Marie Stopes International

Quality Report

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This report describes our judgement of the quality of care at this trust. It is based on a combination of what we found when we inspected, information from our 'Intelligent Monitoring' system, and information given to us from patients, the public and other organisations.

Summary of findings

Letter from the Chief Inspector of Hospitals

Marie Stopes International (MSI) performs in the region of 70,000 abortions (both medical and surgical) a year, which represents around a third of abortions performed in England.

CQC inspected 12 of Marie Stopes International's registered locations in England during a series of inspections between April and August 2016, as part of CQC's planned comprehensive inspection programme. Whilst the inspections identified a number of positive factors they also identified some concerns linked to the provider's governance arrangements which led to an unannounced inspection of Marie Stopes International's UK administrative offices in Conway Mews, London on 28 July 2016 and 8 August 2016. These inspections concluded in August 2016 and led to Marie Stopes International voluntarily restricting its practice in the following areas to address CQC's most serious concerns:

- Suspensions of termination of pregnancy provision for under-18s and vulnerable groups of women.
- Suspensions of terminations under general anaesthetic or conscious sedation.
- Suspensions of all surgical terminations at their Norwich centre.

Marie Stopes International resumed its practice in the above areas over a phased restart programme between 7 and 30 October 2016 as CQC was satisfied that it had taken action to make improvements to address the areas of highest risk to patients.

CQC served four Warning Notices on Marie Stopes International in September 2016 for breaches of the CQC regulations in relation to requirements concerning consent, safeguarding, care and treatment of patients, and governance. CQC served three Requirement Notices in relation to safe care and treatment of patients, governance and compliance with Regulation 20 of the CQC (Registration) Regulations 2009 relating to termination of pregnancy. The Warning Notices served were applied at provider level and at those locations where we found breaches in regulation. The provider was required to make improvements.

As a consequence of the serious concerns identified and the subsequent regulatory action (described above) the CQC undertook an unannounced follow up inspection at the provider's UK administrative offices on 27 and 28 February 2017 to check on the steps taken in relation to the breaches in regulations. Since the inspection in February 2017 we have been informed that significant changes have occurred within the senior management team resulting in further review of management, leadership and governance aspects. We will be continuing to follow up through our ongoing monitoring and regulatory process.

We have not published a rating for this service. CQC does not currently have a legal duty to award ratings for those services that provide solely or mainly termination of pregnancy services.

Our key findings at the time of our follow up inspection on 27 and 28 February 2017 were as follows:

- A new electronic incident reporting system had been implemented across all MSI locations on 1 February 2017, to enable improved reporting, data analysis and focused improvement and learning.
- A process for the review of serious incidents and safety concerns had been created with the establishment of a serious incident group, a safeguarding committee, infection prevention and control group, medicines management group and resuscitation and deteriorating patient group at provider level. These groups were introduced between October 2016 and February 2017.
- The provider had reviewed and updated a large number of policies and procedures, such as the consent policy, anaesthetic policies, safeguarding policies and the incident policy. The provider had sought external review of its anaesthetic policies, by the Royal College of Anaesthetists in order to benchmark and ensure best practice. Following external review a number of revisions were required which were in process at the time of inspection.
- In October 2016 the provider had held a number of roadshows for staff and had organised training, some of which had taken place including safeguarding

training at adult and children level 3 and level 4 where applicable, consent training, basic life support (BLS) and immediate life support (ILS). Advanced Life Support (ALS) competence for anaesthetists had been reviewed and compliance recorded. At this inspection we found that there were variable training completion rates across locations.

- There was an ongoing recruitment strategy for registered nurses, vasectomy nurses, sessional anaesthetists and gynaecology surgeons. HR processes had been strengthened and now included appropriate recruitment checks, registration and revalidation monitoring for clinical staff and fit and proper person checks at director level.
- The provider had recently established processes within the UK administrative offices to monitor compliance with the Department of Health Required Standard Operating Procedure (RSOP) standards.
- A clinical practice guide for registered nurses and midwives had been introduced in October 2016 through roadshows to staff. However, there were limited systems in place to ensure that staff were following this guidance.
- The counselling process and policies had been reviewed and updated. Counselling, by trained counsellors, was mandatory for patients under 16 years of age and booked on a different day to treatment to enable patients' reflection time. All women and young people were offered counselling. There was conflicting information in relation to the counselling age requirements which could be confusing for staff. The booking pre-abortion counselling and counselling call flow chart referred to 16 years and below whereas the policy refers to 15 years.
- The senior management team, at the time of inspection, was aware of the detail of issues raised at the revised governance meetings. The new integrated governance committee (IGC) had a number of sub committees which fed information into the IGC. However it was unclear if the senior teams awareness was more due to the fact they had been actively attending locations rather than via effective reporting mechanisms as the sub committees were in their infancy. They had been cohesive in expressing their vision for the service, current concerns and risks to the service. However a formal strategy was yet to be put in place.
- There was recognition by the senior management team that the culture of the organisation needed to change to ensure that staff were empowered and engaged to drive improvements at location level. This work had commenced at the roadshows but it was unclear how this work was to be continued.

However whilst there had been an impetus to drive improvement to enable the restart in October 2016 of those services that MSI voluntarily ceased in August 2016, there had then been a period of less momentum once those services had recommenced. The pace of change had slowed from November 2016 and only increased again once the new managing director had been appointed in January 2017. Unfortunately this individual then resigned from position at the end of March 2017. We were concerned that further instability of the senior team would impact significantly on the organisation and tentative progress that had been made would fail to be embedded.

There remained areas where the provider needed to make improvements:

- The senior management team at the UK administrative offices had undergone significant change since our inspection in July and August 2016. There were a number of posts still awaiting appointment within the senior management team.
- Senior key clinical roles at the UK administrative offices remained vacant or had interim appointments or were extended to cover dual roles. At the time of inspection, vacant roles included the safeguarding lead, infection prevention lead, risk & governance lead, quality and safety lead and medical director.
- Clinical and corporate processes had been developed and strengthened but needed to be embedded as they had been implemented but had not been operational for long. The regional structure included a number of levels between the board and locations and reporting was inconsistent across the

regions. Governance sub committees were in their infancy and we found that some regions had yet to hold their first governance meetings at the time of our inspection.

- Newly formed systems and processes, such as incident reporting and a process for applying the duty of candour had been put in place. At the time of our inspection in February 2017 several incident investigations were ongoing which meant that the effectiveness and impact of these new process had not yet been measured
- We found that there remained some inconsistency across MSI locations in clinical practice and oversight to ensure quality of care. There had been a system for peer review in place that the provider used to monitor clinical practice and to highlight issues at locations. The format, methodology and consistency of peer reviews had been recognised by the senior management team as ineffective and had been discontinued. At the time of our February 2017 inspection no other mechanisms for achieving oversight and monitoring were in place.
- The provider had introduced formal competency assessments of nursing staff alongside the introduction of the clinical practice guide in October 2016. However, there was a lack of oversight of the numbers of staff assessed as competent in areas outlined within the guide or following training in anaesthetic and recovery training. No nursing staff appraisals, which would enable competency review, had taken place.
- The balanced score card measured safety measures, such as incidents and infection control issues. It had been implemented but had yet to be approved through the UK board. Since the inspection in February 2017, and subsequent change of managing director, we have been informed that the implementation of the balance scorecard is being reviewed.
- A clinical dashboard based around the requirements from various clinical commissioning groups had been drafted but had yet to be approved through the UK board.
- An audit programme had been implemented however this was only commenced in January 2017 and consisted of a rolling programme of audits with a staggered introduction.
- At the time of inspection, the audit template for the World Health Organisation (WHO) Five Steps to Safer Surgery checklist was still in draft format and was yet to be introduced.
- Revised infection prevention and control audits were due to be introduced in March 2017, despite known concerns being highlighted through the peer review process between November 2016 and February 2017.
- There had been no further planned resuscitation scenario training at locations. We were not assured that the proposed oversight of monitoring and learning from scenarios was effective due to the infrequent meetings of the resuscitation
- No significant changes had been made regarding training and competency of staff to undertake ultrasound scanning. We raised concerns at this inspection with senior staff that the ultrasound policy still lent towards staff requiring skills, beyond date scanning competency, in regard to identifying various conditions that would require escalation. Senior managers acknowledged that this required review.
- Further training was required in relation to female genital mutilation (FGM), child sexual exploitation (CSE) and Prevent. It was unclear how the senior management team took reassurance from the data supplied as they were given three different figures in respect of training.
- External review of anaesthetic and medicine management policies had highlighted that policies did not reference the latest guidelines and further amendments were required. However, these policies remained in place whilst amendments were being made. Policies in place had been improved and mitigated risks but still required further amendments to bring into line with national guidance.
- MSI was not meeting the Required Standard Operating Procedure (RSOP) standard 11 where the total time from access to a termination of pregnancy procedure should not exceed 10 working days. For

Summary of findings

patients with a pregnancy over 14 weeks, waits could be as high as 32 days or 4.5 weeks. For pregnancies over 19 weeks waits were between 18 and 45 days. The provider was working with others to address these delays to reduce the impact to women.

- There had been no formal staff survey to evaluate the impact of the changes made and to highlight areas of further improvement in staff wellbeing
- An ageing IT system was still affecting the provider's ability to ensure submission of HSA 4 forms to the Department of Health within the legislative time frame. MSI UK was working with the Department of Health to address this.

We found that whilst the provider had complied with the warning notices issued in September 2016 in relation to:

Regulation 13 HSCA (RA) Regulations 2014 Safeguarding

Regulation 11 HSCA (RA) Regulations 2014 Need for consent.

and complied with the requirement notice in relation to:

Regulation 20 (Registration) Regulations 2009 relating to termination of pregnancy.

It had not fully complied with the warning notices or requirement notices issued in September 2016 in relation to:

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

Regulation 17 HSCA (RA) Regulations 2014 Good governance.

CQC will be undertaking further enforcement action, monitoring Marie Stopes International closely, and reviewing its progress.

Importantly, the provider has been required to :

- Ensure that there is an effective system of leadership and governance in place to monitor the service and reduce the risk of harm.
- Ensure that all risks are assessed, monitored and that mitigations are in place to reduce the risk of harm.
- Ensure that the implementation of an Early Warning Score (EWS) is consistent across all locations and that there is an effective system for monitoring to provide assurance that it is being used appropriately.
- Ensure that all nursing staff are competent in their roles to ensure the safety of patients using the service. Ensure that there is an effective system for monitoring competence and a system for regular staff appraisals.
- Ensure that there is an effective system for monitoring of training compliance across all locations.
- Ensure that effective systems and processes are in place to monitor and improve services, providing consistency across locations
- Ensure that the World Health Organisation (WHO) Five Steps to Safer Surgery checklist is completed accurately, used appropriately at each phase of the surgical procedure and quality audit is undertaken.
- Ensure that effective oversight systems and processes are in place to service and maintain all equipment.

In addition the provider should:

- Review the training, competency assessment and revalidation of ultrasound training.

Professor Sir Mike Richards
Chief Inspector of Hospitals

Summary of findings

Background to Marie Stopes International

Termination of pregnancy refers to the treatment of termination of pregnancy by surgical or medical methods. Marie Stopes International (MSI) is a not for profit organisation and registered charity that was founded in 1976 to provide a safe, legal abortion service following the 1967 Abortion Act. MSI believes that everyone should have the right to choose whether and when to have children, no matter where they live. The organisation has expanded from one centre in London to a global network of more than 600 centres across 37 countries. We are only able to inspect those services that are registered with CQC, which are those within England.

Our inspection team

Our inspection team was led by:

Chair: Fiona Allinson, Head of Hospitals Inspection, Care Quality Commission

The team included one CQC inspection manager and one CQC inspector.

How we carried out this inspection

We undertook an unannounced inspection of the provider's headquarters' location in London on 27 and 28 February 2017. We spoke with senior members of the Marie Stopes International UK team, reviewed evidence both online and presented to us by staff and we reviewed a large number of data items received from the provider following our inspection. We also received and reviewed information from other stakeholders.

We did not speak to women using the service at these inspections as we were inspecting the administrative head office of Marie Stopes international and direct patient care is not provided there.

Facts and data about this trust

Marie Stopes International provides reproductive and sexual health services for over 100,000 women and men every year in their network of clinics around the UK. Patients can obtain services through the NHS or by self-funding options. Marie Stopes International was formed in 1976.

The provider is registered to carry out the regulated activities of :

- Diagnostic and screening procedures
- Surgical procedures
- Treatment of disease, disorder or injury
- Family planning
- Termination of pregnancy
- Transport services, triage and medical advice provided remotely

These activities are carried out and manged locally at the provider's clinic locations and managed centrally from the corporate headquarters at Conway Mews, London.

Summary of findings

Our judgements about each of our five key questions

	Rating
Are services at this trust safe? We have not published a rating for this key question. CQC does not currently have a legal duty to award ratings for those services that provide solely or mainly termination of pregnancy services. We found: • Newly formed systems and processes for the monitoring of safety, such as incident reporting and duty of candour, had been implemented in January 2017. However, whilst these had been operationalised there was limited evidence of the impact these were having on ensuring that patients were protected from harm as they were yet to be embedded. • The HR system for monitoring training compliance in relation to female genital mutilation (FGM), child sexual exploitation (CSE) and Prevent was not effective. Compliance rates varied across locations and ranged from 0% at MSI Essex for CSE and Prevent training to 100% at MSI Maidstone. • The pace of implementation of new procedures and audits for assurance was slow. At the time of inspection the audit template, to enable a quality observational check, of the World Health Organisation (WHO) Five Steps to Safer Surgery checklist was still in draft format and was yet to be introduced. Revised infection prevention and control audits were due to be introduced in March 2017.Despite the providers knowing that there were issues with infection prevention and control at some locations there was no evidence of increased audit at these locations. • A balanced scorecard which included the monitoring of incidents had been drafted but was to be approved. This had been implemented, however since the inspection in February 2017, and subsequent change of managing director, we have been informed that the balance scorecard is being reviewed. • Following the implementation of an early warning score system a pilot had been undertaken in two locations to identify the most appropriate early warning score (EWS) system to indicate patient deterioration. The decision had been reached but had not yet been rolled out across locations. Recognition and management of the deteriorating client was included within the staff clinical practice guide • There was no effective system in place at provider level for assurance that all equipment, including equipment at early	

medical abortion units (EMUs), had been serviced and maintained. Locations maintained their own systems for recording of servicing but this was not drawn together for provider level oversight.
- External review had highlighted that anaesthetic policies did not reference the latest guidelines. However, whilst amendments were made they remained in process.
- Some key clinical roles remained vacant or had interim appointments. Some positions had been recruited but individuals had not yet taken up position. These included the safeguarding lead, infection prevention lead, risk & governance lead, quality and safety lead, medical director and substantive chief nurse.

However:

- A process for the review of serious incidents and safety concerns had been created with the establishment of a serious incident group, a safeguarding committee, infection prevention and control group, medicines management group and resuscitation and deteriorating patient group. We found that some of these groups had not met more than once or twice at the time of our inspection in February 2017.
- The provider had reviewed and updated a large number of policies and procedures, seeking external review to benchmark and to ensure compliance with best practice.
- Safeguarding training had been provided to staff to appropriate levels as outlined in national guidance, compliance rates had significantly improved with 84.6% of staff trained to children's safeguarding level 3 and 100% for staff requiring level 4 safeguarding. An increase in reporting indicated staff awareness and understanding had increased.
- Mandatory training compliance for basic life support (BLS), immediate life support (ILS) and advanced life support (ALS) had increased to 79%, 87% and 87.5% respectively.
- Senior staff had received training in relation to root cause analysis and duty of candour. We saw from one incident investigation that investigation was robust and in this instant duty of candour had been applied.
- There was an ongoing recruitment strategy for registered nurses, vasectomy nurses, sessional anaesthetists and gynaecology surgeons.

Incidents

Summary of findings

- MSI had introduced a new electronic incident reporting system on 1 February 2017. The previous incident reporting system had been a joint paper and electronic system and delays had occurred with reporting as only designated staff had had access to the electronic system.
- Data capture at the time of inspection was in the transition phase between the two systems. Data in Q1 (January to March 2017) was a combination of the two systems. From Q2 senior staff stated that data analysis would be improved, as all information captured would be from the new system. The new system would allow more in-depth analysis. Identification of themes and incidents reported at specific locations would enable focused improvement actions and learning.
- As this was a new system, it was not yet fully embedded and there was some variance in the rates of reporting across regions, with some locations better at reporting than others. However in the one month since implementation, reporting had increased. Data provided demonstrated that there had been 124 incidents reported in December 2016, 98 in January 2017 and 393 in February 2017.
- Incident summaries were included in both the clinical governance and integrated governance meetings minutes. Marie Stopes UK (MSUK) had introduced weekly regional incident review meetings to enable shared learning. The meetings had the option for a dial in conference call to enable staff from all regions to attend. Set agenda items included an incident brief update from each region and individual location and an update on non-clinical incidents. Embedded documents were included in the minutes to support discussions held. Another method for dissemination of information and learning from incidents was via the chief nurse newsletter, produced fortnightly.
- We reviewed the incident review meeting minutes from January and February 2017. Details of open incidents and identified actions were discussed. Not all locations had participated in these meetings but it had been identified where there was no representation from specific locations and actions identified to ensure communication and appropriate actions were fed back.
- An agreed action from the minutes of 12 January 2017 was for managers to bring a synopsis of a low-level incident investigation, care and service delivery problems and analysis, contributing factors, root cause analyses and learning and recommendations to share with the group. It was recorded that Midlands and South West would share an investigation at the next meeting. However the minutes of the February meeting did not reflect that this had taken place.

Summary of findings

- No never events had been reported in the period between August 2016 and February 2017. Never events are serious patient safety incidents that should not happen if healthcare providers follow national guidance on how to prevent them. Each never event type has the potential to cause serious patient harm or death but neither need have happened for an incident to be a never event.
- A serious incident (SI) group had been created to investigate any serious incidents. The SI group met when the need arose. Since its formation on 1 October 2016, the SI panel had sat on three occasions between October and December 2016. There had been four SIs reported during this timeframe. Two were considered by the panel to satisfy the criteria of the SI framework and investigations started; one had been closed and one had been judged to not meet the SI reporting framework 2015. The SI categories followed those used by the NHS and CCG. Issues related to retained products of conception, a migrated implant, patient emergency transfer and requirement for further emergency surgery and nurse working without registration at MSI Manchester. We found that statutory notifications under Regulation 18 (2) Care Quality Commission (Registration) Regulations 2009 had been submitted in some, but not all, of these cases. There was variation across locations. However, this is a statutory requirement.
- Two further SIs had been reported in January 2017. Due to the timings of the incidents four of the six were still in the early stages of investigation. We reviewed the investigation report for one incident in December 2016 which involved the migration of a contraceptive implant. The investigation was completed thoroughly by the SI panel, led by the interim risk management lead, with a full root cause analysis (RCA) undertaken. The RCA highlighted a number of areas for improvement internally and highlighted a specific area that required liaison with other professional bodies and NHS organisations. These actions had been undertaken by MSI.
- The SI panel recognised the need for further training and a two-day RCA training event for centre managers and governance assistants was held on the 20 and 24 June 2016 and 11 out of 16 staff attended.The monitoring of the quality of incident investigations had been raised in the last provider report as a concern. The implementation of the electronic reporting system, additional staff training and SI panel mitigated this.

Duty of candour

- MSI had reviewed and updated their policy on duty of candour which had originally been ratified in April 2016. The updated

policy was due to be approved at the next clinical policy and guidelines group meeting on 30th March 2017. 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.

- Following a serious incident (SI) that related to a migrated implant, in December 2016, the duty of candour requirement was implemented out as soon as the concern became apparent. A discussion took place with the patient on 5 December 2016 and a summary letter was sent to the patient. Serious incidents are events in health care where the potential for learning is so great, or the consequences to patients, families and carers, staff or organisations are so significant, that they warrant using additional resources to ensure a comprehensive response (NHS England, March 2015).
- Duty of candour had also taken place following a failed termination of pregnancy, where the pregnancy had continued, and the interim chief nurse had met personally with the patient to discuss the incident.
- We had requested details of completed serious incident investigation reports. Four of the six reports were still under investigation and reports had not been completed. Therefore these were not provided and we were unable to review if duty of candour had taken place in these specific incidents. Information submitted by the provider demonstrated that medical staff had received training in duty of candour as part of the doctors' forum on 14 March 2017. The format of training was a presentation on duty of candour, record keeping and confidentiality presented by a regional liaison advisor for the General medical Council (GMC).
- We were not provided with any evidence that nursing staff had yet received training for duty of candour. Information submitted by the provider in January 2017 stated that duty of candour training will be provided to team members between April and June 2017Senior staff we spoke with stated that duty of candour was taking place and we saw two examples where this had occurred.
- A balanced scorecard was in the process of being introduced at the time of our inspection. This had been devised but had not yet been presented to the board for approval. Duty of candour had been incorporated into the scorecard as an indicator for a response to a patient within the timeframe set at 10 days of the incident occurring. This was still work in progress.

Safeguarding

Summary of findings

- There were provider wide safeguarding policies in place in respect of adults and children and young people. Since the previous inspection, MSI had introduced a system for policy ratification and both of these policies had been reviewed and ratified. MSI engaged with the local London external safeguarding board to request a review of the policies to benchmark and ensure best practice guidelines. At the time of inspection, the Adult Safeguarding Policy had been endorsed. Minor additions were required to the Children's Safeguarding Policy, which was still in progress. We were informed that these additions would be reviewed at the clinical policy and guidelines group at the beginning of March 2017 along with the Chaperone Policy. The policy had been circulated to staff at the locations for use whilst awaiting further updates.
- There remained a vacancy for a safeguarding lead at provider level within the organisation. This was out for recruitment at the time of our inspection and was yet to be appointed.
- MSI had undertaken a revision of its safeguarding training, changed training providers and strengthened the content of the course to provide more relevance to the work of the local teams. In addition, a safeguarding event had taken place on 11 November 2016 to provide additional training to staff. The event schedule demonstrated links with external providers. Presentations included topics on child sexual exploitation (CSE), female genital mutilation (FGM) and domestic violence. A future event was being planned for June 2017.
- The Intercollegiate Document for Healthcare Staff (2014) states 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. Data provided demonstrated that 84.6% of staff had been trained to safeguarding level 3 and 100% of staff requiring level 4 safeguarding training had completed it (as of 13 February 2017).
- We were informed that staff had an increased awareness and confidence in reporting safeguarding concerns and the introduction of the new electronic reporting system had supported timely escalation of concerns. Information submitted by the provider demonstrated that the total number of safeguarding incidents reported between March and December 2016 had increased. Between March and June 2016, 40 incidents relating to safeguarding had been reported. , This had increased between July and September 2016 to 51, and increased further to 134 between October and December

2016.The latest figures for January and February 2017 also demonstrated a significant increase in reporting when compared to the same months in 2016, with 67 incidents reported in January 2017 compared to 18 in January 2016 and 89 In February 2017 compared to seven in February 2016.

- MSUK had introduced a safeguarding committee in January 2017, terms of reference had been approved and meeting frequency set for each quarter. The safeguarding committee monitors safeguarding reports and compliance with policy and sits as a subcommittee of the clinical governance committee (CGC) which then reports into the corporate integrated governance committee (IGC).
- Data from the minutes of the CGC meeting on 7 February 2017, demonstrated that monitoring was now in place in relation to the number of safeguarding incidents that were delayed, on time, open or closed. There appeared to be no monitoring of compliance with the policy in terms of timeliness of referral. However, the minutes suggest proactive sharing of section 11 reports with the CCG. Of the 134 incidents reported between October and December 2016, 114 had been completed on time, 23 were delayed, 17 remained open and 117 had been closed. However, there was nothing to indicate the reasons for delay or if actions to identify how this could be improved had been taken. In addition, there was no reference to this in the January 2017 safeguarding committee minutes.
- A 30-minute electronic learning module had been rolled out to staff to cover the topics of CSE, FGM and 'Prevent' training. The aim of 'prevent' training is to provide staff with the knowledge to enable them to be aware of people who are at risk of becoming radicalised and to stop them from supporting terrorism or becoming terrorists.
- The staff compliance rate for FGM, CSE and Prevent training was inconsistent across locations with some locations having insufficient numbers of staff trained. In addition the recording of training compliance for FGM, CSE and Prevent was confusing and unclear. Two data sets were submitted to us by the provider in February 2017. One data set stated the percentage of staff who had completed the training and records had been updated on the electronic HR system. The second data set stated where training had been completed but records had not been updated. This meant it was difficult to ascertain how overall compliance could be assured when records were reporting different figures. For example the information submitted was that overall compliance for CSE was 43%, however only 6% were recorded as fully complete and 37% recorded as "complete but records incomplete". FGM showed

58% compliance overall but only 19% fully recorded and 39% showing as records incomplete. Prevent showed 31% overall compliance split between 10% fully complete and 21% with records incomplete. The senior management team were unable to adequately explain the exact numbers of staff who had participated in this training.

- There was a variation in compliance dependent on location and staff group. At MSI Essex no staff had undertaken CSE or Prevent training and only 30% had undertaken the FGM training in contrast with MSI Maidstone which had 100% compliance in all modules (but not all recorded on the system). Within the medical staff group, 5% had completed CSE, 8% FGM and Prevent.

The provider had undertaken an audit in January 2017 of training certificates of FGM, CSE and Prevent compliance at centre level. The audit identified an issue relating to the system access for administration staff to allow uploading of certificates onto the electronic HR system. Steps were being taken to look into access permissions to address this.

Mandatory training

- MSI had introduced an electronic training calendar for staff to access. There were training sessions booked throughout the calendar year (2017) for topics including consent, moving and handling, safeguarding adults level 3, safeguarding children level 3, basic life support (BLS) and immediate life support (ILS). The calendar indicated the venue for the training and remaining spaces available.
- Information submitted by the provider demonstrated that, as of 13 February 2017, 79.4% of staff had completed BLS training, 87.8% ILS training. This was an increase since the last inspection in July / August 2016 when compliance for BLS and ILS was 51%.
- At our inspection in July and August 2016 records had not been readily available to demonstrate the compliance with advanced life support (ALS) training for anaesthetic staff. ALS figures were subsequently confirmed at 79% (August 2016). MSI now included ALS in the training compliance data provided and compliance was 87.5% in February 2017. We were informed by the provider that no anaesthetist would be allowed to run a theatre list without a valid advance life support (ALS) certification. Currency in ALS would form part of the annual appraisal for medical staff.
- Responsibility remained with each anaesthetist to maintain their advanced life support (ALS) training and to participate in

scenario training at the clinics, which would be monitored at MSUK through the training matrix and local review and actions planning from resuscitation simulation reports. Any issues arising from the scenario training would be discussed in the resuscitation

- Data provided showed that ALS certificates had been checked and recorded for all anaesthetic staff. It was recorded that two of the 22 anaesthetists had been highlighted as not meeting the training level requirements and would not be given clinical lists until they were fully complaint. Monitoring was in place via an electronic staff allocation system for booking anaesthetists and surgeon. This system prevents a staff member being allocated to a shift without the necessary certification.
- A program of anaesthetic simulation scenarios and drills had taken place between 4 and 6 October 2016, including airway drills, IV access, anaphylaxis and difficult airway management. The training programme was attended by a number of clinical staff from each location.

Staffing

- The MSUK recruitment and retention strategy was under review at the time of inspection. Senior staff told us that resources had been identified, based on a staff mix review, for both the short term and the medium to long-term. In the short term MSUK were continuing to actively recruit for both nursing and medical staff.
- Information submitted by the provider demonstrated ongoing vacancies, which were out to advert for full and part time registered nurses, vasectomy nurses, sessional anaesthetists, and gynaecological surgeons. We were also told that there had also been approval to recruit a practice development educator and a data management manager. The provider had reduced operational capacity to ensure safe staffing levels were maintained.
- At the time of our inspection there remained vacancies for some key senior positions and recruitment was ongoing. These roles included the risk & governance lead, quality and safety lead, medical director and substantive chief nurse Shortly after our inspection, at the end of March 2017, the UK managing director resigned. The substantive chief nurse role had just been appointed and the plan was for this person to take on the role of chief nurse and acting managing director in the interim.

- There had been some success with an interim quality and risk lead appointed for six months. The infection, prevention and control lead position had been appointed, with the individual due to start in April 2017. The safeguarding lead position had been appointed, due to start in May 2017.
- The current medical director was due to retire. A lead surgeon had been appointed, with the aim of working closely with the UK managing director to assess training, medical staff competence and lead surgeon assessment. Recruitment to the medical director position was ongoing with shortlisting taking place in March 2017.

Cleanliness, infection control and hygiene

- At the time of our inspection, the interim chief nurse was also undertaking the role of director of infection prevention and control (DIPC). At our inspection in July and August 2016IPC had been overseen by a part time employee (only undertaking 8 hours a month in this role) however a lead for IPC had been recruited and was due to start with MSUK in April 2017.
- A new structure of governance had been agreed in October 2016 and an infection prevention and control group had been introduced as a subcommittee of the new structure. The purpose of this group was to provide assurance that controls and monitoring were in place to ensure safe IPC practice across locations and offer professional guidance on standards. They were also responsible for ensuring guidelines, instructions and clinical practices followed legislation requirements. The group met quarterly and reported into the clinical governance committee (CGC).
- The minutes from the clinical governance committee (CGC) on 7 February 2017 highlighted a number of concerns related to IPC following peer reviews. These included surgeons not washing their hands between patient contact and staff not wearing appropriate footwear whilst undertaking procedures in theatre. Actions were to report as incidents and that a standard guideline from Public Health England with cleaning schedules should be implemented across all sites. We reviewed data submitted post inspection and could not identify that these IPC related incidents had been reported on the electronic reporting system. However, the senior team were able to describe actions taken in respect of individuals highlighted in the peer reviews.
- We reviewed five peer reviews that had taken place between November 2016 and February 2017 at MSI Essex, Birmingham, Leeds, Manchester and Sandwell. All of these raised some level of concern regarding IPC. However, information within these reviews was often conflicting and nonspecific with “some

variance in compliance with cleaning standards" and "small number of breaches in IPC not identified in IPC audit" recorded but no further detail provided. In the MSI Sandwell and Essex reviews levels of cleanliness had been included in the areas of good practice under the safe heading yet were then identified as areas requiring improvement in the action plan. We were informed by senior staff that it had been identified that consistency in the format, methodology and consistency of peer reviews needed to improve and that they had been discontinued. It was unclear at the time of our inspection what would replace this monitoring tool.

- In the Birmingham and Essex improvement plan derived as part of the peer review, the IPC lead had been identified as the individual nominated to undertake the actions, at times in conjunction with the registered manager. We were not clear whether the IPC lead meant a link member of staff or the part time staff member or the planned recruitment of IPC lead.
- We were informed during inspection in February that there was a plan to review and incorporate relevant policies into one overarching IPC policy with several appendices as there were currently around 15 separate policies all covering various aspects of infection prevention and control. One of the recommendations made following a clinical commissioning group (CCG) quality visit to MSI Maidstone on 1 November 2016 was that support would be provided by the CCG regarding MSI IPC policy.
- It was recognised by the senior leadership team at MSI that there were inconsistencies in approach to IPC across the various MSI locations and that there was the requirement for focus and standardisation across the service. On the 24 February 2017, communication was sent to regional leads from the UK managing director, highlighting issues with cleaning of clinical areas and included the proposal that oversight responsibility at a local level was with each locations registered manager, ahead of the IPC lead joining the team.
- Senior staff stated that assurance regarding IPC process, ahead of the new lead's arrival, was via raised awareness in the fortnightly chief nurse newsletter and through meetings with the clinical team leaders. Senior staff informed us that the previous audit had not been effective in highlighting areas of concern and as a result the audit tool had recently undergone a review and was due to be launched in March 2017. IPC audit compliance was also included as an indicator on the proposed balanced scorecard (yet to be approved by the board). We raised concern on site regarding the slow pace to implement effective IPC measures.

- We were provided with conflicting information regarding the audit programme for the calendar year 2017. The audit programme 2017 initially provided on 25 February 2017 detailed hand hygiene audits would occur twice a year (March and September) with infection prevention and control audits in April and October. However, additional information, provided on 17 March 2017, stated the clinical audit programme for 2017 was still in development and would be introduced in a staged process with the prioritisation of audits being influenced by the findings of the peer reviews (which had been discontinued). It was said that the IPC audit, to be launched in March 2017, would be monthly and that the audit tool was being reviewed by the new IPC lead, however this individual was yet to start employment.
- Between 6 and 8 March 2017, a 55-point general IPC audit, using the revised audit tool, was undertaken across all Marie Stopes UK clinical locations. This included IPC training, facilities and equipment, adherence to uniform policy and use of personal protective equipment (PPE), waste and sharps management, cleaning and sterile goods. Range of compliance was between 74% at MSI West London and 95% at Blackpool Early Medical Unit (EMU). Areas of strength in the audits we reviewed included "generally good management of sterile goods, linens, curtains, and scrubs" and "documentation of cleaning tended to be robust". It was reported that areas for improvement were "fairly consistent across surgical sites" with management of sharps bins highlighted. The audit demonstrated a need for clarity on PPE use in the treatment room, as there were inconsistent levels of protection across locations. Auditors reported that the audit was more straightforward, clear, easy to use, and relevant than previous IPC audits, it was recognised there was still scope to improve the instructions for its completion. It also highlighted that there was a need for a bespoke audit programme in the EMUs.

Environment and equipment

- The integrated governance committee (IGC) ratified the Managing Medical Devices Policy in December 2016. The policy sets out the responsibilities for staff when working with medical devices. The registered managers at each MSUK location have responsibility for maintaining an equipment register, overseeing corporate contracts for maintenance and repair and the decommissioning and disposal of devices.
- Equipment checklists were completed by each MSI location prior to 7 October 2016. Information submitted by the provider 3 October 2016 demonstrated that most equipment checks and

appropriate servicing were completed at that time. Equipment included anaesthetic machines and monitoring, vital signs monitoring, suction equipment, treatment couches, scales and equipment used to measure whole blood haemoglobin.

- At the time of our previous inspection in July/August 2016 there was no evidence of an effective oversight system for the maintenance of equipment. Evidence was provided of equipment service checks and recorded on a spreadsheet to enable the restart of services in October 2016. However we were not assured that an effective system was in place for ongoing monitoring. In the data provided following inspection in February 2016, we noted several items of equipment had passed their date for servicing. For example the anaesthetic machine in South London had been serviced on 5 February 2016 and three suction units were dated as checked in January and February 2016 (MSI Birmingham, MSI Norwich and South London). This meant either the annual checks had not yet occurred or the spreadsheet had not been updated to reflect recent maintenance.
- Senior staff told us during the February inspection that the electronic spreadsheet was not regularly used for the oversight of equipment safety checks and maintenance. All locations had to complete a year planner, detailing all equipment listed and then the registered manager would organise and book the services. Following this, paper copies of service reports from contractors and each location were forwarded to the UK head of facilities and health and safety. These were then stored in separate files. We saw some of these files at our inspection. However, there was no overarching log of service completion held at provider level.
- Senior staff told us that work had been undertaken to log all equipment and the location where it was held. They were now confident that all 159 scanners had been reviewed and serviced. Some had been redundant; some remained within the five-year warranty provided whilst some older scanners had fallen outside this period. Each location held records of the equipment on site at surgical centres. However, there was no central recording system in place at the time of our inspection.
- Senior staff could not provide assurance or accurate details for any equipment held at any of the early medical abortion units (EMU). The senior member of staff stated that no itemised lists of equipment held and no checks had taken place at any EMU. They felt that this was a low risk as equipment was limited at EMUs to items such as couches, which remained the responsibility of the GP where the EMU was situated, and glucometer, which had a self-check mode. A glucometer is a

medical device for determining the approximate concentration of glucose in the blood. However, they also went on to state that other items such as scanners and vital signs monitoring equipment were held at EMUs. We raised our concern that equipment checks had not taken place and a self-check mode on a piece of equipment did not provide assurance that the item was serviced and maintained ready for patient use. We were not informed of any further actions taken by the provider in this respect.

- We reviewed the minutes for the clinical governance meeting on 29 November 2016, including the health and safety report that was submitted to this meeting. It was reported that following the preopening reviews at each centre, key areas to be addressed were duplicated servicing, equipment missed and equipment no longer in use but still within procedure rooms which had been removed from the treatment area and put into storage clearly marked do not use. It was also noted that discussion identifying that the external contract required closer monitoring had taken place in the previous meeting (31 October 2016). MSI changed to a single contract with one contractor and information provided in January 2017 stated that MSUK was in the process of recruiting a contracts manager who would be responsible for overseeing the management of the external contract however there had been no appointment made at the time of inspection. Equipment maintenance was one of the areas reviewed at the peer reviews that had taken place. Action was taken at location level and an action plan devised.

Medicine Management

- MSI had introduced a medicines' management group in November 2016. The terms of reference outlined the purpose of the group, which included clinical practice and guidance, operational policy and clinical governance in relation to the handling, storage, prescription and administration of all medications. It was also required to provide accountability for all aspects of medicines management, stay appraised of changes in legislation, liaise with external advisors and ensure adherence to best practice within all MSI UK centres.
- In December 2016, MSI had entered into a service level agreement (SLA) with an NHS trust for medicines management support with the aim of ensuring safe, effective and timely use of medicines within the organisation. A review of the agreement

by both parties was due by the end of March 2017. The SLA encompassed consultancy support, audit, policies and procedures, staff training, numeracy assessment, meetings and general support.

- The medicines management group had met three times at the point of inspection. We observed a meeting on the 28 February 2017.This was chaired by the lead anaesthetist at MSI and attended by internal members of the group, as well as representatives from the pharmacy team from the NHS trust (SLA agreement) and relevant external bodies. The agenda included Anti D dosing and availability, controlled drug (CD) licensing, policy development, contraceptive patient group directives (PGDs), audit, incidents and training for staff. The meeting had a structured and organised approach, outstanding actions from the previous meeting in January 2017 were reviewed and an appropriate level of constructive challenge, discussion and identification of actions was undertaken.
- A PGD allows some registered health professionals (such as nurses) to give specified medicines (such as painkillers) to a predefined group of patients without them having to see a doctor. It was highlighted during the previous inspections in July / August 2016 that there were no PGDs or nurse prescribers in place at the locations to prescribe and administer any medication to manage deteriorating patients in respect of conditions such as a haemorrhage. The provider had mitigated this risk by adopting an early transfer of such patients to an emergency centre and medical staff remained on site until all patients had been discharged. We saw that numbers of transfers had increased since our previous inspection.
- MSI had updated and developed policies that were then reviewed by the external NHS trust as part of the SLA to ensure that these were appropriate and in line with national guidance. These included the medicine management policy, prescribing policy and Controlled Drugs (CD) policy. It was outlined in the medicine management meeting minutes from 31 January 2017, that there were concerns raised internally with MSI regarding the recently ratified Anti D policy which did not follow guidelines and contained some inaccuracies and out of date terms. MSI were receiving support from an external body to amend this policy and were in this process at the time of inspection.
- At the time of inspection MSI were proactively seeking to proceed with a CD licence application for Midazolam (used for sedation in anaesthesia) and Gabapentin (an anti-epileptic medication also used for peripheral neuropathic pain).

- Audits by the external NHS pharmacy team had just started and were planned to take place at each MSI location. Initial feedback during the meeting on the 28 February 2017 was that some discrepancies had been seen around storage and stock of medicines no longer in use. It was agreed that this would be taken up with the locations by the senior nursing team.
- Medicines' management pilot training had taken place at MSI Manchester on 3 February 2017. The pharmacy team fed back to the medicines management group that initial feedback had been good. However this generic pilot was going to be amended to provide a bespoke training package specific to the medications used by MSI. It was agreed there would be a drugs' calculation test that all clinical nursing staff would be required to undertake. It was also agreed that this would be included as part of the recruitment process for nurses going forward.

Assessing and responding to patient risk

- When we inspected this service in July/August 2016 we raised concerns in relation to use of the World Health Organisation (WHO) Five Steps to Safer Surgery checklist, policies relating to anaesthesia and sedation, assurance of anaesthetic competency of medical and nursing staff, management of the deteriorating patient and life support. CQC raised their concerns with the provider who voluntarily suspended certain services, as outlined above, until it was assured that these issues had been mitigated.
- Information provided on 24 February 2017 stated that a nursing skill mix review had been undertaken to ensure staff with the appropriate skills were in place. Anaesthetic and recovery training had been revised and provided for theatre and ward staff. Staff members were not allowed to work in theatres unless they had completed this training. In October 2016, following the voluntary suspension of surgical services in August 2016, MSI had used agency operating department practitioners until staff compliance had been reached. Despite requesting details of staff trained we were not provided with this data to be able to confirm that all relevant staff had received this.
- Information, provided on 24 February 2017, stated that the lead anaesthetist managed anaesthetist competency checks. Anaesthetic practice within MSUK would be monitored by both individual and group practice review. Every anaesthetist undergoes an annual appraisal and any serious practice issues arising from the clinician's MSUK work would be notified to the Responsible Officer for that anaesthetist. A bi-annual report to the clinical governance committee as regards the anaesthetic

group practice would commence in 2017 but this was yet to be undertaken. To assist in supporting the regional teams MSI had just appointed regional anaesthetists who were responsible for practices within the regions.

- Resuscitation committees are recommended by the Resuscitation Council (UK) so that they can oversee the risks associated with resuscitation. MSI had introduced a resuscitation and deteriorating patient group on 1 December 2016. The terms of reference for this group included overview and guidance for both the deteriorating and collapsed patient, review of policy, ensuring compliance and standards of training and staying informed of current and changing regulation and guidance. The group reported into MSUK clinical governance committee (CGC). The first meeting took place on 1 December 2016, with planned meetings every six months or on an exception basis.
- Minutes reviewed identified that terms of reference had been agreed. Items discussed included resuscitation training and equipment, medicines management, the deteriorating patient, anaesthetic training for nursing, early warning scoring adaptation and fitness for discharge. The minutes included identified actions and timeframes. We were unable to assess the impact of this as there had only been one meeting at the time of inspection.
- Information provided by MSUK in January 2017 stated that the World Health Organisation (WHO) Five Steps to Safer Surgery checklist had been implemented as “a routine part of every patient’s journey through an MSI surgical clinic”. The new clinical audit programme for 2017 would include monthly WHO checklist audits, with results submitted to the Resuscitation and Deteriorating Patients Group. However monitoring and audit of the World Health Organisation (WHO) Five Steps to Safer Surgery checklist were not included in the terms of reference for this group.
- We reviewed the clinical audit programme for 2017. A medical records’ audit was scheduled at each MSI location, every other month, starting in January 2017. The medical records audit encompassed a quantitative check of 30 patient records and included a check that the “WHO Surgical Checklist completed and signed”. We reviewed this audit data from MSI Manchester and MSI Sandwell that demonstrated 100% compliance in January 2017.
- Senior staff stated that the proposed monthly “WHO checklist audit” was a quality measure to ensure the checklist was undertaken effectively that would incorporate an observational aspect. The audit included all five steps of the WHO checklist,

including the team brief at the beginning of the surgical list and debrief at the end. At the time of inspection the audit template was still in draft format and was yet to be introduced. We noted there was no footnote on the audit template to identify whether this had been ratified by the Resuscitation and Deteriorating Patients Group nor was there an agenda item or discussion at the group's first meeting regarding the implementation of the WHO observational quality audits.

- There had been one incident in January 2017 at MSI Brixton where a patient consent was undertaken after the procedure had taken place. This incident was still under investigation by the SI panel, however, had the WHO checklist been completed effectively by the team at Brixton, the lack of a signed consent form would have been identified and the incident prevented.
- We were concerned that implementation of the WHO checklist and audit had not been undertaken in a timelier manner as we were informed that this would be implemented when services resumed in October following the voluntary suspension of certain services. We raised this with the provider who stated that whilst the checklist had always been used staff had required further training and that audit would commence soon. We could not be assured that accurate and appropriate completion of the checklist, at each phase of the surgical procedure, was embedded into practice or that there was an effective assurance system in place to measure compliance and reduce risk to patients.
- At the last inspection the management of anaesthesia and sedation policy had been significantly out of date and did not address difficult airway management. A suite of anaesthetic policies including general anaesthetic policy, management of the deteriorating patient and clinical emergencies policy, sedation anaesthesia policy and resuscitation policy had been devised and introduced by October 2016. We reviewed these policies at our meeting on 3 October 2016 and whilst they were improved we found that they required some amendments to be in line with current best practice.
- Since October 2016 MSI had sought external review to ensure that these were appropriate, fit for purpose and referenced up to date guidance. Initial feedback from the Royal College of Anaesthetists (RCoA) in relation to three of the policies (general anaesthesia, management of the deteriorating patient and sedation) included concern over the quality of the documents and reference to out of date national guidance. Policies in place had been improved and mitigated risks but still required further

amendments to bring into line with national guidance. Therefore further work was required, prior to policy finalisation and ratification, and MSI were continuing this process at the time of inspection.

- Information provided by MSI in September 2016 indicated that they had invited the RCoA and Royal College of Obstetricians and Gynaecologists (RCOG) to undertake an independent review by the end of the year. This had not taken place as both colleges felt a visit by the end of the year would not allow enough time for MSI to make significant changes and that it would be more beneficial that MSI concentrate on CQC recommendations and a separate review could be discussed at a later date if appropriate.
- The general anaesthetic policy had been updated to include the requirement that anaesthetists remained on site at locations until all patients were clinically fit for discharge. There was a clear discharge criteria outlined in the general anaesthetic policy that included patient observations, orientation, mobilisation, minimal bleeding and pain control, had passed urine and where applicable had arranged someone to accompany them home. This meant that there was a clinician on site to provide emergency support and treatment should a patient deteriorate. Senior staff stated that staff were made aware of the benefit of early transfer of deteriorating patients. We saw that the number of transfers had increased following the voluntary suspension of certain services.
- The Marie Stopes UK Clinical Practice Guide had been devised in October 2016 and had been rolled out to all MSI locations. The guide outlined how patient observations should be taken, detailed what a typical normal range of patient observations would be (temperature, respirations, pulse, oxygen saturation, blood pressure, pain, vomiting and level of consciousness) and the escalation points for each. The guide also outlined steps in recognising and managing the deteriorating patient and guidance on haemorrhage.
- Following the inspection in July and August 2016, MSI intended to use a National Early Warning Score (NEWS) should a patient deteriorate. An early warning tool outlines what actions staff should take should patient observations deviate from the normal expected values. In August 2016 there was no evidence as to how the implementation would be monitored or how staff were to be trained in its use of the NEWS scoring tool. This remained a concern in February 2017, whilst NEWS was in place

there was no effective monitoring system in place to provide assurance that it was being used appropriately. Senior staff stated that the increase in patient transfer indicated staff increased awareness to a deteriorating patient.

- Information provided by MSI in October 2016 indicated that a termination of pregnancy early warning score system (TEWS) had been devised but that training and competence was yet to be developed for its use. At our meeting on 3 October 2016 we were assured that the clinical policy for managing a deteriorating patient had been rolled out to all staff. This highlighted that most centres would use the National Early Warning Score whilst some would pilot the TOPS- EWS a modified version for use in termination of pregnancy services. On inspection we found that there was still confusion amongst the senior team who were interviewed as to which system was to be taken forward. Different terminology was used, which included NEWS, TEWS and MEWS (Modified Early Warning System). The Management of the deteriorating patient and clinical emergencies policy referenced ToP-EWS, rather than TEWS. Whilst there was a "vital sign observations: typical normal ranges and escalation" chart included in the clinical practice guide for staff there was no specific reference to the use of an early warning system.
- A draft TEWS was presented at a meeting of clinical operations managers and clinical team leaders on 3 October 2016 and final suggestions for amendments were made. It was decided to pilot the TEWS in two locations; MSI West London and MSI Manchester, and compare TEWS and NEWS. Staff at West London received an on line learning programme and face-to-face training on NEWS and TEWS on 20 October 2016 prior to the pilot. The pilot took place between 21 October and 12 November 2016.
- We were provided with a draft narrative of findings from West London that found TEWS was more beneficial than NEWS. We were informed by senior staff during inspection that this was due to be introduced across all locations although this had not yet taken place. We were concerned that this had not been undertaken in a timelier fashion.
- There were service level agreements in place for transfers of care from the MSI individual locations to local NHS hospitals should the need arise for emergency transfer and acute care provision. Information provided showed that in Q4 2016 (October to December 2016) there had been 11 clinical transfers and one non-clinical transfer to NHS hospitals. Of the 11 transfers, one required emergency surgery to repair the cervix,

two required blood transfusions due to haemorrhage, one required intravenous antibiotics, one required intravenous fluid management, two were diagnosed with ectopic pregnancies and four were monitored and discharged the next day.

- Provision of care for later stage terminations is a challenge for all providers of termination services. MSI capacity to treat patients in later gestation of pregnancy was limited, with waits as high as 32 days or 4.5 weeks for those patients pregnant over 14 weeks. For pregnancies over 19 weeks waits were between 18 and 45 days. Delayed access to treatment can result in an increased safety risk as later stage procedures can be more complex and have the potential for additional complications. Where unacceptable waiting times were probable, patients were offered the option of travelling to other MSI clinic locations with shorter waiting times or were advised that other services were available, with other providers, who may be able to treat them in a timelier manner.

Are services at this trust effective?

We have not published a rating for this key question. CQC does not currently have a legal duty to award ratings for those services that provide solely or mainly termination of pregnancy services.

We found:

- No nursing staff appraisals had taken place at the time of our inspection.
- Although a competency framework had been put in place by 3 October 2016 we were not assured of effective monitoring processes for staff competence across the service.
- In October 2016 we were assured that training was planned to ensure that staff were competent to fulfil their roles.
- No significant changes had been made regarding training and competency of staff to undertake ultrasound scanning. The ultrasound policy had been reviewed in October 2016 however, it continued to highlight abnormalities staff should be identifying. We raised concerns on site with senior staff and following the inspection we were informed that a discussion meeting was planned to investigate the possibility of a bespoke accredited course.

However:

- The provider had recently established processes to monitor compliance with the Department of Health Required Standard Operating Procedure (RSOP) standards.

- Measures had been taken to alert location managers when the registration of nursing staff was coming up for renewal. MSUK had also introduced a system to track those nurses who were due for revalidation with the Nursing and Midwifery Council (NMC).
- A process for recording and monitoring doctor appraisals had been implemented. Regional anaesthetists had been appointed and were responsible for monitoring the service within their regions.
- A clinical practice guide for registered nurses and midwives had been introduced in October 2016.
- Consent training for staff had increased to 96% (E learning) and 79% staff had received face-to-face training. Staff taking consent were trained to level three safeguarding and were required to be registered nurses.

Evidence based care and treatment

- When we inspected this provider between July and August 2016, they had no system or process in place to monitor compliance with the Department of Health Required Standard Operating Procedure (RSOP) standards. The RSOPs set out minimum legal and professional standards that, if followed, help ensure that care and treatment is provided in a safe, effective, responsive and well-led manner. There was a lack of knowledge at that time amongst the senior management team at headquarters regarding these standards. However, following our inspection in 2016 a set of standards were issued to all of the senior team and the provider began to collect data to meet the RSOPs.
- When we inspected in 2016, the practice of simultaneous administration of abortifacient medication was not in line with the Royal College of Gynaecologists' guidance. When we re-inspected the provider in February 2017, the practice of simultaneous administration of abortifacient medication for EMA had stopped. Senior staff stated this would not be offered as a treatment option until there was a strong evidence base for its use. We reviewed the provider's abortion policy for medical and surgical procedures, which had been issued in December 2016 and found that it gave guidance on a two-stage approach to inducing an early medical abortion by the use of abortifacient medication and did not refer to simultaneous administration of the medication as a treatment option.
- RCOG guidance 'the care of women requesting induced abortion' sets out recommendations that services should make available information about the prevention of sexually transmitted infections (STI) and that all methods of

contraception should be discussed with women at the initial assessment and a plan agreed for contraception after the termination. MSI had an effective process for monitoring of STI testing and contraception advice.

- STI testing (chlamydia, syphilis and HIV), and future contraceptive decision was recorded as part of every patient record on the electronic system. MSI produced monitoring reports for the local clinical commissioning groups (CCGs). We reviewed one CCG report for Q1 to Q3 2016 (January to September 2016) that demonstrated the percentage of women accepting testing was 84% for HIV testing, 78% for Syphilis, 67% for gonorrhoea and 65% for Chlamydia testing. The report also included test opt out reasons.
- The report also detailed 100% of women receiving abortion care also received contraception advice, with those receiving long-acting reversible contraceptive methods (LARC) such as IUDs, implants and injectable methods, as 37% in Q1, 28% in Q2 and 32% in Q3, 2016., this was against a target of 50% . MSI's patient survey, across all locations, for October to December 2016 showed that 72% of women left with a method of contraception.
- MSUK provide medical termination to nine weeks plus three days and surgical termination of pregnancy to 23 weeks plus six days (not all services were undertaken at each location). Treatment options were dependent on the gestation of pregnancy. Surgical termination could be carried out under general anaesthetic, conscious sedation, by either vacuum aspiration or dilatation and evacuation or no anaesthetic according to each patient's choice and needs. Treatment option information was available on the provider website and the MSI patient survey, across all locations, for October to December 2016 showed that 94% of women were satisfied that the options for treatment were explained to them.

Patient outcomes

- All termination of pregnancy providers should have in place clear locally agreed standards against which performance can be audited, with specific focus on outcomes and processes as outlined in RSOP 16. This should include subjects such as waiting times, outcome of consultation (and the number of women who do not proceed to a termination, the availability of a female doctor, number of staff competent to provide all methods of contraceptive, patient experience for those who have returned home after taking the second drug for medical abortion, complications and failure rates).

Summary of findings

- A serious Incidents and transfers report for Q4 2016 (October to December) was reported to the integrated governance committee and detailed the number of transfers and ectopic pregnancies within the quarter. The highest numbers of transfers out involved patients undergoing termination of pregnancy under sedation at between 9 to 12 weeks, and all of those patients underwent one return to theatre before the decision to transfer was made.
- Information submitted by the provider showed there had been 373 failed terminations of pregnancy between January to February 2017 where women had gone on to have an ERPC (evacuation of retained products of conception). We were not provided with a total number of procedures undertaken to enable this to be analysed as a percentage. MSI stated that they track whether patients who return for post op consultation are booked for ERPC or a second termination procedure.
- Data for the number of women that following consultation did not proceed (DNP) with termination was provided by way of a weekly report across all 13 MSI locations. Information reviewed showed that 928 women were treated in the week ending 26 February 2017. 157 of which (20%) did not proceed to termination.
- The capacity report for January 2017 included data for patient flow including DNAs (did not attend), DNPs (did not proceed). 39 patient DNA in January 2017 (which equated to an average of 7% across all locations) and 21% of patients DNP in January 2017 compared to 18% in January 2016.
- MSI recorded the number of patients with ectopic pregnancy via the incident reporting system, by filtering the reason for transfer which was reliant on the classification being entered by staff. Data provided showed that 14 patients had been transferred due to ectopic pregnancy in December 2016 and one in January 2017.
- MSI stated that they record post-operative queries and filter these to track patient experience after taking the second drug for a medical abortion. If patients are advised to attend an accident and emergency department there was a flow chart which is used to follow up with the patient the next day to enquire on their progress and well-being. We reviewed the data spreadsheet that was provided which showed 1051 post op queries between 1 February 2017 and 8 March 2017. Follow up actions were recorded by way of a drop down menu of options that included, rest and monitor, attend GP, return to clinic and reassurance given, no further action. There was a choice from a drop down menu for query type which included bleeding, infection, pain and post-op query amongst others. Of the 1051,

110 (10%) had been recorded as bleeding, 11 (1%) as infection, 49 (4.6%) related to pain and 1 had related to vomiting after taking the medical abortion medication. The majority, 665 (62%) were recorded as a post op query with no further detail added regarding the specific nature of query. We were not provided with details of who reviewed this information or whether this was collated and reported to local, regional teams, the clinical governance committee or integrated governance committee for oversight and monitoring.

- The provider stated that details outlining the availability of female doctors when requested by patients could not be provided due to the lack of female doctors available for gestations over 13 weeks plus six days.

Competent staff

- When we inspected this provider between July and August 2016, we found that MSI did not have effective systems in place to monitor the registration of nursing staff. When we inspected this service in February 2017, we saw that measures had been taken to alert location managers when the registration of nursing staff was coming up for renewal. MSUK had also introduced a system to track those nurses who were due for revalidation with the Nursing and Midwifery Council (NMC).
- We asked to see the appraisal data for nursing staff; however we were told that the appraisal programme for 2016 had been delayed due to the challenges arising following our previous inspection. MSI had concentrated on ensuring other training aspects had taken place, such as consent, safeguarding and anaesthetic competence prior to the restart of services. Senior staff stated that MSI were about to embark on an interim appraisal review, which would be concluded by the end of May 2017. Previous appraisals were heavily focussed on bonus achievement and a complete review of the system, including behaviours and clinical key performance indicators, was under way but we were not provided with any further details.
- Previously when we inspected the service we were not able to determine whether doctors were receiving appraisals, as these were not recorded on the providers' electronic recording system. Action to address this had been undertaken and we saw there was a system in place for tracking and recording doctor's appraisals. We reviewed the appraisal and revalidation schedule that was provided, of the 23 doctors 21 required internal appraisal and two external appraisals. 17 had been undertaken between November 2016 and February 2017, with the remainder scheduled for March 2017.

- The clinical practice guide for registered nurses and midwives had been introduced in October 2016. Implementation instructions referred to clinical competencies associated to the guide with instructions that all registered nurses and midwives were expected to work through these, regardless of how long they had worked for MSUK in an attempt to standardise care. We were provided with two examples of where competency had been assessed. However there was no centralised database of competency across the organisation.
- A document entitled clinical competencies in vital sign observations had been devised in November 2016 which would enable staff to be assessed and signed off once competent. It was identified in the first meeting of the resuscitation and deteriorating patient group that some health care assistants, in MSI Manchester, were not confident in undertaking patient observation recordings. A training programme was put into place; each regional lead (senior nurse) was responsible for ensuring health care assistants received training within a month. We were only provided with data for two members of staff that demonstrated they had achieved competence.
- At our previous inspection between July and August 2016, we raised concerns regarding ultrasound scanning. Training occurred internally through a non- accredited course and assessment of competency was limited and not in line with the provider policy. At the time of inspection in February 2017 there had been no change with regard to the training or monitoring of competence of those staff undertaking scanning. Information provided in February 2017 stated that the Ultrasound scanning policy had been reviewed and altered to clarify that scanning technicians are not expected to diagnose conditions but should escalate any suspected concerns to surgeons or doctors. The training course remained four days at a course run by a university following which the staff member is required to perform a specified number of scans, supervised by a scanning mentor, after which a clinical assessment would be performed by the head of ultrasound services/assessor to gain competence.
- During our inspection in February 2017 senior staff stated that staff were required to undertake gestational scanning only and not diagnosis. However wording from the policy stated “In the event of any pelvic condition being suspected e.g. implantation of embryo in a previous caesarean scar, uterine fibroids, co-existent mass, polycystic disease, fluid in the Pouch of Douglas, ectopic pregnancy all clinicians should escalate to the surgeon or doctor present on the day for review”. We raised our concerns

that this required skills to identify the conditions mentioned and asked if they were assured that the level of training matched the scope of policy. We were told that this would be taken up with the ultrasound lead for exploration.

- Subsequently we received information stating that the head of ultrasound services was due to meet staff from the university on 21 March 2017 to discuss moving forward with a bespoke MSI training programme, with the aim to gain accreditation, review the theory content, and implement a theory examination, which would be externally marked. The current training programme had been sent to BMUS (British Medical Ultrasound Society) to consider endorsement and a planning meeting had been arranged for April 2017.

Consent, Mental Capacity Act & Deprivation of Liberty safeguards

- The Royal College of Obstetricians and gynaecologists (RCOG) guidelines 2011 and the Department of Health Standard Operating Procedure (RSOP) 8states that providers should have protocols in place for obtaining consent and pathways and support for all women who lack capacity to consent.
- The provider had an informed consent policy, in line with RSOP 8, the policy stated that young people aged 16 or 17 years are presumed to be capable of consenting to their own medical treatment, and any ancillary procedures involved in that treatment, such as an anaesthetic. When it is suspected that a patient may not have capacity, or withholds consent they must not be accepted for treatment and where appropriate would be referred back to their GP.
- The provider's policy relating to medical and surgical abortions states that consent must take place prior to treatment. This could be a one or two stage process, the first being provision of information, discussion of options and the second being confirmation that the patient still wants to proceed. There had been one incident relating to consent reported in January 2017, at MSI Brixton, where a patient had not been consented prior to going to theatre. This was currently under investigation; initial information provided demonstrated that the process had not been in line with the provider's policy.
- When we inspected this provider between July and August 2016, we found that 35.8% of staff had received training to enable them to undertake consent from patients in line with the provider's consent policy. In October 2016 we were assured that all staff had completed on line training and most had attended face to face training or had this planned. Information submitted by the provider indicated that as of January 2017,

96% of staff had completed consent training through the electronic learning system and 79% had completed face-to-face training when we re-inspected this service in March 2017. There were another eight courses due to take place throughout 2017.

- We had raised a concern with the provider on 5 August 2016 that staff taking consent, at that time, had not received the appropriate level of safeguarding training (level 3). The provider took immediate action to ensure that only nursing staff with a level 3 safeguarding qualification undertook consent from patients. However, we found that the monitoring of this was not effective. In October 2016 MSI had provided safeguarding training and latest data (February2017) demonstrated a compliance of 84.6% for safeguarding level 3.
- A review of the provider's abortion policy indicated that registered nurses could obtain consent providing they had attended consent training and had this competency signed off, by a clinical operations manager, a clinical team leader and/or a doctor.
- Information submitted by the provider indicated that consent training included subjects such as assessing capacity to consent and consent to treatment for patients under the age of 16 years; including Gillick and Fraser guidelines in order to assess whether the young person would have the maturity and intelligence to understand the risks and nature of treatments.
- The provider shared with us a records' audit, which had taken place at the Manchester centre in February 2017. The audit looked at 29 sets of patient records and indicated that 100% of the records examined contained an appropriate consent that had been undertaken by a skilled and competent nurse or doctor. The proposed clinical audit programme 2017 identified that consent audit should be undertaken bi-monthly but this was yet to be introduced.
- A senior member of staff involved in quality performance had been involved in undertaking peer reviews throughout several MSI locations. They told us they had evidenced concerns relating to consent being taken appropriately through the peer reviews. We reviewed all six peer reviews that had been completed. In three of the six reviews consent was not mentioned. At MSI Birmingham, it was recorded that consent was taken and clearly explained and at MSI Norwich staff were aware of changes to policy and felt the new training had been helpful. Only one peer review, MSI Essex, had a concern around consent. It was recorded that "a single incident of consenting practice was observed that fell below the standard expected" but no further detail was documented and the action plan was vague and did not reflect accurately areas to be addressed.

Summary of findings

- When we inspected this provider between July and August 2016, we raised concerns about the processes around obtaining consent from patients who had a learning disability. When we inspected the provider in February 2017, we reviewed their abortion policy, which indicated the provider was unable to treat patients who did not have the capacity to consent to treatment. The policy indicated that where a patient with a learning disability did not have the capacity to consent to treatment, they should be referred to the National Health Service (NHS) for assessment and treatment.

Are services at this trust caring?

We have not published a rating for this key question. CQC does not currently have a legal duty to award ratings for those services that provide solely or mainly termination of pregnancy services.

However we found:

- Caring was assessed, and reported, as part of the inspections of the 12 MSI locations between April and August 2016, as those locations all provided direct patient care.
- Caring was not assessed at the provider's headquarters as part of the inspection in July and August 2016, nor at this inspection, as direct patient care is not provided at MSI's administrative offices at Conway Mews. We noted that patient feedback was sought at each location and that overall 96% of patients were satisfied with the care provided in Q4 2016 (October to December). 92% of patients were satisfied with the amount of time and attention provided by staff and 98% felt they were treated with dignity and respect. The response rate for the survey in Q4 2016 was 27%.

Are services at this trust responsive?

We have not published a rating for this key question. CQC does not currently have a legal duty to award ratings for those services that provide solely or mainly termination of pregnancy services.

We found that:

- The average wait for consultation was four days, with five centres having appointments available immediately. Similarly, appointments for patients with a gestational age of less than 14 weeks were available within 10 days at all centres.
- Senior management staff were reviewing the efficiency, viability and sustainability of service provision at the time of inspection. Numbers of patients on operating lists had been reduced, to improve patient safety, which affected capacity and availability.

- If an appointment delay was anticipated, patients were offered treatment at alternative MSI locations or signposted to other service providers or NHS hospitals.
- The provider had reviewed the counselling process including the counselling service offered to young people. The booking process required counselling information to be populated before appointment bookings could be made.
- Policies had been updated to reflect that counselling is mandatory for patients under 16 years of age and should not be booked on the same day as treatment to enable patients' reflection time. All women and young people were offered counselling.
- The provider website contained information in various languages and provided information regarding the options available for the disposal of pregnancy remains.
- There was a 24-hour helpline number for women to use after treatment. This was in line with RCOG guidance: Care of Women requesting induced abortion (2011) recommendation 8.5.
- A system had been established for monitoring of complaints. Learning from complaints was shared through local governance groups.

However:

- Data provided demonstrated that MSI were not meeting the Required Standard Operating Procedure (RSOP) standard 11 where the total time from access to procedure should not exceed 10 working days. For patients with pregnancy over 14 weeks waits could be as high as 32 days or 4.5 weeks. For pregnancies over 19 weeks waits were between 18 and 45 days.

Service planning and delivery to meet the needs of local people

- Commissioners were involved with planning of services. They reviewed the local need and placed contracts for services out to tender. Marie Stopes and other abortion service providers then tendered for these contracts.
- At our inspection in 2016 we found that in order to provide services across a wide geographical area there had been a period of expansion of services to the current level of 13 locations where surgical termination of pregnancy were carried out and numerous early medical abortion units (EMUs). At this inspection, MSI was reviewing the efficiency of the services they provide, as well as their viability and sustainability in the long

term. Areas identified were London, Essex, Norwich and Telford. Earls Court, Finsbury Park and Guildford & Camberley EMUs were all closed temporarily in late December. Patients were booked into alternative locations with travel costs reimbursed.

- Provision of care for later stage terminations is a challenge for all providers of termination services. There is a national shortage of staff experienced in undertaking abortions for pregnancies over 19 weeks. This means that access to these services is restricted to only five centres in the MSI portfolio. The local NHS services in London had recently ceased to provide treatment for patients with pregnancies over 19 weeks, which further reduced provision. MSI staff signposted women elsewhere in times of high demand.
- Whilst services were commissioned from Clinical Commissioning Groups, senior staff stated that the monitoring requirements and input from each once commissioned was variable with different data information requests being made. At this inspection Marie Stopes International (MSI) had prepared a variety of data for commissioners to be able to monitor services. However, further work was being undertaken to consolidate information for commissioners to ensure that all locations provided standard information to commissioners.

Meeting people's individual needs

- The Department of Health, Required Standard Operating Procedures (RSOP) standard 14 states that “all women requesting an abortion should be offered the opportunity to discuss their options and choices with, and receive therapeutic support from, a trained pregnancy counsellor and this offer should be repeated at every stage of the care pathway”. During August and September 2016, MSI reviewed the counselling process, including counselling arrangements for patients under 15 years of age and concerns raised previously regarding privacy and confidentiality.
- There were two policies in place, Counselling for patients’ policy and counselling for young people aged 15 years and under policy. There were three young person's pathways outlined, in the counselling for young people aged 15 years and under policy, that specified either face to face counselling, webcam counselling or the option for a young person to attend clinic for telephone counselling. The policies were stored centrally on MSUK’s electronic system for staff to access. All women and young people were offered counselling.
- All patients’ first contact with the service is through the One Call centre. Information provided at this inspection demonstrated that the counselling section of the patient record system, used

at the One Call centre, must be populated before appointments can be booked. Information for booking pre-abortion counselling and a counselling call flow chart was available for one call staff to reference. Both state counselling is mandatory for patients under 16 years of age and should not be booked on the same day as treatment to enable patients' reflection time. We noted that both of these pieces of information referred to 16 years and below whereas the policy refers to 15 years, which could be confusing for staff.

- The information for booking pre-abortion counselling included a section on eligibility criteria for telephone counselling one of which was no language barriers. However, there was no indication or further links for staff as to what options were available should a patient require counselling in different languages or translation service availability. The Marie Stopes website had a Google translation bar to enable patients to access information in other languages and stated at the time of booking interpreters could be arranged for those where English was not their first language.
- There were links available on the Marie Stopes website for pregnancy, grief, relationship and self-esteem counselling with contact methods either by telephone or through a web form. There was a 24-hour helpline number for women to use after treatment. This was in line with RCOG guidance: Care of Women requesting induced abortion (2011) recommendation 8.5.
- Information was available on the provider's website regarding abortion methods, contraception and sexually transmitted diseases and the disposal of pregnancy remains. The website also stated that women could discuss options available in further detail with staff during consultation.
- Whilst we could not assess the manner in which staff dealt with patients with a learning disability we noted in October 2016 that training had been provided in ensuring patients with a learning disability were giving informed consent.

Access and flow

- The Required Standard Operating Procedure (RSOP) standard 11 states that good practice is that service arrangements should be in place so that patients are offered an appointment within five working days of referral or self-referral and offered the termination procedure within five working days of the decision to proceed. The total time from access to procedure should not exceed 10 working days.

- At our inspection, the average wait for consultation was four days, with five centres having appointments available immediately. Similarly, appointments for patients with a gestational age of less than 14 weeks were available within 10 days at all centres.
- For patients with pregnancy over 14 weeks waits could be as high as 32 days or 4.5 weeks. For pregnancies over 19 weeks waits were between 18 and 45 days. We discussed the rationale for these waits with the senior management team and were told that some of these patients were the "usual post-Christmas" increase the service usually saw, some were delays from previous months and some were because of the changes they had made to their service provision, which included shortened operating lists and having the appropriate staff on duty, both in terms of numbers and in terms of competency
- In February 2017, MSI realised that it could not always meet the waiting times outlined by RSOP guidance. When monitoring demonstrated that unacceptable waiting times were probable, patients were offered the option of travelling to other MSI clinic locations with shorter waiting times.
- MSI also advised patients who were facing waits that other services were available, with other providers, who may be able to treat them in a timelier manner. The provider worked with some services to ensure that these patients were offered viable alternatives. All providers were working to ensure that women had access to services when they required them.

Learning from complaints and concerns

- There was a process in place for complaints to be managed through the corporate clinical governance committee and the local and corporate integrated governance committees. The annual complaints report 2016 was presented to the integrated governance committee (IGC) on 21 February 2017. There had been 74 formal complaints (72 related to MSI locations and two related to the One Call centre) in 2016 compared to 84 complaints in 2015 (76 in relation to locations and eight to One Call). Two legal claims were received compared to none in 2015. This equated to 0.11% complaints received from patients attending treatment in 2016, which was on par with 2015. Percentage of complaints has risen marginally at MSI Manchester and MSI Birmingham and the rate of complaints upheld / partially upheld in 2016 was 16 % compared to 27% in 2015.
- Of the 74 complaints received, the five key concerns were retained products of conception, continuing pregnancy after treatment, heavy bleeding, infection and haematoma after

vasectomy. Poor staff attitude and lack of care issues accounted for 26% (21) of all complaints received. Seven complaints (9%) related to waiting time and delays in 2016 compared to 15 complaints in 2015.

- There were five MSI locations with an increase in complaints in 2016 when compared to 2015. These were MSI Manchester (8 compared to 4 in 2015), MSI Birmingham (7 compared to 3 in 2015), MSI Leeds (7 compared to 6 in 2015) MSI Bristol (4 complaints compared to 3 in 2015) and MSI Essex (12 compared to 11 complaints in 2015). MSI South London, MSI Maidstone and MSI Norwich had seen a decrease in complaints and MSI Sandwell had received no complaints in 2016.
- A lack of complaint posters and complaint leaflets and information in other languages had been raised as an area for consideration during a Clinical Commissioning Group (CCG) quality team walk around at MSI Manchester on 18 January 2017. MSI reported actions in February 2017 included displaying "Giving us your feedback" leaflets and posters around the location and that alternative language leaflets were available for downloading from the Marie Stopes website.

Are services at this trust well-led?

We have not published a rating for this key question. CQC does not currently have a legal duty to award ratings for those services that provide solely or mainly termination of pregnancy services.

We found:

- The senior management team at the UK administrative offices had undergone significant change since our inspection in July and August 2016. There were a number of posts still awaiting appointment on the senior management team.
- Senior key clinical roles at the UK administrative offices remained vacant or had interim appointments or were extended to cover dual roles. At the time of inspection vacant roles included the safeguarding lead, infection prevention lead, risk and governance lead, quality and safety lead and medical director.
- There had been significant work undertaken following the organisation's decision to voluntarily suspend certain services between August and October 2016. However, since services had recommenced the pace of change had slowed and only increased again once the new managing director had been appointed in January 2017. We were concerned that the

resignation of the UK managing director on 31 March 2017 would impact significantly on the organisation and tentative progress that had been made as that individual had been a driving force in moving MSUK forward.

- Quality measures, such as the balanced scorecard, clinical dashboard and comprehensive audit programme, had been developed but were yet to be approved and implemented. Since the inspection in February 2017, and subsequent change of UK Managing Director, we have been informed that these are being reviewed and may not continue in the same format.
- There had been insufficient progress to ensure that an effective mechanism was in place to monitor and provide assurance to the senior management team that safety measures and new ways of working across all locations were in place and that local managers were effective and supported. For example there was a lack of an effective system for ongoing monitoring of equipment, incident reporting, mandatory training compliance and statutory notification completion varied across locations.
- Clinical and corporate processes had been developed and strengthened but needed to be embedded as they had been implemented but had not been operational for long. The regional structure included a number of levels between the board and the locations and reporting was inconsistent across the regions. Governance sub committees were in their infancy and we found that some regions had yet to hold their first governance meetings at the time of our inspection.
- Newly formed systems and processes, such as incident reporting and a process for applying the duty of candour had been put in place. However, at the time of our inspection in February 2017 the effectiveness and impact could not be measured as actions taken following incidents were yet to be implemented due to the recent completion of investigations.
- We found that there remained some inconsistency across MSI locations in clinical practice and oversight to ensure quality of care. There had been a system for peer review in place that the provider used to monitor clinical practice and to highlight issues at locations.The format, methodology and consistency of peer reviews had been recognised by the senior management team as ineffective and had been discontinued at the time of our February 2017 inspection. At this time other mechanisms for achieving oversight and monitoring were not in place.
- Action had been taken to address HSA1 form compliance. The provider was working the with Department of Health to resolve IT issues in the sending and receipt of HSA4 forms. A manual system had been put in place to mitigate this during our inspection.

- There had been no formal staff survey to evaluate the impact of the changes made and to highlight areas for further improvement in staff wellbeing.

However:

- The managing director, chief nurse and newly appointed deputy chief nurse were aware of the detail of concerns and issues.
- The senior management team, as outlined above, at the time of inspection, had been cohesive in expressing their vision for the service, continued concerns and risks to achieving a patient focused high quality service.
- There was a recognition that the culture of the organisation needed to change to ensure that staff were empowered and engaged to drive improvements at location level. However, there was no formal plan in place to address this.
- The service had a ratified policy in place to ensure that directors were fit and proper people to manage the service. The HR service had been restructured and there was now a system in place to ensure appropriate pre- employment checks and that staff were appropriately registered to undertake the role to which they were appointed.
- The provider was working with stakeholders to address issues due to old IT systems that were hindering the notification of HSA 4 forms with the Department of Health.

Leadership of the service

- Since our inspection in August 2016 a number of key positions in Marie Stopes UK (MSUK) had been either filled with interim staff or appointed to on a permanent basis. The chief executive officer in January 2017 appointed a UK managing director who has had day-to-day oversight of the service. To support him there is an interim chief nurse appointed in August 2016, who is supported by a number of governance and quality leads. The medical director was in the process of stepping down and MSI had sought to replace this person. However, as at the time of inspection this post was out to advert. Medical advice was currently provided by the incumbent medical director.
- Shortly after our inspection, at the end of March 2017, the UK managing director resigned. The substantive chief nurse role had just been appointed and this person was to take on the role of chief nurse and acting managing director in the interim. This change in senior management meant that the stability of the core leadership within the organisation was further fragmented and remained in a period of high flux.

Summary of findings

- Multiple key positions were structured as dual roles whilst recruitment was ongoing, or where positions had been appointed but the individuals were not yet in post. For example, the newly appointed substantive chief nurse was also the acting managing director, the interim chief nurse was also undertaking the role of director of infection prevention and control (DIPC) and the newly appointed deputy chief nurse covered the risk and governance lead role (which had been their previous role).
- At this inspection, at regional level there was a triumvirate management structure in place, which consisted of a nurse leader, clinician and a manager responsible for oversight of the locations and for reporting to the senior team. However, some of these posts had yet to be recruited.
- There was a newly formed leadership structure. The interim chief nurse and director of governance line manage post holders who cover; safeguarding, infection prevention and control, contraception and sexual health advisors, quality and risk management and governance. However some of these posts had yet to be recruited.
- The senior leadership team were concerned that there were a number of vacancies across the structure and this inevitably leads to instability. However at our inspection in February 2017, the managing director and their colleagues were keen to appoint people with the appropriate skill set and have therefore had difficulty in recruiting to some posts. There was recognition that they are on a continual journey of improvement and appointing the most appropriate people into job roles would assist them in achieving this.
- Information submitted on 24 February 2017 stated the new post of medical director would provide clinical leadership and support to the lead anaesthetist and anaesthetic workforce, however this post was still to be recruited to at that time. To assist in supporting the regional teams MSI had appointed regional leads and anaesthetists who were responsible for practices within the regions. Senior staff informed us that the strength of leadership at a location level remained variable despite managers training having been organised by the provider
- The senior management team recognised that leadership across the locations was inconsistent. For example incidents and risk were not all managed in the same way, there was variation in statutory notification submission and staff training compliance. Despite this recognition there was no clear system of support in place for location managers and no effective

system to provide assurance that inconsistencies were being actively addressed. At the time of inspection peer reviews had not been replaced and new governance processes remained in their infancy.

Vision and strategy

- The managing director had implemented a new vision and strategy for the organisation. The new strategy was quality driven and focused on patient care. We found that there was recognition that expansion of the service had stifled providing a quality service. We found that the senior management team recognised this and had taken steps to address this. An example of this was the recognition that the service could not continue to treat the same numbers of patients whilst continuing to develop a quality patient focused service. Therefore, the numbers of patients operated on in one day had been reduced to allow staff to focus on the individual patient's needs.
- The managing director was also aware of the impact this action would have on the provision of termination of pregnancy services in the wider context. He was proactively seeking to work with others to ensure that termination of pregnancy services met the needs of patients.
- The organisation was also involving other bodies to quality review the actions they were undertaking. Since our inspection in August 2016 MSI had become more outwardly facing and accepting that in order to achieve a quality patient focused service they had to engage with recognised bodies to ensure that services were meeting national guidance and expectations. Examples of this included working with the Royal College of Anaesthetists to review new policy development to ensure they met the latest national guidance.
- The senior management team had plans in place or in development to review the service provision. They recognised that having a quality led and patient focused service was not compatible with the previous vision and strategy. They had identified that some services were better provided through a hub and spoke approach and were developing pathways to address this.
- The vision for the future was that there would be greater working with others to address some of the nationally recognised challenges within the termination of pregnancy services. This included the potential to offer rotational posts to junior doctors to enhance the skills and experience of doctors

and to encourage more doctors into this field of surgery. It is a recognised fact that the numbers of junior doctors entering this field of specialty is reducing year on year and that this is in part due to the low numbers of terminations carried out by the NHS.
- However we were concerned that the exit of the UK managing director would impact significantly on the organisation and the tentative progress that had been made as that person had been a driving force in moving MSUK forward.

Governance, risk management and quality measurement

- There had been a new strengthened governance structure put in place following our inspection in August 2016. The new integrated governance committee (IGC) had a number of sub committees which fed information into the IGC. These include the clinical governance committee, audit committee, information governance and remunerations committees. We reviewed minutes of the IGCs held since the restructure and found these to include reports from these committees. Minutes were more robust and demonstrated the discussions held and actions to be taken.
- MSI had re-established some of the previous monitoring systems, which were not functioning at the time of our inspection in August 2016. There was now a resuscitation committee, medicine management group, safeguarding committee and quality, safety and risk committee. Whilst these committees were in place they were yet to be embedded and due to the number of vacancies for members of these committees, remained fragile.
- Monthly regional governance committee meeting fed up into the central governance committee. However, we found that this structure was still in its infancy and there were inconsistencies in how these were managed and held regionally. To address this issue of inconsistency in reporting a new dashboard had been designed for centres to report key issues through to region and then through to the UK board. However, this had yet to be ratified at board level at the time of our inspection.
- To enhance the senior team awareness of issues and risks there was a planned schedule of visits to locations. These had been commenced in October 2016. When we discussed issues highlighted in minutes of governance and quality meetings the senior team were aware of these issues and able to cite the detail of the issues. This was an improvement since our previous inspection. However, there was a level of micromanagement of issues at locations within the senior team. Whilst we were assured that the senior team had an

improved understanding of what was happening at locations, through this micromanagement, we were unable to ascertain the understanding of issues at a regional level as minutes were not available for governance meetings at this level.

- MSI held a corporate risk register. We reviewed this and found it contained strategic, operational and clinical risks. Risks were rated in terms of priority and had a risk owner. The mitigating actions were time bound and reviewed in a timely manner.
- The managing director was aware that the regional structure was not yet embedded and was concerned that there were a number of levels between the board and locations. There were plans in development for the review of the number of layers from location to board and to implement a flatter reporting structure.
- There were regular executive management team meetings in place. Again, the senior team were reviewing and evolving these and a new meeting structure was proposed to start in March 2017.
- The senior team were aware of risks within the organisation and could articulate these. Most of the risks had mitigating plans in place. These included the appointment of a temporary responsible officer for medical appraisal when the medical director retired. Other risks included the embedding of the Department of Health Required Standard Operating Procedure (RSOP) standards and the timeliness of action taken due to the significant amount of work required. We found there had been significant work undertaken following the organisation's decision to suspend certain services. Staff had received training, new policies and procedures had been implemented and plans had been put in place in order to recommence services. However, since services had recommenced the pace of change had slowed and only increased again once the new managing director had been appointed.
- There was recognition by the senior management team that the organisation still had to improve and develop a robust quality and governance structure. The introduction of a new electronic incident reporting and management system had improved the recording and awareness of incidents occurring at a location level. We saw robust incident investigation reports and action plans developed in response to key themes identified. However, these were recently implemented and we could not assess the effectiveness of these actions as these were on going. Action was still required to assess the competency of nursing staff, to ensure that the system for ongoing monitoring of equipment was robust amongst other issues highlighted in this report.

Summary of findings

- The senior management team recognised that actions taken required embedding into every day practice at location level and that they needed to establish systems to drive quality improvement and promote a quality culture within the organisation.
- We saw that a policy ratification process was now in place through the clinical policy group reporting to the clinical governance group and policies then being ratified by the IGC.
- Governance around revalidation and registration had been strengthened and the entire human resources department had been restructured. There was now a system in place to ensure that staff were appropriately registered to undertake the role to which they were appointed. This system appeared to be working well and had been refined after an incident occurred.
- Senior staff were able to discuss on-going concerns such as consistency of practice at locations and the age of the IT infrastructure and were united in their main worries for the provision of the service.
- We found during our inspection in August 2016 that risk management arrangements were not in place in relation to ensuring certificate(s) of opinion, HSA1 forms, were completed in line with the requirements of the Abortion Act 1967 and Abortion Regulations 1991. Systems were not in place to ensure that treatment, including the prescribing of abortifacient medication, cannot be commenced unless a certificate(s) of opinion HSA1 forms had already been signed by two registered medical practitioners. The provider also had no process through which it could be assured that HSA4 forms were submitted to the Department of Health within the legal timeframe of 14 days. Action had been taken to address these issues, a practice control notice had been sent to all staff, medical staff had been provided with time to review notes prior to signing HSA1 forms and an audit had been undertaken. The provider was working with stakeholders to address issues due to old IT systems that were hindering the notification of HSA 4 forms with the Department of Health.
- It was planned that HSA1 and HSA4 audits would be incorporated into the 2017 clinical audit programme. Information showed that these were planned to be completed monthly. The HSA4 compliance within timeframe had also been incorporated into the quality combined dashboards that were due to be introduced however; both the audit programme and dashboard were yet to be introduced at the time of inspection.

Culture within the service

- There was recognition from the senior management team that the culture of the service required change. The senior management team reported that the culture of staff in some locations remained heavily dependent on the national team to direct improvements to services. The managing director was working to devolve accountability and responsibility to a local level. However, they recognised that this was still a work in progress.
- We found that there remained a culture where action was not always taken in a timely manner, as there was no perceived expert in that area. An example of this was within infection prevention and control where staff knew a new lead had been appointed and so were waiting to initiate changes that they knew needed to be made until this person was in post.
- The managing director had been given autonomy to develop and improve the service. He was supported in plans through appropriate challenge at the UK board. He was due to present an improvement plan and future strategy at the international board in March.
- There was recognition that previous lack of investment had had an impact upon the service's ability to develop and improve services. This was currently being rectified and investment was available to implement changes to ensure compliance with regulations and to develop services for the benefit of patients. An example of this was the financial implication of proceeding with an application to hold controlled drugs (CDs) at locations in order to provide a better service to patients. This initiative had the full support of the UK and international boards.
- The senior team were aware of the need to rebuild the reputation of the organisation following the suspension of certain services and the publication of CQC inspection reports. They recognised that this was required with stakeholders and regulators, as well as restoring public confidence. They were confident that the current message to staff of recruitment and development of staff and a focus on providing quality services would assist in empowering staff to [detail of what they wanted to empower them to do].
- There had been service wide engagement of staff prior to recommencing the suspended services, in part, to engage staff in the change process that was in progress. However, there had been no formal staff survey to evaluate the impact of the changes made and to highlight areas of further improvement in staff wellbeing.

Fit and Proper Persons

- At our previous inspection in July and August 2016 there had been no policy or process in place to ensure that directors were fit and proper people to carry out their functions. However, at this inspection we found a ratified policy in place and action had been taken to ensure that all directors had appropriate checks in place to demonstrate compliance.
- The service had rolled the check for fit and proper persons out to include all staff. Recruitment processes had been strengthened and existing staff files had been reviewed to ensure that disclosure and baring service (DBS) checks and references were in place and that all checks met current legislation.

Public engagement

- The organisation continued to seek feedback from patients using the service. However, they understood that some patients did not want to provide feedback.
- In order to engage patients in providing support to others and to learn from patients' experience the organisation provided patients with an opportunity to share their story. This facility was available on the MSI web site and patients completed a web form in order to share their experience with both MSI and with potential patients.
- We reviewed this website and found that the experiences were generally positive in nature. Most patients wanted to share their experiences for the benefit of others.
- Other ways in which the organisation was receiving feedback was through duty of candour meetings. Senior staff met with patients who had experienced or had received treatment where potential harm was highlighted and used this feedback to improve services.
- We were provided with a print publication action plan for 2016-2017 that outlined the objective to ensure the best information possible for patients throughout the entire treatment journey. A review of all patient facing print materials was underway with the plan to ensure all health information would be developed in accordance with NHS England's information standard criteria and processes. Included in the plan was the aim to launch a patient passport which would be a combined pre and during treatment booklet outlying all options alongside which a similar post abortion booklet would be produced.

Staff engagement

- MSI had undertaken a number of "Keeping updated roadshows" following our previous inspection and prior to the

recommencement of the services it had voluntarily suspended. These roadshows were used to introduce new policies and procedures such as the clinical practice guide and early warning scores.

- The senior management team had reviewed feedback from the roadshows and had made changes as a result. For example, a new surgical list structure was being implemented by operations as a direct result of staff feedback. This would improve efficiency and mean more availability and shorter wait time for patients.
- The senior management team recognised the need to ensure that staff were engaged with the programme of improvement and had scheduled visits to individual locations to meet and understand the concerns of staff. This schedule included the managing director, the chief nurse and the non-executive directors.
- The senior management team had recognised that staff engagement was paramount and specific organised events were planned for each staff group. This included a nurses' away day in February 2017 with a doctor's forum and a healthcare assistant's forum planned in the months following our inspection.
- The interim chief nurse had set up an email inbox in order that staff could contact them directly with concerns or comments. They also wrote a chief nurse newsletter to ensure staff were informed of developments.
- The managing director also communicated with staff via newsletters and email. He had ensured that staff felt listened to when he received communication from front line staff. Following his departure the interim managing director was committed to continuing open communication with staff.

Outstanding practice and areas for improvement

Areas for improvement

Action the trust MUST take to improve

- Ensure that there is an effective system of leadership and governance in place to monitor the service and reduce the risk of harm.
- Ensure that all risks are assessed, monitored and that mitigations are in place to reduce the risk of harm.
- Ensure that the implementation of an Early Warning Score (EWS) is consistent across all locations and that there is an effective system for monitoring to provide assurance that it is being used appropriately.
- Ensure that all nursing staff are competent in their roles to ensure the safety of patients using the service. Ensure that there is an effective system for monitoring competence and a system for regular staff appraisals.
- Ensure that there is an effective system for monitoring of training compliance across all locations.
- Ensure that effective systems and processes are in place to monitor and improve services, providing consistency across locations
- Ensure that the World Health Organisation (WHO) Five Steps to Safer Surgery checklist is completed accurately, used appropriately at each phase of the surgical procedure and quality audit is undertaken.
- Ensure that effective oversight systems and processes are in place to service and maintain all equipment.

Action the trust SHOULD take to improve

- Review the training, competency assessment and revalidation of ultrasound training.

This section is primarily information for the provider

Requirement notices

Action we have told the provider to take

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

Regulated activity	Regulation
Diagnostic and screening procedures Termination of pregnancies	Regulation 17 HSCA (RA) Regulations 2014 Good governance At our previous inspection between July and August 2016, we raised concerns regarding ultrasound scanning. Training occurred internally through a non- accredited course and assessment of competency was limited and not in line with the provider policy. At the time of inspection in February 2017 there had been no change with regard to the training or monitoring of competence of those staff undertaking scanning. The ultrasound policy had been reviewed in October 2016 however it continued to highlight abnormalities staff should be identifying. The policy still lent towards staff requiring skills, beyond date scanning competency, in regard to identifying various conditions that would require escalation. Wording from the policy stated “In the event of any pelvic condition being suspected e.g. implantation of embryo in a previous caesarean scar, uterine fibroids, co-existent mass, polycystic disease, fluid in the Pouch of Douglas, ectopic pregnancy all clinicians should escalate to the surgeon or doctor present on the day for review”. There was no assurance at provider level that the level of ultrasound scanning training matched the scope of policy. Regulation 17 (1) (2) (a) (b) Regulations 2014 Good governance

This section is primarily information for the provider

Enforcement actions

Action we have told the provider to take

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

Regulated activity	Regulation
Diagnostic and screening procedures Termination of pregnancies Treatment of disease, disorder or injury	Regulation 17 HSCA (RA) Regulations 2014 Good governance There had been insufficient progress to ensure that an effective mechanism was in place to monitor and provide assurance to the senior management team that safety measures and new ways of working across all locations were in place and that local managers were effective and supported. There was variance across locations regarding incident reporting and participation in regional incident review meetings to enable shared learning. At the time of inspection nursing staff had not received training for Duty of Candour. There was variation across locations in completion of statutory notifications. The senior management team recognised that leadership across the locations was inconsistent. Despite this recognition there was no clear system of support in place for location managers and no effective system to provide assurance that inconsistencies were being actively addressed. At the time of our inspection in February 2017 a resuscitation committee, medicine management group, safeguarding committee and quality, safety and risk committee were in place. Whilst these committees had been introduced they were yet to be embedded and some had not occurred at the time of inspection. The pace of implementation of new procedures and audits for assurance was slow. Quality measures, such as the balanced scorecard, clinical dashboard and comprehensive audit programme, had been developed but were to be approved and implemented.

This section is primarily information for the provider

Enforcement actions

The audit template, to enable a quality observational check, of the World Health Organisation (WHO) Five Steps to Safer Surgery checklist was still in draft format and was yet to be introduced.

There was no effective assurance system in place to measure that accurate and appropriate completion of the checklist, at each phase of the surgical procedure, was embedded into practice.

Revised infection prevention and control audits were due to be introduced in March 2017. There was no evidence of increased audit at locations where the provider knew there were issues with infection prevention and control.

A termination of pregnancy early warning score system (TEWS) had been devised, piloted but was yet to be rolled out across locations. Whilst NEWS remained in place there was no effective monitoring system to provide assurance that it was being used appropriately.

There was no effective system in place at provider level for assurance that all equipment, including equipment at early medical abortion units (EMUs), had been serviced and maintained.

External review had highlighted that anaesthetic policies did not reference the latest guideline, despite a policy ratification process having been put in place.

Monthly regional governance committee meetings fed up into the central governance committee .The governance structure was still in its infancy and there were inconsistencies in how these were managed and held regionally.

There remained a culture where action was not always taken in a timely manner, as there was no perceived expert in that area.

There had been no formal staff survey to evaluate the impact of the changes made and to highlight areas for further improvement in staff wellbeing.

Regulation 17 (1) (2) (a) (b) Regulations 2014 Good governance