie Stopes centres made up approximately 50% of the workforce. Staff we spoke with highlighted long working hours as a frustration at times although they recognised the need for flexibility due to the clinical demands of the service. The managers recognised that recruiting more local staff for continuity and stability would be beneficial and were currently advertising.

Infection control audit results were poor and there was no clear action plan available to improve scores and lower the risk of infection.

Staff were not trained to recognise and respond to a deteriorating patient. A resuscitation simulation had taken place in MSI Norwich on the 25 February 2016 and the result had been significantly poor and had indicated a high risk with urgent action required. However there was no evidence that actions had been taken to address this or to act upon recommendations.

There were no effective systems in place for equipment maintenance. There were no visible labels on equipment to identify service dates and no records were held of any equipment checks at the satellite units.

Policies were accessible for staff but were not 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.

Information provided prior to the inspection did not include any appraisal data for staff. Managers could not access information from the corporate system and no records were held locally to show how competent and qualified the centre staff and regional staff were to carry out their effectively in line with best practice.

Only 40% of the centre staff had received consent 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.

The centre benchmarked itself against the Department of Health Abortion statistics produced annually. 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.

Patient flow through the centre was compromised at times. There were periods of extended waiting times due to the lack of recovery space causing theatre backlogs. Commissioners and stakeholders were involved in service planning including consideration for a second weekly surgical list to reduce waiting times and improve capacity management and patient flow through the centre.

MSI Norwich did not have a formal strategy although staff were clear about supporting the patients to deliver high quality care, promote good outcomes for patients, and encompass key elements such as compassion, dignity and equality.

There were gaps between the governance process at corporate and location level in communication and engagement which needed to be addressed to ensure evidence based care can be demonstrated at all times. There was no effective system in place to ensure action plans were completed, reviewed and audited to improve patient safety and quality of care.

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. Bulk signing of HSA1 forms took place and we were informed by doctors 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. The local audit process was not specific enough to identify the practice. The audit results were based on a quantative measure only that HSA1 forms had two signatures.

There was no process in place for assurance that HSA 4 forms were submitted to the Department of Health within the legal timeframe of 14 days.

Leadership had been inconsistent with six different managers at MSI Norwich in the last three years. Staff stated that this had affected continuity and stability for the clinical teams. The culture was viewed as being top down and corporately led. Teambuilding was difficult due to approximately 50% of the staff, at times, coming from other centres and the lack of leadership on site had reduced staff morale. Staff told us they did not feel valued by the organisation.

However we also found that:

Services were planned and delivered in a way that met the needs of the population.

Patients were positive about the care provided by staff and those we spoke with felt that care was individually centred. Marie Stopes Norwich scored the national average for rating the overall service at 95% very good or excellent in patient satisfaction surveys.

Staff adopted a non-directive, non-judgemental and supportive approach to women receiving treatment for termination. Staff were observed to be helpful, caring and treated patients with dignity and respect.

Translation services were available for patients who did not have English as a first language. There was a complaints procedure in place. Complaints advice was given in the back of the patient literature and displayed in the patient information folder in waiting areas.

There was evidence that attempts to improve the instability created by multiple staff and leadership changes were being undertaken with the introduction of new managers, attempts to recruit local staff and through communication and engagement groups. Staff we spoke with stated that the new managers on site were supportive and approachable.

Termination of pregnancy

Are termination of pregnancy services safe?

Our key findings for safety were:

- There was an inconsistent approach to action planning and ensuring that lessons learnt from incidents were shared with all relevant staff locally.
- Incidents were not a standard agenda item on staff meetings.
- Senior staff involved in incident investigations had no formal training in root cause analysis which would be beneficial to the risk management process.
- Staff did not have the appropriate level of safeguarding training to manage safeguarding issues.
- 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.
- Infection control audit results were poor and there was no clear action plan available to improve scores and lower the risk of infection.
- Staff were not trained to recognise and respond to a deteriorating patient.
- There were no effective systems in place to monitor equipment servicing and maintenance. No records were held of any equipment checks the satellite units.
- The quality of the photocopied templates (flow charts) were poor and unreadable in parts, which was a concern as they formed part of the patient record.
- 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.
- Regional staff from other Marie Stopes centres made up approximately 50% of the work force which potentially increased the risk to patient care as continuity and stability was difficult.

However

- Staff were confident to report serious incidents, whistleblow or challenge if they suspected poor practice.
- There were systems in place for medicine management that included obtaining, recording, handling, storing and security of medicines.

Incidents

- Staff reported incidents, such as medication errors and poor clinical waste collection practices, in hard copy format to the manager who raised an incident report through an electronic incident reporting system. Staff we spoke with gave examples such as drugs not signed for and aggression and violence towards staff.
- An incident log was maintained on site. Data provided prior to the inspection demonstrated that there had been 46 incidents reported in the period between March 2015 and February 2016. Of the 46, 14 (30%) were recorded as clinical complications (8 were incidents of retained products of conception, 4 were continued pregnancies, 1 was a missed ectopic and 1 was prolonged pain). 10 out of the 46 (21%) were for pre-existing conditions, 9 out of the 46 (19%) were for equipment failures, 3 (6%) were for medication errors, 2 were for violence and aggression towards one member of staff and one patient.
- There were inconsistences in the recording of the incident data provided. For example one incident of retained products of conception was recorded not as a clinical complication but as failure to follow policy and procedure with the incident type / details outcome recorded as “other”. One incident of continued pregnancy the incident type / details outcome was left blank. This meant that any analysis of this data to identify trends may not be accurate.
- Staff were confident to report serious incidents, whistle blow or challenge if they suspected poor practice. However, the current arrangements to learn lessons from incidents and implement good practice were not effective. Actions included in the incident log were vague. These included statements such as “change to information” and “other preventable action”. There was no further evidence to outline what specific actions were required, who was accountable and a timeline for completion. There was no monitoring or audit to ensure that changes had been implemented.
- Staff stated that feedback was not always provided to the reporter on actions taken and it was not clear how lessons learnt were shared consistently with all relevant staff locally and across the organisation.
- Review of incidents was not a standard agenda item at team meetings. There had only been one team meeting since the beginning of 2016. The minutes did not include incidents or practice changes to heighten awareness and prevent reoccurrence.

Termination of pregnancy

- There had been two serious incidents reported between March 2015 and February 2016. We reviewed both serious incidents and found investigations lacking detail and in one case no statements and no immediate actions noted. In one incident the lessons learnt and recommendation to scan all women post-surgery was not actioned and there was no explanation as to why.
- 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. Duty of Candour became a regulatory duty applicable to Independent Health sector providers on 01 April 2015. In the two serious incidents reviewed there was no evidence or record of any patient contact or that the relevance or need for duty of candour had been considered.
- We reviewed one serious incident (SI), which had occurred in the last 12 months, regarding violence and aggression towards a member of staff. There had been an investigation but no root cause analysis (RCA) or action plan completed to reduce the risk of reoccurrence. Senior staff involved in the investigations had not had any formal training in root cause analysis and evidence of follow up support for the member of staff involved was poor.

Cleanliness, infection control and hygiene

- There was an infection control policy in place and staff had received up-to-date training as per MSI policy.
- Bi-annual infection control audits were undertaken. The centre scored 60% compliance in April 2016 with the environment scoring just 22%. The Hand hygiene audit undertaken in March scored 67%.
- There was no history of cleaning checks being in place. The clinical operations manager stated they were currently introducing cleaning schedules and reviewing the external cleaning contract to improve these scores, however, a clear action plan was not available to cover all areas raised. The action plan submitted with the local audit plan, prior to inspection, had no actions identified for infection prevention and control.
- Infection prevention and control was included in the local risk register as of 21 March 2016 however this was rated green with a score of 2, as a low risk with the only action identified as "IP lead to be identified, trained and supported". There was no reference to the lack of cleaning schedules or external cleaning contract.
- The provider carried out a series of "nominated Individual visits" (NI) that comprised of two days of assessment at individual locations. These visits were undertaken by the health and safety manager and the head of nursing (when they were in post). MSI Norwich had a NI visit 1-2 February 2016 which resulted in a self-rating of inadequate for premises and equipment. Cleaning schedules were identified as a recommendation however a new cleaning contract was not completed until July 2016.
- A colour coded system for segregation of waste was in place however we were concerned that multiple surgical termination products were 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). A container left open for several hours containing multiple products could be considered an infection risk and is not recognised as best practice. 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.
- There were separate sink arrangements in the main theatre. The theatre sluice contained a janitor sink. This was identified as part of the NI visit and recorded as an infection control risk. This issue was documented on the NI action plan as ongoing due to the fact that any changes need consent from the property owners. There was no evidence that a formal risk assessment had taken place and this was not included in the local risk register.
- There was an electronic registers utilised in theatres and a tracking system for operation packs and implants to ensure follow up for any recalls could be actioned.

- Single use medical devices were used in theatre alongside certain reusable items. Any reusable items were sent off site for decontamination and sterilisation. There was a process in place to enable tracking of instruments trays that had been sent for processing.

Environment and equipment

- The landlord for the premises was responsible for building maintenance and issues were logged and reviewed weekly by the contractors. There was a planned preventative maintenance assurance audit in January 2016. It was reported that there were asset registers, maintenance schedules and PAT testing records for all the equipment on site but there was no evidence held on site for the satellite units and equipment reviewed during the inspection did not have maintenance dates visible.
- There was no effective monitoring of equipment servicing and maintenance. Equipment concerns were included in the "nominated Individual visits" (NI) in February 2016 where it had been identified that the anaesthetic machine was last serviced in April 2014. In the Norwich action plan it was recorded that the anaesthetic machine had subsequently been serviced in March 2016 however it was noted that parts were required, but did not specify exactly what these other parts were. It was recorded that a "monitor ordered". There was no evidence that a formal risk assessment had taken place or that adequate steps had been taken to ensure equipment was fit for purpose whilst operating lists continued.
- During the inspection we reviewed equipment and saw that a new patient monitoring system was used in theatre which had a clearance check which was documented in the theatre folder but had no label on the machine to confirm it had been checked.
- The Health & Safety Audit, April 2016 scored 84%. There were four actions identified with only one being marked as completed which was to print and display the health and safety statement. It was noted that the planned preventative maintenance (PPM) assurance audit which was due in April had not yet been completed. The landlord was recorded as responsible however the only action was for the operations manager to make contact with no measures to ensure this had taken place.
- Another aspect identified as part of the NI visit was insufficient resuscitation equipment and lack of grab bag. The NI visit had taken place on the 1 and 2 February 2016 but the emergency trolley checklist had last been completed on 22 January 2016, despite a surgical list having taken place on 29 January 2016. Some actions had taken place and at the time of inspection 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. Monthly checks of this machine were noted to have been undertaken and an annual maintenance check had been completed. 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).
- Following the NI visit there was a local action plan produced however this lacked detail. For example one recommendation was for training checklists for equipment. Actions undertaken were "in progress" and action to do "training to be arranged". Another recommendation was that recovery chairs inadequate, actions to do were "new to be obtained or revert to trolley system – still in discussion", mitigation action was "addressed plan in place". Despite this lack of detail the complete section was coloured green to indicate completed.

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.
- Some medications were prescribed by doctors remotely via an electronic system. Medication was given as per prescription and signed for electronically. The clinical operations manager was responsible for medicine management, there were no controlled drugs stored or given in the clinic at the time of inspection. Patients were prescribed antibiotics in accordance with local antibiotic formularies and patients with allergies wore red wristbands and allergies were clearly labelled in the records to ensure safe medicine practices.

Termination of pregnancy

- Staff we spoke with were aware of medicine management procedures and monitoring systems were in place to identify medication errors. There had been three medication errors reported as incidents between the 4 September and 6 November 2015. All three 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.
- It was recognised following the NI visit in February that medicines management training was required to mitigate medication errors. However the responsibility to action this was the head of nursing that subsequently left the organisation and no further action was taken to complete this recommendation.
- The current medicine management policy was out of date having been due for review in March 2016.
- The last medicine audit in February 2016 had an overall compliance score of 78.9%. An action plan to improve compliance was not provided despite being requested.

Records

- Patient records were a combination of paper records and electronic records. Paper records were held securely behind the reception area or in locked boxes. Electronic records were password protected and access was limited to appropriate personnel with the right to access them.
- Records showed that team members were trained in information governance and data protection practices. An electronic system was used for documenting patients' care; however there was also paper records maintained such as the World Health Organisation (WHO) Five Steps to Safer Surgery checklist and consent forms. Bi-Monthly audits of 30 sets of notes were carried out. The audit included six sections: One Call booking, central records system (CRS) workflow, ultrasound scans, pre-operative, procedure and post-operative. Results for January were 95.4% overall with pre-operative results scoring a red at 79.2%. 13 out of 30 patients had not had a VTE assessment recorded and none had an algorithm completed. In March 2016 overall result scored was 98.8% with all six sections scoring green, preoperative section achieved 98.3%. This was a quantative audit check to ensure all fields are completed however there were no observational audits to ensure a quality measure.
- An electronic system was used intraoperatively to record all aspects of the care during the operative phase. This included staff members, procedure performed, swab and instrument counts and implant details. 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. At MSI Norwich 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.
- We reviewed two sets of patients' notes. All were fully completed with appropriate risk assessments. Treatment decision flow charts were seen to be used, consent forms for treatment were signed and dated and two doctors signatures obtained on the HSA1 form to authorise the termination procedures. The quality of the photocopied decision flow chart was poor and unreadable in parts, which was a concern as they form part of the patient record.

Safeguarding

- Safeguarding policies and procedures had been updated, to reflect the 'Working Together to Safeguard Children document 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 and neglect.
- The assessment for all patients under the age of 18 included a safeguarding proforma which had questions around relationships, contraception and safety to highlight issues and protect them from abuse and neglect.
- There was a corporate safeguarding adviser for additional support however there was no formal training provided to staff regarding female genital mutilation reporting (FGM Act 2003) or child sexual exploitation.
- A safeguarding audit dated February 2016 scored 41.7%. Specific details of what the audit encompassed were not included in the data provided. However there were

five actions identified as a result which showed updated training was due for some staff and that lessons learnt were not always shared. The five actions were; "Lead safeguarding person", "Level 1 required", "Discuss escalation process", "Forward UK safeguarding leads details to team members" and "Lessons learnt". The only action marked as complete was against "level 1 required" in that logins had been requested for staff. The clinical operations manager was unable to provide records that demonstrated staff compliance with safeguarding training.

- Staff did not have the appropriate level of safeguarding training to manage safeguarding issues. Data provided showed that four out of six staff had received level 1 safeguarding training in April 2016, three health care assistants and only one registered nurse had level two training. There were no staff trained at MSI Norwich to level three. The clinical operations manager at the time of inspection had only completed level one.
- 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. Which 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.

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.
- The resuscitation policy stated that resuscitation drills should be carried out every three months. An external company provided resuscitation advice and led these scenarios and drills. A resuscitation simulation had taken place in MSI Norwich on the 25 February 2016 and the result had been significantly poor. The centre had scored only 14 out of 34, indicating a high risk with urgent action required and a repeat of the scenario in two weeks was recommended, however this was not undertaken until May 2016.

Specific areas for improvement included the following:

- Reception staff did not respond to emergency call bell as they could have been used to place (9)999 call
- Structured ABCDE not conducted
- Algorithms not utilised during the event
- Decreased conscious state and airway compromise not recognised or acted upon
- There was no confirmation of cardiac arrest resulting in a long delay between patient collapse and compressions
- Chest compressions were at the wrong rate
- Crash trolley not brought to scene and equipment not utilised
- Defibrillator not attached to patient
- Staff left multiple times to retrieve individual equipment items
- Staff we spoke with stated there had been a closure day in March 2016 which provided training on intermediate life support including early warning systems to recognise the deteriorating patient. Training data provided demonstrated that five out of six staff had received life support training on 14 April 2016. The data did not clarify whether this was basic life support of intermediate life support. There was no further evidence that any additional actions or recommendations from the scenario had been undertaken.
- Data provided demonstrated mandatory training attendance for MSI Norwich staff was 89% however this was not accurate. On review of this data the overall percentage was incorrect in several areas. For example 4 out of 6 staff had received safeguarding training which should have been recorded as 66% but was recorded as 83%, only 5 out of 6 had infection control training dates recorded (83%) yet this had been recorded as 100%.

Assessing and responding to patient risk

- 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 MSI Norwich. 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 Norwich 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 two records which demonstrated that this checklist had been completed. However staff 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 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.
- Patient records contained venous thromboembolism risk assessments (VTE); these were completed prior to patients receiving surgery. The risk assessments informed staff if prophylactic treatments were required. Data provided, prior to inspection, stated that VTE assessments were routinely completed and that all 723 patients who underwent surgical termination between March 2015 and February 2016 were risk assessed for VTE. However this was contradicted in the record audit in January 2016 that stated 13 out of the 30 patient records audited had not had a VTE assessment recorded.
- All patients 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. We were not assured that staff at MSI Norwich were appropriately trained to assess and respond to a deteriorating patient. The resuscitation simulation had highlighted significant concerns and despite this the resuscitation council guidelines were dated November 2013 and had not been updated. This meant that staff did not have access to current guidelines. The action plan following the NI visit in February 2016 recorded that "team did not understand that a suspected ectopic should have an emergency transfer to an acute hospital".
- 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 24 weeks 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 pre-surgical stage of the termination. The NEWS chart had clear escalation steps to escalate any patient deterioration; however this was dependent on staff recording the patient observations accurately. We saw one NEWS chart where a blood pressure was outside of the normal range and the total score was incorrect.
- The NI visit in February 2016 also identified that the emergency patient transfer agreement with the local NHS hospital in place was not effective and required

review. This review was still in process at the time of inspection and had yet to be finalised. In the interim staff stated they would apply MSI policy and call 999 for an emergency ambulance.

Nursing staffing

- Adequate staffing levels were in place. All staff rotated from consultation to working in the theatre in order for them to have an understanding of the service provided.
- Staff highlighted long working hours as a frustration at times although they recognised the need for flexibility due to the demands of the job. Regional staff from other Marie Stopes centres made up approximately 50% of the work force. The managers recognised that recruiting more local staff for continuity and stability would be beneficial and were currently advertising.
- 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 one incident reported in January 2016 of violence and aggression towards a member of staff and an injury sustained. A health and safety audit undertaken in April 2016 had highlighted the need for this training to support the clinical staff but this was yet to be implemented.
- Lone working and violence and aggression training were recorded on the local risk register in March 2016 both were rated as a minor risk. Identified actions were the need for training and for CCTV to be purchased.

Medical staffing

- The Corporate Health Systems Director confirmed that 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.
- Surgery was performed at the centre one day per week. During this time there was an anaesthetist present who was employed on a sessional basis and worked at another local trust as an anaesthetist.

Major incident awareness and training

- There was a contingency business plan in place in the event of an emergency. The centre had a backup plan should the power fail and was classed as a priority for restoring failure with the power company should the need arise.

Are termination of pregnancy services effective?

Our findings for effective were:

- Policies were not always updated to reflect practice changes in a timely manner and there was a lack of consultation and engagement of staff to support evidence based care practices.
- There was limited accessible evidence to provide assurance of the qualification and competency of centre staff and regional staff to carry out their roles safely and effectively in line with best practice.
- The number of staff receiving continual professional development was unclear and the clinical appraisal rates were poor with no documented history of any performance review for any staff at the centre
- There was no information to show that the nursing staff were being supported regarding the revalidation process for ongoing nursing registration.
- We were not assured that staff taking consent had the appropriate knowledge, skills and competence to support patients who may be vulnerable or lack capacity to make a decision.

Evidence-based care and treatment

- 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.
- RCOG guidance 6.19 sets out the recommendation that "services should make available information about the prevention of sexually transmitted infections (STIs)". RCOG 8.6 states, "effort should be made to ensure that women leave the abortion facility with effective contraception".
- The clinical commissioning groups (CCG) set MSI Norwich targets. Key performance indicators included long acting reversible contraception (LARC) and sexual

transmitted infection testing (STIs). The centre performed well in both areas achieving 55% LARC against a target of 50% and STIs 97% against a target of 70%.

- The service treated patients for early medical abortion (EMA) where pregnancy was confirmed by abdominal or transvaginal scan to be under nine weeks and four day's gestation. Patients who underwent early EMA confirmed they were offered different options based on gestation. Staff we spoke with were aware of the different options, which reflected the required standard operating procedures (RSOP) 2014.

Pain relief

- Pre and post procedural pain relief was prescribed on medication records. Non-steroidal anti-inflammatory medication and intravenous paracetamol was administered during the procedure. Non-steroidal anti-inflammatory medication was 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.
- Pain relief effectiveness was measured through the scoring system in the patient's notes and also through questionnaires to patients following their surgery. Patients' comments did not highlight pain as a problem and the records audits we reviewed did not indicate a trend or poor pain management.
- On discharge patients were given advice on 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 535 early medical terminations and 723 surgical terminations in the last year 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 and patient transfers, including reasons. These numbers were also 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 to improve quality measurements were being introduced. Whilst there were numerous areas of non-compliance highlighted, such as mandatory training 89% and all incidents reported 75%, there were no action plans to show how these areas could be improved. Outcomes from some audits had action plans, others such as medicine management were missing.
- There was an annual audit schedule for MSI Norwich. Data provided prior to inspection demonstrated that a regulatory compliance audit should take place in February and August. Data recorded for 2015 was zero and there was no evidence to support that audits had been undertaken.
- Local audit data for 2016 showed a regulatory compliance audit for February. Overall compliance achieved an amber rating of 76%. Out of 19 indicators, 12 scored green (recorded as 100%), five scored red (50%) and the remaining two were blank (marked 0). The red indicators included topics of COSHH, health and safety risk assessments, local operating procedures, policy management and staff sign off and review of infection control audits. The two blank indicators were regarding a local risk register and lack of medical gas training. The audit identified actions at both provider and local level and actions were recorded as in progress. A number of the identified actions (such as the requirement for local standard operating procedures following risk assessments were recorded as being identified as part of the NI visit in February 2016).

Competent staff

- There was limited accessible evidence on site or from requests to the corporate HR department to show how competent and qualified the centre staff were to carry out their roles effectively in line with best practice.
- 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. The training matrix provided prior to the inspection 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. There was no evidence provided of competency documentation or annual updates or specific dates of when and how competency was achieved and who was acting as mentor to sign off an individual's competency.
- Approximately 50% of the staff came from other MSI centres. One bank member had difficulty with the national early warning system scoring (NEWS) and when questioned had not had the training. We raised concerns during the inspection that there was a lack of competency and identification checks for temporary staff. No members of staff wore photographic identification. The regional and clinical operations manager could not access any central information to clarify the competency of staff from other MSI centres.
- The learning needs of staff should be identified through a system of appraisals, meetings and reviews of practice development needs. There was no documented history of any performance review for anyone at the centre and only one recent team meeting which indicated that staff had not been supported to carry out their roles safely and effectively in line with best practice.
- The training matrix provided prior to the inspection demonstrated that two registered nurses had received the MSI anaesthetic training on 3 August 2015. 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. Staff had failed to recognise airway compromise during the resuscitation scenario.
- There was no information to show that the nursing staff were being supported regarding the revalidation process for ongoing nursing registration.
- There was no information available locally to confirm that medical staff had undergone mandatory training and clinical appraisal. All medical staff were required to complete their mandatory training as for the other clinical staff. 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 process was known there was no evidence available to confirm that this occurred. No local checks of competency and training 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.

Seven-day services

- The centre did not operate seven days per week; however patients had access to the MSI 24 hour helpline operated from the One call centre.
- Commissioners and stakeholders were involved in service planning including consideration for a second weekly surgical list to reduce waiting times and improve capacity management and patient flow through the centre.

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

- Only 40% of the centre staff had received the MSI consent training. This equated to two staff, one health care assistant and one registered nurse. 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
- 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. However the two records reviewed did not apply to this age group and we noted that there was no section included in the records audit to consider either consent for children and young people, assessment of capacity to consent or deprivation of liberty safeguards.
- There were consent forms in place for contraception options and the supply of chosen method and also testing for sexually transmitted infections including HIV and strategies in place for infection prevention (such as prophylactic antibiotics which cover uterine infection and chlamydia).
- The two care records reviewed contained signed consent forms for the procedures and where applicable consent to contraception implants. Possible side effects and complications were recorded.
- Pocket sized Mental Capacity Act guidance was being distributed to all staff at the time of inspection for information.

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.
- Marie Stopes Norwich scored the national average for rating the overall service at 95% very good or excellent in patient satisfaction surveys.
- Staff were clear on the range of emotional responses that may be experienced during and following a termination.

Compassionate care

- Administration staff were polite and helpful to patients both attending at the reception desk and on the telephone. Staff in clinical areas were observed to be courteous to patients and treat them with dignity and respect. Patients told us that staff addressed them in a polite manner and reception staff were careful about what could be overheard near the waiting room. If patients wanted to discuss sensitive issues or appeared distressed staff 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. Marie Stopes Norwich scored the national average for rating the overall service at 95% very good or excellent. The patient comments supported this finding.

- Patient comments and the satisfaction surveys were mainly positive such as:

94% patients satisfied with information provision.

95% patients received information they could understand

96% patients were satisfied with the overall care they received

- 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. Post procedure relatives were able to join the patient in the ward area, screens were used for privacy.
- Patients and partners experienced frustration at times due to extended waiting times with minimal information as to the reasons for delay.

Understanding and involvement of patients and those close to them

- We spoke with seven patients who gave positive views about the care provided, which they noted was patient centred. Staff offered a good service and were caring.
- Patients said they were satisfied with information provision and felt involved in the decision making process. Both staff and patients noted that staff adopted a non-directive, non-judgemental and supportive approach to women receiving treatment for termination.

- Patients were introduced to all healthcare professionals involved in their care, and were made aware of the roles and responsibilities of the members of the theatre healthcare team prior to the procedure.

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. 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.
- 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" however there was no further evidence provided or forthcoming during inspection that confirmed that this took place.
- Staff were clear on the range of emotional responses that may be experienced during and following a termination.

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.
- Translation services were available for patients who did not have English as a first language.

However:

- Waiting times could be 16 days as opposed to the 10-day waiting target due to the limited number of surgical places available weekly.
- Patient flow through the centre was compromised at times with extended waiting times due to the lack of recovery space causing theatre backlogs.
- Data from patient satisfaction survey showed that only 67% 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.
- Days and times were designed to ensure short wait times and access to the full range of services. However staff at the Norwich centre said it could be 16 days as opposed to the 10-day waiting target at times due to the limited number of surgical places available weekly. Future service planning included consideration for a second weekly surgical list to reduce waiting times and improve capacity management and patient flow through the centre.
- The majority of patients were funded by clinical commissioning groups (CCG). Commissioners and stakeholders were involved in service planning. The growth of the "Early Medical Units" (EMU) in the community included a new vasectomy service due to start in Peterborough in June 2016.

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 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.
- Patient flow through the centre was compromised at times. On the day of inspection one patient had waited three hours due to incorrect administration and poor communication and staff we spoke with agreed that waiting times were too long at times mainly due to the lack of recovery space causing theatre backlogs.
- The average patient time spent in the centre was 107 minutes in March 2016 (against a target of 95 minutes).

Termination of pregnancy

- The majority of comments from patients in the satisfaction survey January – March 2016 were positive however some scores were below target, such as only 67% felt informed about delays during their visit. We discussed this with staff who stated they would apologise for the delay but no solutions had been raised .There was no information in the waiting area to keep patients informed of delays.

Meeting people's individual needs

- The centre was equipped with a small screened area where young people and vulnerable adults could be taken ensuring a discreet service.
- Staff told us 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 patients' physical and mental health needs. Staff said that treatment options were presented to the patient determined by their specific needs and requirements. For example domestic abuse or drug use etc. would be referred or sign posted to the appropriate support. 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.
- Translation services were available to support patients whose first language was not English but no written information regarding this was found in the waiting areas and there had been a complaint that an interpreter was not provided in August 2015.
- There was written information for patients and partners explaining what to expect during and after the termination (to include potential side effects, complications and any clinical implications).
- 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. Any non-standard disposal option was documented in the patient's record and on a freezer log sheet indicating reason for storage and date for either collection or disposal. Products were only released to the patient or the police once stringent checking had taken place. Where products had not been collected and if appropriate, the patient would be contacted to ask for further instruction or a decision would be made to dispose of products after three months.
- Patients were informed of the options for foetal disposal on request, however very few patients request the information. A patient information leaflet was provided which details the options 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 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. Issues could also be raised via the patient feedback questionnaires.
- The centre received eight complaints in the last fifteen months. Two complaints were about poor care and one stated "unhelpful counselling", three were around failed medical abortions, one referred to a missed ectopic pregnancy, one related to a medication incident and one to delay in treatment and availability of translator.
- Staff said 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 clear in the meeting minutes seen.

Are termination of pregnancy services well-led?

Our key findings for well led were:

- There was no clear vision or strategy although staff were aware of the improvements needed in the centre
- There were gaps between the governance process at corporate and location level in communication and engagement. Marie Stopes International provided the Norwich centre with an Integrated Governance Framework which they stated was in line with the NHS governance agenda and the CQC Essential Standards of Quality and Safety. The CQC Essential Standards of Quality and Safety were replaced by the fundamental standards in 2014.

- There was no robust system to ensure action plans were completed, reviewed and 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.
- The process for completion of HSA1 forms did not support the opportunity for medical staff to have full access to information and patients' medical records to enable an opinion in good faith. Local audit process was not specific enough to identify the practice.
- 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 centre had only one formal team meeting this year and the minutes did not incorporate key performance indicators, risk assessments and quality measures.
- The culture was viewed as being top down and corporately led.
- Teambuilding was difficult due to approximately 50% of the staff coming from other centres
- The multiple changes of management at a local level meant consistency and stability had not been possible and had reduced staff morale.
- Communication in general was recognised as an area for improvement. Staff told us they did not feel valued by the organisation

However:

- Staff were positive about the new managers and could see potential improvements with recruitment and staff engagement groups.

Vision and strategy for this this core service

- MSI Norwich did not have a formal strategy that staff were familiar with. Staff were clear about supporting the patients to deliver high quality care and promote good outcomes for patients and encompass key elements such as compassion, dignity and equality. Overall staff were aware of the improvements needed in the centre such as additional theatre time to cope with demand and capacity issues.

Governance, risk management and quality measurement for this core service

- Marie Stopes International provided the Norwich 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.
- There were gaps between the governance processes at corporate and location level in communication and engagement which should be addressed to ensure evidence-based care can be demonstrated at all times. For example a recent additional treatment option for early medical termination of simultaneous administration of medicines for early medical termination had been temporarily withdrawn, but staff were not clear as to why. Minutes of meetings both corporately and locally were reviewed and demonstrated that there was not a consistent joined up approach to reporting and monitoring quality.
- Standardised Integrated governance meeting templates were currently being introduced, however, the centre had only one formal team meeting this year and the minutes did not incorporate key performance indicators, incidents and learnings, risk assessments or quality measures. Communication in general was recognised as an area for improvement
- 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 Norwich completed the NISA in March 2016 and included an action plan to address non-conformances such as medicine management and intermediate life support training to be actioned to reduce drug errors and support the deteriorating patient, however there was no robust management process in place to ensure action plans were completed, reviewed and audited. There was the added confusion that there were two versions of action plans produced following the NI inspection. One entitled Norwich action plan (corporate), one entitled (NISA) local action plan, and these differed in content.
- 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. During the inspection we were made aware of concerns regarding HSA1 form completion. There was evidence that 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.
- Eight members of staff, five medical staff, one member of administration staff, one registered nurse and one senior manager, were interviewed about the process for obtaining signatures on the HSA1 forms. All eight confirmed that forms were printed and signed in advance. Administration staff confirmed forms were printed in batches and given to theatre staff to request signatures from the surgeon and anaesthetist. The clinical operations manager confirmed they were aware of this process but not exactly what information was reviewed before signing.
- We were informed by doctors 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 Norwich 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

- At the time of inspection there was no registered manager in place. An application had been submitted to CQC in April 2016 for the regional manager to become the registered manager; this application was approved on 15 July 2016. This individual is also registered manager at MSI Maidstone. We were concerned that the regional manager would have the capacity to fulfil the responsibility of registered manager at multiple locations. Information provided by MSI Norwich prior to the inspection indicated that the new clinical operations manager would be applying in the future as a second registered manager but this has not yet taken place
- There was a newly appointed clinical operations manager in post having been recruited in early 2016. They were responsible for the day-to-day management at MSI Norwich and they were being supported by the regional manager.
- Staff were concerned that they had six different managers in the last three years and that this had affected continuity and stability for the clinical teams, but staff were hopeful that the new managers would provide much needed support. The new managers were seen by staff to be visible and approachable.
- The culture was viewed as being top down and corporately led. Teambuilding was difficult due to approximately 50% of the staff coming from other

centres and the lack of leadership on site until recently had reduced staff morale. However there was evidence that this was being addressed with the introduction of the new managers, attempts to recruit local staff and through communication and engagement groups.

- Staff were positive about the new managers and told us there was an open culture where they could raise concerns. Staff felt that the new managers recognised there were actions that could be taken to improve the quality of care at MSI Norwich.

Public and staff engagement

- All patients were given a questionnaire during their stay and quarterly reports were produced by an external company. January to March 2016 showed Marie Stopes Norwich scored 100% for the person they first spoke to was helpful and understanding. The majority of scores were in line with other Marie Stopes centres.

Innovation, improvement and sustainability

- Senior staff stated that there was a plan 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 WHO 'Five Steps to Safer Surgery' checklist is completed accurately and used appropriately at each phase of the surgical procedure.
- Ensure that all equipment at MSI Norwich and the EMU has been serviced and is in good working order.
- Ensure there is an effective system in place to record and monitor servicing and maintenance of equipment.
- Improvements in corporate and location level communication and engagement, should be addressed to ensure evidence based care can be demonstrated at all times.
- Establish a robust 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 staff have regular appraisals to establish continual professional development requirements to ensure staff have the right skills to perform their job role.
- Ensure a robust 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.
- Ensure the quality of photocopied templates (flow charts) is improved to enable clarity of patient records.

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. Infection control audit results were poor and there was no clear action plan available to improve scores and lower the risk of infection. There was no history of cleaning checks being in place. Infection prevention and control was included in the local risk register as of 21 March 2016 however this was rated green with a score of 2, as a low risk with the only action identified as “IP lead to be identified, trained and supported”. There was no reference to the lack of cleaning schedules or external cleaning contract. Multiple surgical termination products were 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. A container left open for several hours containing multiple products could be considered an infection risk and is not recognised as best practice. 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.

This section is primarily information for the provider

Requirement notices

The theatre sluice contained only one janitor sink with no other separate handwashing facilities. There was no evidence that a formal risk assessment had taken place and this was not included in the local risk register.