

Marie Stopes International

Quality Report

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Date of inspection visit: 28 July 2016 and between 1
and 8 August 2016
Date of publication: 20/12/2016

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. Most of these are carried out on behalf of the NHS. 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 inspection programme. During the quality assurance of the reports of the registered location it became clear that whilst the inspections identified a number of positive factors they also identified some concerns linked to the provider's governance arrangements. As a result, CQC carried out an unannounced inspection of Marie Stopes International's UK administrative offices in Conway Mews, London on 28 July 2016 and 8 August 2016.

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. We did, however, find that the provider did not have sufficiently effective governance arrangements across registered locations so as to be assured of the safety and quality of all of the services it provided to patients. Therefore we inspected the provider in respect of these concerns and not at all domains using the key lines of enquiry. A full assessment of the caring domain can be found in the individual location reports.

We sent the provider a letter setting out our significant concerns and the fact that we would have to take urgent action unless the provider immediately addressed the risks we had identified. In response, the provider decided to voluntarily suspend services as follows on 19 August 2016, with immediate effect:

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

This action negated the requirement for CQC to take urgent enforcement action as patient groups in relation to whom we had major safety concerns had their safety risks addressed by MSI suspending the above services.

At the time, NHS England activated 'contingency arrangements' to ensure that all patients seeking the services that had been suspended could receive safe quality care. This included diverting around 250 patients a week to alternative providers and setting up a helpline for anyone with any questions or concerns.

Since 19 August 2016 CQC has been monitoring Marie Stopes International very closely and reviewing its progress. CQC served four warning notices (as referred to in the section of the report entitled 'Enforcement Action' which is at the end of this report) in relation to consent, safeguarding, the care and treatment of patients and governance processes as the provider had breached the CQC regulations relating to these matters. The provider needed to take action to remedy the breaches identified. MSI is working to remedy these breaches. CQC continues to monitor these services with regard to compliance with the regulations and will re-inspect these services in due course. CQC also worked with other stakeholders to ensure the provision of termination of pregnancy services are available to patients who require this service.

Having demonstrated to CQC that it has addressed the most serious areas of concern, including staff training in the key areas identified, Marie Stopes International began to lift the restrictions it placed on its termination services on 7 October 2016.

Our key findings at the time of inspection were as follows:

- There was limited clinical oversight of the quality of the service provided. There was a vacancy for the head of nursing. The medical oversight, provided by a consultant in gynaecology and obstetrics worked eight hours a week. This person reviewed policies and procedures, was responsible for the clinical quality and had responsibility for medical staff. There had been concerns about the anaesthetic leadership of the service.
- There was no process for ensuring that the senior team were fit and proper persons to manage the service.

Summary of findings

This is a duty required by the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014. Key documentation on the recruitment of individuals was missing from personnel files.

- The professional registration of clinical staff, both nursing and medical staff, working at the service was routinely checked at employment. Some locations maintained their own annual checks but the provider did not ensure that professional registration was routinely checked on an ongoing basis.
- There was limited oversight of the training required and undertaken by staff. Monitoring of competence of staff was ad-hoc.
- Poor quality monitoring of services in areas such as consent and safeguarding, with staff not appropriately trained and practice not adhering to national guidance.
- There was a lack of oversight as to the completion and submission of HSA1 and 4 forms respectively.
- Whilst location staff were able to verbalise what the duty of candour meant the senior team were unaware of their responsibilities in this respect.
- Poor risk management arrangements have given rise to specific immediate concerns relating to the lack of assurance in MSI, in areas such as consent and safeguarding and the lack of assurance in relation to training and competence in conscious sedation and general anaesthesia.
- The provider was not complying with the required monitoring of the service under the Department of Health Required Standard Operating Procedure (RSOP) standards and had limited understanding of these standards.
- The provider was aware that there was an “inadequate reporting system.” However, no action had been taken to identify the cause and to mitigate the risks of non-reporting of incidents. Therefore learning from incidents was low throughout the organisation.
- Staff taking consent from children and young persons were not appropriately trained to explore issues such as female genital mutilation or child sexual exploitation.
- Staff were not trained to ensure that vulnerable patients had a good understanding of procedures.
- Processes for counselling services for children and young people were not consistently described.
- There was a policy for the management of anaesthesia and sedation however this was due for review in 2013

and had not been reviewed. The policy did not address the management of difficult airways. At location level the staff told us that there was no policy in place.

- Competency checking on anaesthetists, doctors and staff was ad-hoc.
- Whilst the provider had a planned programme of maintenance, equipment there was a lack of oversight of this programme.
- Staff were unaware about the management of deteriorating patients as there was no policy in place. Medical personnel left the premises before all patients were discharged and nursing staff were not trained to deal with emergency situations which may arise.
- Staff had limited training in resuscitation. Unplanned simulation drills were poorly attended and staff in attendance rarely knew what the correct actions were. Feedback from these simulations was limited.
- There was no resuscitation committee in place to ensure that policies were up to date nor to provide guidance to the provider on improvements required. This committee was incorporated into the clinical governance committee however records demonstrated a lack of discussion of resuscitation issues.
- The policy and practice of the organisation limited who could report potential safeguarding alerts. Despite staff at location level being able to verbalise what constituted a safeguarding referral staff were not trained to the appropriate level in safeguarding in order to recognise when referral was required. The limitations on the grades of staff who could report alerts delayed reporting of some serious concerns. The provider was aware of this issue but had not taken remedial action in all of its locations.
- Ultrasound scanning was undertaken by staff who received internal non-accredited training. Staff, whilst dating the pregnancy, were also diagnosing potential medical issues for the patient without assurances around competence to do so. Competency checking of staff undertaking scanning was limited and not in line with the provider’s policy.

As noted above, there were areas of poor practice identified where the provider needed to make improvements.

Importantly, the provider has been required to :

Summary of findings

- Ensure that staff taking consent have the appropriate knowledge, skills and competence and have a full understanding of the procedure for which they are taking consent.
- Ensure that vulnerable patients are able to give informed consent.
- Ensure that there is an effective counselling system for children and young people, and vulnerable patients, to assist in enabling informed consent.
- Ensure that effective oversight systems and processes are in place to service and maintain all equipment.
- Ensure that there are effective systems in place for timely reporting and management of incidents and safeguarding concerns.
- Ensure that all risks are assessed, monitored and that mitigations are in place to reduce the risk of harm.
- Ensure that all medical and nursing staff are competent to ensure the safety of patients using the service.
- Ensure that effective systems and processes are in place to monitor and improve services.
- 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 the World Health Organisation (WHO) Five Steps to Safer Surgery checklist is completed accurately and used appropriately at each phase of the surgical procedure.
- Ensure audits undertaken in relation to the World Health Organisation (WHO) Five Steps to Safer Surgery checklist include observational audit to assess the quality of the check and embedded practice.
- Ensure that there are effective processes in place to ensure that the certificate(s) of opinion HSA1 forms are signed by two medical practitioners in line with the requirements of the Abortion Act 1967 and Abortion Regulations 1991.
- Ensure that there is an effective process for submission of HSA 4 forms to the Department of Health within the legal timeframe of 14 days.
- 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 (TOP) 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 1973 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 look at those services that are registered with CQC, which are within England.

Our inspection team

Our inspection team was led by:

Chair: Heidi Smoult, Deputy Chief Inspector, Care Quality Commission

The team included two Head of Hospital Inspections, one inspection manager and two CQC inspectors with specialist advice from CQC's national specialist advisor for obstetrics and a specialist in radiology and scanning.

How we carried out this inspection

We used information gathered following inspection of 11 clinic locations and the One Call service registered in England by Marie Stopes International to inform our inspection. We reviewed a large number of data items received from the provider following our inspection on 28 July 2016 to inform our further inspections during August 2016.

We inspected the provider's registered administrative offices in London on 28 July 2016 and again 8 August 2016. Both of these inspections were unannounced, with

arranged interviews taking place on 1 and 3 August 2016. At these inspections we spoke with senior members of the Marie Stopes International's UK team and reviewed evidence both online and presented to us by staff.

We did not speak to women using the service at these inspections as we were inspecting the UK administrative offices of Marie Stopes International and no patients were present. Following our inspections we spoke with other stakeholders such as the Department of Health and NHS England about our concerns.

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 1973. The provider is registered for:

- 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

Summary of findings

Our judgements about each of our five key questions

	Rating
<p>Are services at this trust safe?</p> <p>We found that:</p> <ul style="list-style-type: none">• The incident reporting process was not effective. Incidents were not investigated in a timely and appropriate manner.• We found no evidence in the reports to the MSI board, the central governance committee (CGC) or the clinical leads' meeting that any trends in incidents, any themes or any learning from incidents had been discussed.• There was no policy in place, no training for staff and no auditing of when the statutory duty of candour was to be implemented within the organisation.• Not all staff had the required level of life support training in place and compliance levels varied immensely across locations.• The provider was unable to provide assurance that staff working in the early medical abortions units were trained and competent to the correct level of resuscitation training.• Records for anaesthetist compliance with advanced life support training were not readily available.• There was no evidence of an effective oversight system for the maintenance of equipment.• The provider had not ensured that there was a system in place to ensure that nursing staff were trained and competent to assist an anaesthetist to administer anaesthesia and monitor patients undergoing conscious sedation or general anaesthesia.• There was a policy for the management of anaesthesia and sedation however this was due for review in 2013 and had not been reviewed. The policy did not address the management of difficult airways. At location level the staff told us that there was no policy in place. This meant that we could not be assured that patients receiving conscious sedation or general anaesthesia were being managed safely.• Staff did not carry out the World Health Organisation (WHO) Five Steps to Safer Surgery checklist appropriately and the format of local audit was not effective to ensure compliance.• Safeguarding training was not in line with best practice guidance and staff were not trained to an appropriate level in relation to children's safeguarding. The recording of training did not differentiate between adult and child safeguarding.	

Summary of findings

- There were delays and inconsistent reporting of safeguarding incidents. We were concerned that the safeguarding committee was aware of deficits and delays in reporting issues relating to safeguarding yet there was no evidence provided that action had been taken to resolve this issue.
- Staff had no training in respect of female genital mutilation or child sexual exploitation, putting these patients at risk of further abuse.

Incidents

- The incident reporting process was not effective and the provider could not be assured that all incidents were being reported. Staff did not have access to the incident reporting system and had to make paper records which were uploaded onto an electronic system by governance administrators, which created a delay in reporting and responding to concerns. There were plans in place to bring in a new incident reporting system to improve the process later in the year.
- There was an incident reporting policy in place which the director of governance told us was in need of review. There was no guidance in place for staff to categorise incidents.
- There were 2634 incidents reported during 2015/2016, which was an increase of 704 incidents from 2014/15. There was a very limited narrative to accompany the graph sent to CQC by the provider, to give context and explanation of the data. However, there was reference that the number of incidents reported was increasing year on year. This did not take into account the significant growth in UK activity during 2015/16. The increase in the total number of incidents being reported may have reflected the increase in activity but there was no evidence that any consideration had been given as to the number of incidents reported as related to the increase in activity.
- We found no evidence in the reports to the MSI board, the central governance committee (CGC) or the clinical leads' meeting that any trends in incidents, any themes or any learning from incidents had been discussed. Furthermore, it was difficult to follow the records of these meeting discussions, due to the poor quality of notes available. Discussions were not clearly recorded and action points were not clearly defined. Reports were not always dated so it was unclear as to which month, quarter or year they related to.
- During our location inspections, it was found that the incident process was ineffective in most locations. Staff told us they did not get feedback from incidents at eight locations. However local systems were in place at four locations for the

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dissemination of feedback. Clinic leads found it difficult to extract information from the incident system in terms of what incidents had been reported, what stage of the investigation process they were at and if they were closed.

- During our inspection of one location, we observed an incident involving a patient who became very distressed, where we witnessed inappropriate behaviour by a surgeon. Although we wrote to MSI to inform the provider of the incident and ask for an update as to how it had been dealt with, the incident was not reported through the MSI incident reporting system. However we did not witness the practice of dealing with patients with a learning disability at the other seven clinical locations.
- The national safeguarding lead had raised issues with the reporting of incidents in June 2016 at the clinical governance committee meeting. However, no action had been taken to address these concerns.
- Incidents were investigated by clinical operations' managers and regional managers. These staff had received training on root cause analysis in May and June 2015. We were not assured that the process for investigating incidents was effective because there were no audits in place to monitor the quality of incident investigations.
- We reviewed five investigation reports sent by the provider. These did not effectively investigate incidents immediately upon becoming aware of any referral of an allegation or evidence of abuse. One investigation report showed that the investigation was not commenced until two months after the incident. There was limited sharing of the learning from this case as it described the arrangements for sharing learning as discussion with commissioners and doctors. Evidence provided demonstrated that learning from incidents was shared with the team involved but not utilised to enhance the knowledge of all staff across the service in order to reduce the risk of reoccurrence.

Duty of Candour

- Regulation 20 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 places a statutory duty of candour requirement on all providers of health and social care. This regulation requires the provider to notify the relevant person that a notifiable safety incident has occurred, to provide reasonable support to the relevant person in relation to the incident and to offer an apology.

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- There was no policy in place for the duty of candour requirements which meant staff did not have a process to follow when they were dealing with incidents.
- There had been no training for staff on the requirements of the regulation.
- We interviewed senior members of the provider's management team. We were told by the regional director of commercial operations that duty of candour awareness was discussed at a meeting. There were no audits to monitor the provider's compliance with the regulation. The director of UK commercial operations told us they did not get involved with the duty of candour. This meant that the two most senior members of the provider's executive team had no involvement in ensuring they met the requirements of the duty of candour regulation. We were not assured that the directors we interviewed were fully aware of the requirements the regulation placed upon MSI.

Mandatory training

- The provider had a training matrix in place to identify training that should have been undertaken by staff at all locations. We reviewed this training matrix and found that many staff were out of date with training. Following us highlighting this to the provider, updated training in many areas was provided.
- A review of the training records indicated that not all staff had the required level of life support training in place. Across 13 registered locations, a total of 51% of staff had completed basic life support (BLS) and intermediate life support (ILS) training as at May 2016. In some locations, training compliance was as low as 26% (Manchester) but in others, it was higher, such as 83% of staff trained in the Maidstone location.
- No medical staff worked in the early medical abortions units (EMU). MSI policy indicated that registered nurses would have ILS training and health care assistants would have BLS training. The provider was unable to provide assurance that staff working in the EMUs were trained and competent to the correct level of resuscitation training.
- We asked the provider for information about advanced life support (ALS) training. There were no records that were readily available. Following the inspection, it was confirmed that 79% of anaesthetists had ALS training in place as at 26 August 2016. Senior staff were unaware, however, of the requirement for staff that have ALS training to undergo an annual update as per Resuscitation Council (UK) guidelines and confirmed to us on 28 July 2016 that there were no records of any annual updates.

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- Evidence provided on 26 August 2016 demonstrated that the provider had contracted an external provider to undertake six training sessions of ILS training to be provided between 19 August 2016 and 10 October 2016.
- In addition nine scheduled training scenarios and unannounced simulations were planned at the following locations:
 - Essex
 - South London
 - Bristol
 - Leeds
 - Norwich
 - Maidstone
 - Birmingham
- However, there was inconsistency across the locations as to the format this training would take. For example, the West London location was to have a training scenario only and the Central London location was to have an unannounced simulation exercise only. No details were provided as to why these may differ and the reasoning behind this. There was no confirmation of the numbers and designation of staff that were due to attend this training.
- As part of the update on 26 August, it was stated that the overall compliance rate with ILS/BLS training for staff was 69% across the whole organisation. This information was not available separately for ILS or BLS.

Safeguarding

- There was a provider wide safeguarding policy in place in respect of adults and children and young people. Both these policies were dated April 2016. However, we could find no evidence that these policies had been ratified by any internal committee.
- There was no director in place who had the lead role for safeguarding adults or children. The provider had a contract with an external consultant to provide safeguarding advice. We were told this person was on call for any queries.
- Not all of the clinically focused staff were trained to the required level. Whilst the Safeguarding Children at Risk Policy stipulated that it was written in line with best practice from the Intercollegiate Document for Healthcare Staff (2014), we found that the levels of training required did not match the Intercollegiate Document for Healthcare Staff (2014) guidance.
- The children at risk policy stated that “Level 1 training is for all staff that have client contact either directly or indirectly. Most staff will receive this as part of their induction programme.”

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However, on review of the data sent to CQC dated May 2016, we found that only 81% of staff had level one training that was in date. In Leeds the percentage trained at level one was 36.4% and in West London the percentage was 33.3%.

- The policy stated that “Level 2 training is intended for all that staff that are able to take responsibility for making a referral if abuse is suspected. This would include clinical staff (registered nurses, doctors, anaesthetists). Additionally client liaison officers, Supervisors at call centres, and the management team within the clinical centres and call centres should attend this training.” On average we found that 59.8% of staff were trained at this level in child safeguarding identification and processes. In Maidstone only 16.7% of staff had had training on child safeguarding in the previous year. This does not comply with the Intercollegiate Document for Healthcare Staff (2014) which states that all staff who have any contact with children or young people should have level two training. This includes non-clinical staff.
- The Intercollegiate Document for Healthcare Staff (2014) stated 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. On review of the evidence provided by the organisation, we found that level three safeguarding training was undertaken by one or two members of staff at each location. This was usually the clinical operations manager or team leader and the second was usually a registered nurse. We found that early evidence submitted by the provider demonstrated that this level of training varied across locations. Three centres (Birmingham, Essex and Leeds) had only one person trained at level three, Bristol and Maidstone centres had two members of staff trained, one centre (West London) had three members of staff trained, one centre (Manchester) had four members of staff trained at this level whilst the South London centre had nine members of staff trained at level three. Three centres (Central London, Coventry and Norwich) had no staff trained at level three working at the centre. This meant that there were insufficient numbers of appropriately trained staff to appropriately assess, plan, intervene and evaluate the needs of children and young people attending the service.
- This concern was raised with the provider on 5 August 2016. At our inspection on 8 August 2016 we found that the provider had taken action to ensure that all patients under the age of 18 years of age would only be consented by a member of staff with

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level three safeguarding training. However, at the time of our inspection there was no effective mechanism for ensuring that this was occurring in centres around the country. There was no process for monitoring this revised process for consent or how deficits were to be raised or addressed.

- On 10 August 2016, the provider confirmed that they had secured a training provider who would undertake this training for all staff prior to 16 September 2016. However, on review of the planned dates and allocation of training we saw that 29 out of 57 medical staff had no training planned.
- The training provided to staff at the time of inspection did not address the issues of child sexual exploitation or female genital mutilation. We found that there was no evidence to demonstrate that any training was given to staff on these issues. However, we also found that in seven locations staff were aware of the issue of female genital mutilation through previous experience or recent training. The proposed training outlined from a new training provider and from MSI's safeguarding lead, for future training content, did not refer to staff receiving training on child sexual exploitation. Therefore, we were concerned that staff would be at risk of failing to recognise this factor of abuse. During our inspections of the locations operated by the provider, some staff were aware of issues relating to child sexual exploitation from their own personal knowledge. However, the provider had not provided training on this issue.
- The policy entitled Safeguarding Adults and Young People Policy dated April 2016 did not address the issue of the frequency of the training provided. The document supplied by the provider entitled Mandatory and Statutory Training Guidance MS UK states that safeguarding training at all levels should be undertaken every three years. Whilst there is no statutory requirement to undertake annual refresher training, it is good practice to update staff when changes in the legislation occur. On review of the training matrix sent by the provider, we found that 37.4% of staff either were out of date by the terms of the policy or had not received level one safeguarding training within three years. The recording of training did not differentiate between adult and child safeguarding.
- We were concerned that the safeguarding committee was aware of deficits and delays in reporting issues relating to safeguarding. A review of the safeguarding committee minutes (dated June 2015 to July 2016) highlighted that, despite discussing the issue three times, there was little evidence of progress. The minutes note that the Essex centre demonstrated an increase in July 2016 of reporting, following additional

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training and raising awareness of staff. This demonstrated that, prior to this training, staff were not appropriately trained to identify and report safeguarding concerns. The safeguarding lead recognised that the process for reporting incidents was inappropriate and raised concerns in an internal interview in May 2016 with senior managers. However, no evidence was provided that action had been taken to resolve this issue.

- We reviewed a list of safeguarding incidents that MSI supplied. This showed that there had been 22 referrals this calendar year across seven centres and four early medical centres. However, at our inspection in West London we found evidence that the registered manager had been concerned about the reporting of safeguarding concerns and had undertaken some training. This had increased the number of safeguarding referrals to 14 in the current operating year, 2015/2016. Eleven of these referrals had occurred since the registered manager had undertaken the training. However, none of these were in the data sent to us by MSI.
- On review, the data showed that nine of the 22 referrals were referred within 24 hours, nine within a week, two at nine days and three over 15 days. In the minutes of the safeguarding meeting in June 2016, we noted that the provider had acknowledged the unacceptable delay in reporting an particular incident. We asked for information about a delayed case and did not immediately receive any but were then informed that a referral had been made. There was no evidence that MSI was taking the necessary steps to mitigate the risks to children and young people in relation to safeguarding them from abuse and improper treatment

Equipment

- We saw documentation which had previously highlighted an issue with equipment. There had been a delay in responding to the issue raised. We raised our concerns over the servicing and repair of equipment with the provider.
- The provider sent a practice control notice on 22 August 2016 to centres to ensure that staff at locations were ensuring that equipment used for anaesthesia and conscious sedation was checked in line with the Royal College of Anaesthetists (RCOA) 2012 checklist of anaesthetic equipment. This practice control notice also stated that all patients having conscious sedation and anaesthesia should be monitored and recordings documented on the central records system.
- A copy of the provider's service level agreement in relation to equipment was included with the action plan sent on 26 August 2016. Within this agreement there was a plan in place to ensure

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that equipment be regularly serviced. However, there was no audit confirmation or evidence provided to demonstrate how this would take place. Alongside this, CQC received a copy of the daily audits of the equipment used. We noted that details of checks were vague such as “BP and SATS leads checked”. This may be that the leads were checked and present but does not explicitly demonstrate that the leads and equipment were in good working order.

Assessing and responding to patient risk

- We found evidence at nine locations that staff were not completing the World Health Organisation (WHO) Five Steps to Safer Surgery checklist appropriately. However good practice was seen at Leeds and Manchester centres where staff were adhering to the principles of the safety checklist. There was no effective monitoring process or audit undertaken to ensure staff across locations complied with MSI policy and completed the check appropriately.
- At both MSI Essex and MSI Norwich, staff in the operating theatre were observed completing all aspects of the WHO Five Steps to Safer Surgery checklist before the surgery had started. This included the ‘sign out’ and recovery sections. These sections are designed to record the correct number of swabs and instruments after a procedure had been conducted to ensure none were retained and also record any concerns in the recovery phase. Staff, when questioned, stated this was due to the speed of throughput of patients. At MSI Maidstone there were inconsistent and incomplete WHO Five Steps to Safer Surgery checklists seen and staff had limited understanding of the checklist and were unaware of MSI policy. At both MSI Sandwell and Birmingham the checklist was completed in advance by a healthcare worker without the involvement of any clinicians present.
- MSI locations are required to undertake a bi-annual medical records audit that encompassed a quantitative check of 30 patient records. The medical records audit did not identify this practice. The audit template entry stated “WHO Surgical checklist completed and signed” and we noted that this was included in the preoperative section of the records audit and not the procedure section. There were no observational quality audits to ensure that the check was completed appropriately.

Management of the deteriorating patient

- There was a policy for the management of anaesthesia and sedation however this was due for review in 2013 and had not been reviewed. The policy did not address the management of

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difficult airways. A draft general anaesthetic policy was provided to CQC in August 2016, which was drafted by the anaesthetic lead. This had not been approved or ratified by MSI and therefore had not been implemented. On 26 August 2016 we were sent an action plan that stated a new anaesthetic and conscious sedation policy would be completed by 26 August 2016. However, no new policy was sent to CQC by the provider at that time.

- There was no recognition in the draft policy referred to above that staff needed to consider how they would manage a difficult airway. The Difficult Airway Society (DAS) guidelines for management of unanticipated difficult intubation in adults 2015 highlights the need to have equipment to manage a difficult airway available in operating theatres. The action plan sent to CQC on 26 August 2016 had stated that the revised policy would contain references to managing a difficult airway.
- The provider had not ensured that there was a system in place to ensure that nursing staff were trained and competent to assist an anaesthetist to administer anaesthesia and monitor patients undergoing conscious sedation or general anaesthesia. The risk of this is significant in that if a patient deteriorates during anaesthesia and requires emergency intubation, nursing staff may not be competent to assist. Anaesthetic practice includes having a healthcare professional (either a registered nurse or operating department assistant) who is competent to provide dedicated anaesthetic support, should this be required.
- At MSI Essex the lack of trained competent staff to assist during anaesthesia was raised as an issue as there were no staff on site who had undertaken any recovery or airway management training.
- The lead anaesthetist told us during our interview on 3 August 2016 that they had highlighted a concern with the provider in the past that nursing staff did not receive training in anaesthetics or recovery. However, there was no evidence that action had been taken to address this concern.
- Following CQC raising concerns with the provider, the update provided on 26 August 2016 stated that MSI had secured a two day training course via an external training provider which was to commence on 30 August 2016. However, the training provider's website stated that this was a three-day course. We noted that 16 nurses were booked to attend. We noted that the course content was a standard content which included respiratory emergencies rather than difficult intubations.
- There was a risk assessment for the management of the deteriorating patient dated November 2015. The risk

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assessment did not consider the full extent of risks associated with this issue. It focused on process rather than on how to mitigate the risk. The risk assessment did not take into account the root cause of the risk and the steps that needed to be taken to respond to it. It failed to take account of the fact that there was no policy and training programme for staff. There was limited evidence that this risk assessment has been discussed in detail by the senior management team and clinical leads through review of the minutes of meetings with this group of staff. The provider had failed to mitigate key risks to patients when they undergo general anaesthesia or conscious sedation. The management of the deteriorating patient was not included within the nurses' induction and competency checklist. The provider had not set out the expectations for nursing and health care assistant staff on what to look for and what action to take.

- Furthermore, the provider confirmed that anaesthetists left the MSI premises once the theatre list was finished and they had completed a final ward round. This meant nursing and healthcare assistant staff were left to monitor patients until discharge. However, information submitted to CQC stated that staff did not have the appropriate training to ensure patients' safety should a patient's condition deteriorate. Staff were not trained in advanced life support for instance. However there was no recent evidence of harm to patients.
- On 26 August 2016 the provider sent CQC a clinical practice guide which outlined how observations should be taken and what to do if these are not within expected normal ranges. The status of the clinical practice guide was unknown, in terms of ratification and roll out to staff, but the information it contained was relevant to the management of the deteriorating patient. The provider intended to use a National Early Warning Score (NEWS) should a patient deteriorate. The guidance outlined what actions staff should take should patient observations deviate from the normal expected values. It was a useful resource to staff at the clinics and units.
- There were no Patient Group Directions (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. There was no algorithm in place to give guidance to staff on how this should be managed.
- The clinical practice guide, provided on the 26 August 2016, outlined the management of a deteriorating patient. Whilst the

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management of the deteriorating patient addresses most points, the guide did not address what the centres would do if no doctor was present to administer the recommended medications which require a prescription.

- There was no evidence provided that the clinical practice guide had been ratified or implemented at the locations. There was no evidence as to how the implementation would be monitored or how staff were to be trained in its use and that of the NEWS scoring tool.

Are services at this trust effective?

We found that:

- The provider had no system or process in place to monitor compliance against the Department of Health Required Standard Operating Procedure (RSOP) standards or Royal College of Gynaecology guidance.
- The practice of simultaneous administration was not in line with current RCOG guidance. Staff could not assure us that treatment was evidence-based. Managers could not direct us to risk assessments or action plans for the evaluation of this treatment, or any evidence of outcome monitoring since the practice had changed.
- Assessment of the competency of staff was not in line with the provider's policy. Staff undertaking ultrasound scanning were trained internally through a non-accredited course. There was limited assessment of their understanding or competency checks undertaken to assess their skills in performing this role.
- There was no policy in place to ensure that nurses continued to be registered by the Nursing and Midwifery Council. There were no plans to assist and monitor nurses for revalidation.
- There was a lack of oversight of the ongoing competence of doctors.
- MSI did not have effective oversight of situations when concerns were raised regarding the fitness to practice of their clinicians.
- There was no effective system in place whereby the competence of anaesthetists administering general anaesthesia and conscious sedation was assessed and monitored to ensure they were carrying out their practice in line with national guidance.
- Consent processes were not in line with national guidance nor were staff following the provider's own policy of countersigning the initial consent taken.

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- We were not assured that those staff undertaking the consent procedure had the appropriate training in consent for children and young people and those with learning difficulties.
- Staff taking consent from children and young persons were not appropriately trained to explore issues such as female genital mutilation or child sexual exploitation.

Evidence based care and treatment

- Independent places carrying out termination of pregnancy must by law hold approval given by the Secretary of State for Health. This is in addition to being registered with CQC. The Secretary of State will consider the approval if providers comply with:
 1. The Abortion Act 1967 and regulations made under that Act – currently the Abortion Regulations 1991
 2. The requirements set out in regulations made under the Health and Social Care Act 2008; and
 3. The Required Standard Operating Procedures (“the RSOPs”)
- 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.
- The provider had no system or process in place to monitor compliance with the Department of Health Required Standard Operating Procedure (RSOP) standards. There was a lack of knowledge amongst the senior management team at the headquarters regarding these standards. However, following our inspection on 8 August 2016 a set of standards were issued to all of the senior team. Following our inspection the provider began to collect data to meet the RSOP.
- RSOP standards require that policies and procedures are in place to ensure that termination of pregnancy is in line with legislation and national guidance. The provider could not provide assurance that policies were up to date with the legislation, current guidance and that staff were appropriately trained to undertake their roles. However, following CQC highlighting this to the provider a remedial action plan was put in place to review all aspects of these standards.
- RSOP standard nine requires that services are carried out in line with the statement of purpose which is provided to CQC in order to set out in detail the types of care and treatment that will be provided at locations. Through our inspection of the locations we found that services provided at each location were in line with those described in the provider’s statement of purpose. However, there was limited review by the provider of

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the facilities needed at locations, in order to provide the services. Following our inspection we received an action plan that a review would be undertaken at all locations by 1 October 2016.

- Whilst most services offered by the provider were in line with current RCOG guidance, the practice of simultaneous administration of abortifacient medication was not in line with current RCOG guidance. This is an acceptable treatment option, dependent upon the evidence base for its introduction and the manner of its implementation. During four location inspections we raised concerns regarding the way in which the treatment option of the simultaneous administration of abortifacient medicines in order to effect an early medical abortion (EMA) had been introduced on 22 February 2016. Corporate emails and consent forms were circulated across the service's locations regarding these practice changes. However, the MSI policy dated October 2015 had not been updated to reflect the introduction of simultaneous administration of medicines.
- Staff at the locations, including the centre managers, had not participated in the development and implementation of this treatment option and were unable to provide us with an explanation or evidence of the decision making process behind the introduction of the new treatment. Staff could not assure us that treatment was evidence-based. Managers could not direct us to risk assessments or action plans for the evaluation of this treatment, or any evidence of outcome monitoring since the practice had changed.
- One member of senior staff stated that this treatment option had been introduced on the basis of one paper. MSI had not informed patients that this was a trial, did not have evidence of efficacy and did not inform patients of the potential of any increased risks of a failed abortion or the retention of the products of conception.
- Information provided demonstrated that concerns regarding the implementation of this treatment option and monitoring clinical outcomes had been raised internally by staff with senior managers. Staff from the One Call centre had raised concerns that there had been no information provided when this treatment option was introduced, no new consent forms issued and no information provided on how to deal with concerns. On 12 April 2016, the regional manager at Manchester had reported a rise in patients requiring an evacuation of retained products of conception (ERPC) procedure at that location (16 out of 26 cases) which were stated to be related to the simultaneous administration of abortifacient medicines.

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- Information provided following inspection demonstrated that the head of quality and customer services was not aware that this treatment option had commenced until they received an email communication announcing the suspension of the option in April 2016. As a result, this treatment option had not been reported to the provider's insurers.
- Marie Stopes International reached the corporate decision on 15 April 2016 to suspend this treatment option, in order to enable a substantiating review to ensure best practice and support both clients and staff.
- Information provided in the July 2016 review document demonstrated that MSI would relook at data on this treatment option in order to calculate the overall success rates based on clients up to 49 days gestation and undertake some comparisons with two studies that only looked at this gestation range.

Patient outcomes

- We reviewed the provider's process for gaining assurance regarding clinical complications. The central governance committee (CGC) meeting on 20 April 2016 provided a document entitled Q1 surgical complications by three regions; Northern, Bristol and Midlands and Greater London and South East. The text in the report stated, "Only noteworthy point here is the quality of the data entered is not as good as previously. Data quality reminders continue to be sent." There was no analysis of the data in the report despite there being incidents such as incorrect drugs given, adverse response to medication and a perforated uterus. The only learning point from an incident that was mentioned in these minutes was to improve relationships with third party provider. Furthermore, the graphs in this document indicated there had been 97 surgical clinical complications. Of these, 44 had "No value" stated and there was no indication as to what that meant. We were therefore not assured there was any process for the provider to review the clinical complications and ensure learning was identified and implemented.
- On 15 August 2016 MSI provided further information to CQC and stated it was "illustrative of our commitment to ensure first class quality for our clients and a strengthening of our governance process." One of these documents was information about the clinical complication rates in a word document entitled Clinical Information. This document stated that the clinical complication rate for surgical procedures in 2016 to July was 0.02%. The complication rate nationally is around 0.09%. Therefore the provider performed better than the national

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average. However, it was not clear how that figure was determined, given that the data on clinical complications provided in CGC minutes, and as referred above, had such a high number of clinical complications with no value recorded.

- Each location had an audit programme which included: hand hygiene, medicines management, infection control, safeguarding, medical records, equipment monitoring and health and safety monitoring. However, we could not find discussion of any issues at any of the governance meeting minutes. Whilst most centres scored above 90% in these audits, there were some notable exceptions such as handwashing at the Norwich clinic was 67%, infection control was at 82% in the Central London clinic and safeguarding was between 42 and 67% at the Essex, West London and Norwich clinics. Health and safety compliance was 69% at the South London clinic and between 84 and 87% at the clinics in Essex, Norwich and Maidstone. We saw no action plans to address these deficits.
- The RSOP standard 16 states that there should be a number of clear locally agreed standards in relation to patient care and experience against which performance can be audited, with specific focus on outcomes and processes. The RSOP set out a number of measures that should be audited. Whilst we found that centres submitted this data to the centre only four locations were aware of their own data.
- The provider collected data on the performance of individual doctors. These reports contained data relating to individuals' complication rates, serious incidents and complaints. Whilst this information was available for individual doctors, this was not collated and correlation within the service did not occur.
- The provider sent us information on 15 August 2016 which stated that clinical incident rates between January and March 2016 were 2.35. Clinical incident rates measure the number of clinical incidents as opposed to the clinical complications rates which measure when treatment has been less than optimal. However, there were no comparators given so that the service can demonstrate how it measures quality. This figure had been consistently around 2.3 since January 2013 except for a dip to 1.36 in 2014.

Competent staff

- There was a policy in place for ultrasound scanning, entitled Ultrasound Policy, and dated January 2013. This policy stated that it had been ratified by the integrated governance

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committee. The policy set out the scope, responsibilities, and requirements for training, consent, clinical protocols and monitoring arrangements as well as the servicing requirements for equipment and infection prevention and control principles.

- The Ultrasound Policy dated January 2013 stated that there were four stages of training including:
 - MSI Pre Scanning course
 - MSI UK Internal ultrasound training course
 - CASE accredited transabdominal course (through a University)
 - CASE accredited transvaginal course (through a nominated provider)
- The head of ultrasound service assessor informed us during interview on 11 August 2016 that the MSI internal training comprised of a theory module delivered by way of lectures from staff working at a university and a practical module delivered by mentors within MSI. We were told that all staff who undertook ultrasound scanning and did not have an accredited course qualification undertook the MSI internal course.
- The head of ultrasound service assessor and approximately eight other members of staff had completed the Consortium for Accreditation of Sonographic Education (CASE) course.
- The Royal College of Radiographers Standards for the provision of an ultrasound service December 2014 in relation to training states that: “Ultrasound practitioners must hold recognised qualifications such as: Qualifications approved by the Consortium for Accreditation of Sonographic Education or equivalent either from overseas or within the UK or Qualifications awarded through post graduate medical education or training.” Evidence submitted by the provider showed that the organisation took advice from the Royal College of Radiographers. This highlighted that dating scans were not normally undertaken as a Foetal Abnormality Screening Programme (FASP) was now in place. FASP scanning reviews the pregnancy for signs of fetal abnormality rather than simply using the size of the fetus to date a pregnancy. This process had replaced simple dating scans which are no longer undertaken at most centres within the NHS. The FASP programme recommends that “sonographers should be qualified to PGC (Post Graduate Course) level or equivalent.”
- Evidence provided to CQC from the provider relating to a meeting on 26 May 2016 between the head of ultrasound and the quality and clinical governance lead stated that the training programme currently in use had been put in place five years previously. This same evidence stated that the organisation had anticipated staff becoming trained in ultrasound scanning

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within a three to six month period. In documentation submitted by the provider dated 1 June 2016, in a meeting between the quality and clinical governance lead and the director of projects, the director of projects stated that “we introduced an in-house programme (training) which is not accredited but used university lecturers.” This was done in order to shorten the year-long accredited course.

- Having reviewed the course content submitted by the provider, the theory module explores abnormalities of gestation, gestational age, abnormalities of adnexa (uterine appendages) and recognition of whether the pregnancy is viable or non-viable. Whilst delivered by university lecturers, this course is not accredited or recognised by professional bodies. We were concerned that there was no minimum entry requirement for staff to undertake this course and that staff attending may not have the anatomical knowledge to understand the abnormalities discussed at this course. There was also no evidence that there was a theory test after the course to ascertain the understanding of those staff members who had undertaken the course.
- The provider told us that the use of ultrasound scanning was to confirm and date the pregnancy and to review for abnormalities which may affect the procedure but not to then proceed to make a diagnosis of the abnormality. However, we found on review of scanning reports that the staff were reviewing scans for abnormalities and making a diagnosis of these. They were acting in line with the service’s policy in this respect as the scope of the Ultrasound Policy included “Reveal the presence of any pelvic conditions, which could influence the choice of surgical approach.” We were concerned that the exposure of staff to situations where there was the appearance of pelvic conditions such as fibroids or pelvic masses would be limited, as patients presenting at the MSI clinics with pelvic pathology would be minimal. This meant that there was a risk that staff carrying out scanning may miss some significant pathology which would affect treatment options and may have an impact on patient outcomes and any further treatment required.
- The Ultrasound Policy (2013) outlined a system for maintaining competence as follows: “Team members who have successfully achieved a Consortium for the Accreditation of Sonographic Educations (CASE) course within the past 3 years and have maintained their level of skill by scanning an average of 30 clients per month.” Also that “Team members who were successful in achieving a CASE accredited course more than 3

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years ago and have maintained their skill level by scanning 30 clients per month and have participated in at least 2 days of continuing professional development (CPD) during the past 3 years.”

- For all staff who were deemed competent following all types of training, the policy states they: “Must attend a minimum of 2 days CPD every 3 years. Must scan at least 30 clients trans-abdominally per month. For those trained in Transvaginal (TV) scanning, team members must scan at least 10 clients TV each month will, when required, demonstrate continuing competence to the ultrasound mentor “
- However, on discussion with the head of ultrasound service assessor on 11 August 2016, we were informed that a record of the number of scans undertaken by individuals was not routinely kept. On 8 August 2016 we were shown by the director of governance a spreadsheet identifying the number of scans undertaken by individuals. On review of this record, we asked what the process was where someone did not achieve their recognised 30 scans per month. The process was not known. The head of ultrasound service assessor stated that there was no process for review of a member of staff’s competencies in this manner. Competencies were reassessed by the head of ultrasound and assessor every three years.
- We were concerned that there was a great emphasis placed on the head of ultrasound service assessor both in the training and assessing of staff. This individual stated that they had undertaken the CASE accredited course, a teacher training course and a mentor and assessor course but had no professional qualifications. The Royal College of Nursing (RCN) was contacted by the provider for advice. Information evidenced by the provider stated that the RCN “confirm that a transvaginal ultrasound scan should always be performed by a nurse or midwife on the NMC register and not a health care assistant, even when providing termination of pregnancy care.“
- As evidenced in the meeting notes of 26 May 2016 between the head of ultrasound and the quality and clinical governance lead, the head of ultrasound service assessor when talking about mentors stated that “One is a nurse and rest are HCAs.” This was in direct contravention of the advice from the Royal College of Nursing. Therefore we were not assured that the training put in place nor the process for checking the ongoing competency of staff undertaking ultrasound scanning was in line with national best practice.
- There was also a lack of oversight of the ongoing competence of doctors. There was no formal policy in place which detailed how doctors’ competencies should be monitored by MSI. We

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were informed by MSI staff that doctors' performance and outcomes were monitored by the CGC and the Doctor Activity and Outcome Data Report was shared as evidence. However, this report only included performance broken down by quarter, not by individual clinician and therefore offered no oversight of competency or patient outcomes by clinician. We were also informed that the CGC reviewed the incident and complication rates for each doctor. This data was not included in the CGC minutes submitted to CQC by MSI. Data submitted subsequently included a sample Doctor Activity and Outcome Data Report that included individuals' complication rates, serious incidents and complaints. However, this information was not collated and correlation within the service did not occur.

- The provider did not have an effective system for the oversight of situations when concerns were raised regarding the fitness to practice of their clinicians, including having oversight of the responsible officer's (RO) correspondence with the General Medical Council regarding doctors employed by MSI.
- MSI had a policy in place for the revalidation of doctors. However, MSI was not acting in line with this policy. For example, during our inspection MSI was unable to provide evidence of individual doctors' clinical appraisals as these were held by the RO and not stored on MSI's central electronic system as per the policy. Following our inspection, MSI obtained copies of the appraisals on the 5 August 2016 (up to seven months following the completion of the appraisals) and uploaded them onto the MSI 'open door' system. We were informed by HR that work was ongoing to decide what level of detail could be stored on the central electronic system. However, this issue was not indicated in the policy and no concerns were raised in evidence sent to CQC as to why it was not appropriate for the full appraisal to be stored. No quality assurance was undertaken of the appraisals (as per MSI policy) and the appraisals only covered clinical work. Doctors were not engaged in the MSI corporate appraisal process.
- The policy stated that an Annual Medical Appraisal Information Governance (IGC) report would be compiled. However, the policy did not state who was responsible for this report nor the governance route for sign off and oversight. MSI provided us with a copy of the Annual Responsible Officer Report, however this report did not cover all areas stated in the policy. There was no detail of the number of completed personal development plans (PDPs), audit results, development needs or recommended actions.

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- The Annual Responsible Officer Report (July 2016) failed to provide sufficient oversight to board. The report did not fulfil the duties of the responsible officer, as stated in the MSI policy. For example, the report did not include evidence that the provider was assured that they had a system to ensure that appraisals took account of the whole of the doctor's practice. The policy required that the provider should know where else the doctor works, should make sure the doctor works within their area of competence and expertise and also ensure that the RO is aware of any issue or concerns about fitness to practice. This was not included in the report to the board. During interviews with the RO, they confirmed that at the time of our inspection there was no working arrangement between MSI and relevant NHS trusts or other providers to ensure information was shared between employers regarding key areas such as fitness to practice or clinical competencies of those clinicians who worked at MSI under practising privileges.
- There was no effective system in place whereby the competence of anaesthetists administering general anaesthesia and conscious sedation was assessed and monitored to ensure they were carrying out their practice in line with national guidance. In the action plan sent to CQC dated 26 August 2016 the provider stated that this was achieved on this date through "Competency check list; tracking of competency assessments, Quarterly reports filed on Open Door." However, no evidence of such a system has been provided to the CQC. We noted from the action plan that the quarterly reports were to be completed by the lead anaesthetist by October 2016. However, no evidence was submitted that an initial assessment of competency had commenced.
- The Professional Registration Policy states that "the Head of Resourcing and Director of Quality and Assurance within MSI shall jointly be responsible for reviewing and amending this policy. Reviews will occur every two years, or as required if a significant change to legislation or operating procedures occurs within the interim period." However, the policy had not been updated in light of the introduction of the NMC's revalidation requirements for nurses (approved by the NMC council in October 2015 and introduced in April 2016).
- MSI had a policy in place regarding professional registration of nursing staff which required that up to date registration details should be held on the central electronic system. However, we found evidence during our inspection that these records were not always up to date. Also, senior staff we spoke with as part of our inspection stated that MSI did not have an effective system in place for monitoring the registration of nursing staff. During

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our review of the system we saw examples where the incorrect details had been recorded in the system, including NMC registrations being recorded as expired when they had not. Whilst we received assurances following our inspection that NMC registrations were in date, the system was not effective in ensuring an up to date record was in place.

- At the time of our inspection, MSI did not have a policy in place for the revalidation of nurses. During our inspection, the head of governance informed us that MSI intended to introduce a policy. However, there was no policy in place at the time of our inspection to ensure that MSI had oversight of whether nursing staff had met the requirements of revalidation and the position in relation to who was acting as confirmers or reflective partners. The head of governance also confirmed in writing that MSI had no oversight of revalidation dates for nurses. There was inconsistency in the replies from senior staff as to who they stated was responsible in the organisation for the revalidation of nurses. Following our inspection, the policy has been updated and MSI now hold details of the revalidation dates of nurses and has stated that compliance with the policy will be audited in the future.
- The risks in relation to the lack of oversight of registration and the competency of doctors and nurses, as well as the lack of a revalidation policy for nurses and inconsistencies in the central electronic system were not recognised and assessed in MSI risk registers. This was not in line with Required Standard Operating Procedure (RSOP) standard 20. The lack of governance in relation to the competency and training of staff had resulted in an immediate risk to patients due to a lack of assurance that staff working at MSI have the appropriate qualifications, competencies, skills and experience. Following our inspection the provider began collecting data as required by the RSOP.
- The resuscitation policy stated that resuscitation drills should be carried out every three months. An external company who provided the resuscitation advice and training led these scenarios and drills. There was a lack of effective governance around these drills. No themes or actions were identified, and there was no evidence that recommendations were followed. The records of the drills indicated that they were both announced and unannounced. A limited number of staff attended the unannounced drills and there were no records kept centrally of staff who had undertaken drills and those who had not. For example, a simulation had taken place in MSI

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Norwich, the results of which were that one scenario had been significantly poor, scoring 14 out of 34, resulting in a high risk with urgent action required and repeat of that scenario in two weeks. However, this was not undertaken.

Consent, Mental Capacity Act & Deprivation of Liberty safeguards

- There was an Informed Consent Policy dated 2014. This policy stated that “In MSI, this delegated role is only performed by Registered Nurses, and Healthcare Assistants trained and signed off as competent to take consent.”
- We reviewed the training data relating to staff having undertaken consent training in line with the policy above. We found that only 38.5% of staff had received this training. The policy entitled Safeguarding Adults and Young People Policy dated April 2016 referenced the need for staff to assess the competency of patients to give consent. We were concerned that staff had not had the appropriate training to undertake an assessment of the competency of children and young people.
- We reviewed the training documents provided on 8 August 2016 and entitled Consent Training- Assessment, Consent Training – Those who have capacity and Consent training – Those who may not have capacity. We found that these were not specific to the termination of pregnancy. There were only two questions relating to assessing the competency of children and young people in relation to Gillick competency. The training did not reference the Fraser Guidelines. Whilst the training had questions relating to patients with a learning disability, these did not equip staff with the relevant skills to ensure that staff understood how to care for and treat someone with a learning disability with regard to their understanding of procedures and capacity to consent to treatment.
- The Informed Consent Policy (2014) stated, “As part of MSI treatment pathway, clients will normally complete stage one of the process on the day of treatment. Following a consultation, the client will be seen by a registered nurse or Healthcare Assistant, trained and competent to take consent for all MSI procedures. This is normally at the admissions stage and MUST be undertaken by a Medical Doctor a Registered Nurse or Healthcare Assistant trained and signed off as competent in accordance with MSI “Obtaining Informed Consent Competency Framework” to take consent.” National guidance from The Royal College of Surgeons document Surgical Good Practice

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(2014) highlights that whilst the taking of consent can be delegated, “The person obtaining consent should have clear knowledge of the procedure and the potential risks and complications.”

- The Royal College of Surgeons document Surgical Good Practice (2014) at 3.5.1 states “Ensure that consent is obtained either by the person who is providing the treatment or by someone who is actively involved in the provision of treatment. The person obtaining consent should have clear knowledge of the procedure and the potential risks and complications.” During our inspections at locations, we found that healthcare assistants were obtaining consent from patients against a checklist which comprised of complications for the individual procedure. Where the patient asked a question, in some instances the health care assistant had to leave the consultation room to find another member of staff who could answer their question. This did not allow for a two-way discussion about the intended procedure and demonstrated that the person with delegated responsibility did not in fact have sufficient knowledge of the proposed investigation or treatment and did not understand the risks involved. Also, at inspection we found that some consent forms were only signed by healthcare assistants despite the policy stating that these would be countersigned by a clinician.
- Whilst inspecting at one location we observed a woman with a known learning disability attend the clinic without a friend or supporter. The patient had noted on their record from the telephone consultation that they had learning difficulties. Although advised to attend the clinic with a friend or relative for support, they came alone and the treatment continued. Consent to treatment for this patient was not carried out in a way they could understand and we observed the situation was poorly and insensitively handled by doctors. It became apparent that staff had not checked discharge arrangements for this patient. Local leaders confirmed there was no pathway in place to support adult patients with learning disabilities, including no signposting to independent advocacy services.
- We were therefore not assured that those staff undertaking the consent procedure had the appropriate training in consent for children and young people and those with learning difficulties. We were also not assured that those staff taking consent had the necessary knowledge of the procedure proposed to be carried out, so as to ensure that an informed discussion could

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be held, as is required. The provider was also not taking into account best practice guidance, in respect of consent being obtained by the person undertaking the procedure or through effective delegation. This gave rise to a risk of harm to patients.

- Staff taking consent from children and young persons were not appropriately trained to explore issues such as female genital mutilation or child sexual exploitation, as highlighted above. On 12 August 2016 we were provided with evidence of the provider beginning to monitor the taking of consent by staff trained at safeguarding level three in their clinics. Initial data showed that the provider was not compliant with the standard it had set itself in that the initial training did not explore these issues with staff. However, further to us again raising concerns, the provider secured training which included these issues.

Are services at this trust caring?

We assessed caring at each of the locations that provided direct patient care, but not at too rate headquarters. We noted that client feedback was sought at each location and that overall 96% were satisfied with the care provided. The provider reviewed patient satisfaction at their governance meetings.

Are services at this trust responsive?

We found that:

- Services for those with a learning disability or those who are considered vulnerable were not centrally led. The care received was wholly dependent on the experience of staff at the location patients attended.
- Audits of timely access to services in accordance with the Department of Health RSOP 11 were not completed.
- Access to counselling services was not effectively managed across the organisation. We found confusion between the head office staff and location staff as to the provision of counselling services to children aged 15 or under. There was no consideration given to children aged between 16 and 18 who may attend the service.
- The provider had no policy to support care for patients with a learning disability. Staff had not received training in the care of patients with a learning disability.
- Learning from complaints was not disseminated across the organisation's locations. Actions to improve services were not identified through active complaints management.

Service planning and delivery to meet the needs of local people

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- All patients' first contact with the service was via the One Call centre. Staff at the centre directed patients to the nearest or preferred service. The provider has 13 locations where surgical terminations of pregnancy are carried out and a number of early medical abortion units (EMU) where medical termination of pregnancy is offered. These are described in the provider's statement of purpose which is available on their website.
- Audits of the timeliness of services offered were undertaken. The provider could assure itself that patients were offered services in a timely manner in line with RSOP 11. Following our inspection the provider submitted an action plan which included the reporting of the treatment times to the clinical decision making group for analysis of trends which was to be completed by 1 October 2016.

Meeting people's individual needs

- RSOP standard three requires that there are protocols in place to support women following an abortion. This includes the provision of sufficient information, counselling and support services and consent to share information with their GP and the Department of Health. We found that the counselling services for children and young people were not consistent and we were told of different practices across the locations that we inspected. However we were assured that young people under the age of 15 received counselling services.
- The MSI policy entitled Counselling for young people aged fifteen years or under dated October 2015 outlined that the young person had three options; face to face counselling, webcam counselling or telephone counselling. The policy entitled Counselling for young people aged fifteen years or under dated October 2015 was ratified at the integrated governance committee. It was available on the provider's intranet.
- On 8 August 2016 the director of governance informed CQC inspectors that young people under the age of 16 received counselling via telephone from the One Call centre. Confirmation of this was requested and on 12 August 2016 they confirmed, "All counselling is provided by our counselling team, based in One Call, and in centres. Choice is always given." However, during inspection at the One Call centre on 12 August 2016 we were informed by counsellors and management that young people under the age of 16 years were not offered telephone counselling and had to attend a centre near to them.
- On 8 August 2016 we were sent evidence that related to counselling. This was an email trail from the director of operations on 29 June 2016 which stated "Further to having

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been asked to review the counselling arrangements for Fifteen Years and Under in our Early Medical Units and following approval from xxx earlier today – it has been agreed that we will place a temporary suspension on these services whilst we undertake an assessment of the appropriateness of these environments. The key issues that have been raised are around privacy and confidentiality as well as the logistical arrangements of providing these services in a facility that essentially may be made up of just one room.” Therefore we could not be assured that the processes for ensuring that children and young people received counselling services were effective. Following our inspection the provider submitted an action plan to address this issue with a resolution date of 1 October 2016.

- Information was provided to patients requesting services. However, the provider was not assured that this was up to date and was in line with Required Standard Operating Procedure (RSOP) standard 12. Following our inspection the provider sent us an action plan which stated that all information would be reviewed to ensure that it was in line with RSOP standards by 1 October 2016.
- The provider had no policy to support care for patients with a learning disability. Staff had not received training in the care of patients with a learning disability. At the one centre we saw care provided to a patient with a learning disability which demonstrated that those staff were not trained to care for this patient group. However at four locations staff were aware of the care required for patients with a learning disability.

Learning from complaints and concerns

- Fourteen formal complaints (13 relating to the centres and one to the One Call centre) were received in quarter 1 2016 compared to 23 complaints in quarter 1 2015. The rate for complaints received from clients attending treatment was 0.08% compared to 0.14% in 2015.
- Complaints relating to the client’s treatment accounted for 64% of all formal complaints, compared to 47% in 2015. There were no trends for any particular centre.
- The provider recorded complaints at a central level. These were reviewed at the central governance meeting. However, review of the minutes of meetings from February 2015 to April 2016 demonstrated that there was no evidence of learning from complaints. It was also not clear how complaints information was shared with staff across the locations to improve care.

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Are services at this trust well-led?

We found that:

- There was an ineffective governance framework in place to support the delivery of safe, good quality care.
- There was a lack of identification of risks and ineffectual management to mitigate these through effective risk registers or appropriate discussion and acknowledgement of risk where highlighted by internal staff.
- There was no systematic approach to safety or improvement with in the service There was no effective governance process to monitor or learn from clinical complications.
- Leadership of the part of the organisation that provides services in England was weak and lacked a clinical focus.
- There was no adherence to the fit and proper person's regulation despite this being introduced in 2015.
- There was a lack of a cohesive training strategy or monitoring of staff competencies.
- Appropriate systems and processes were not in place for the organisation to be assured at board level that all nurses are registered with their regulatory body or that doctors have undergone revalidation.
- There were no systems or processes in place for the board to be assured that MSI was acting in line with the Department of Health Required Standard Operating Procedures (RSOP) standards and a lack of knowledge amongst the senior team relating to this.
- Risk management arrangements were not in place to make sure that the certificate(s) of opinion HSA1 forms were signed by two medical practitioners in line with the requirements of the Abortion Act 1967 and Abortion Regulations 1991.
- The provider had no process through which it could be assured that HSA 4 forms were submitted to the Department of Health within the legal timeframe of 14 days.
- There was no effective governance or monitoring processes in place to ensure that children and young people were safeguarded from abuse and improper treatment.
- There was a lack of learning from complaints and incidents.

Governance, risk management and quality measurement

- MSI is a global provider, with the part of the organisation that provides services in England being registered with the Care Quality Commission. Within England, MSI was structured across five directorates, including finance, policy, communications and marketing, personnel and development, operations and the health systems directorate. The directorates were all led by

Summary of findings

a UK and Europe director of commercial operations who reported to a regional director. The regional director had responsibility for Marie Stopes' services in other countries as well as England.

- The health systems directorate (HSD) was responsible for clinical governance. There was a director of governance and quality, director of projects, surgical lead and anaesthetic lead, all of whom reported to the UK health systems director. At the time of the inspection, the UK health systems director had resigned and was not at work. The provider had appointed a temporary replacement who had been appointed to hold the post for one year. This person had been in post approximately 10 days at the time of our inspection.
- Underneath the directors there were a further five posts which included a governance manager, head of customer services, head of nursing, head of information governance and head of safety. The information governance manager and head of nursing posts were both vacant. We were told that the governance manager had left the post after several days and the head of nursing after nine weeks.
- There was a lack of comprehensive assurance systems to effectively manage the risks of the service being provided across MSI. There was no effective governance process to monitor or learn from clinical complications. We asked the director of commercial operations and the regional director of commercial operations, both of whom were the most senior directors responsible for the service, how they were assured about the quality and safety of the service. They both told us they received their assurance through the reports that went to the clinical governance committee (CGC). We reviewed minutes of the meetings from February 2015 to April 2016 and found these to be brief with limited actions being taken. The January 2016 minutes noted that risk management would be undertaken locally rather than centrally. This did not provide assurance that the central team had a sufficient grasp on the risks to the organisation.
- The central governance committee (CGC) meeting on 20 April 2016 noted that the reporting of incidents by locations was variable. However, no action was taken to address this variability.
- At the time of inspection there was a clinical and corporate risk register in place. The risks from the individual MSI locations were amalgamated into one entry within the corporate risk register. This meant that several different risks were included in one risk register and were at times repeated. The risk register in July 2016 contained five risks that had been rated "red" as a

Summary of findings

high risk. These included issues with capacity, meeting regulatory requirements and the limited number of ultrasound scanners available within the organisation. Actions taken to address these were limited to statements such as “change to policy/procedure/work instruction”. This had then reduced the concern with no further process for monitoring or audit to provide assurance that changes had been undertaken, complied with or improvements made.

- The provider carried out a series of “nominated Individual visits” (NI visits) that comprised two days of assessment at individual locations. These visits were undertaken by the health and safety manager and the head of nursing (when they were in post). The purpose was to identify areas that were in need of further development and each of the registered managers would then be asked to develop an action plan. We received conflicting information about one of these visits. The director of operations and commercial development told us that an NI visit to the Norwich clinic, on the 1 and 2 February 2016, had identified a number of concerns. We asked the director if any actions were taken to limit clinical practice while the areas of concern were addressed. She told us that there were no limitations placed on clinical practice at this clinic. We asked the director of governance about this NI visit. She told us the concerns raised were very serious and that there had been a telephone conference with the senior directors in order to make them aware and receive support to rectify the immediate concerns. The Norwich centre only held a surgical operating list one day a week (Friday). Information provided demonstrated that initially there had been a decision to suspend the surgical list until certain issues had been rectified, specifically equipment issues in theatres such as faulty alarms on the anaesthetic machine. However, this suspension did not take place and operating lists continued without adequate controls in place to ensure patient safety. The announced location inspection at the Norwich centre took place on 6 May 2016. The director of governance informed us that the week prior to this announced inspection, senior staff were deployed to the Norwich centre to take some actions and prepare for the inspection. Following CQC raising concerns at provider level, MSI voluntarily suspended surgical services at this clinic. This was as a precautionary measure on the basis of local issues and the cumulative issues raised nationally.
- Risk management arrangements were not in place to make sure that the certificate(s) of opinion HSA1 forms were signed by two medical practitioners in line with the requirements of the Abortion Act 1967 and Abortion Regulations 1991. The

Summary of findings

Abortion Act 1967 clearly outlines that an abortion can take place only if two registered medical practitioners are of the opinion, formed in good faith, that at least one and the same grounds for an abortion is met within the terms of the Act. The following notifications are a legal requirement under the Abortion Act: HSA1: two doctors are required to sign the HSA1 form, which is the certificate of opinion before an abortion is performed. HSA2: to be completed by the doctor within 24 hours of an emergency abortion and HSA4: notification to the Department of Health, either manually or electronically, within 14 days of the abortion taking place.

- The Required Standard Operating Procedure (RSOP) standard one requires providers to ensure that the completion of legal paperwork (HSA1 and HSA4 forms) is undertaken in a timely manner. However, on inspection we found that in two centres there was bulk signing of HSA1 forms by clinicians, of between 30 to 60 forms at a time. Surgeons and anaesthetists were requested to do this as the demand was too great for remote doctors and we were informed by doctors that HSA1 forms were being signed on the basis of the 'reason for termination' information only, which was printed or handwritten on the back of the form. We were not assured clinicians had access to all patient information. Completion of HSA1 forms was mentioned specifically in job plans for remote doctors, surgeons and anaesthetists. We noted that there was no allowance for time taken to review patient information as relevant, within these specific job plans.
- We were also concerned that there was a lack of assurance that two signatories had been obtained before prescribing abortifacient medication. We raised this matter with the provider, who undertook a review of the signing process and issued further guidance to MSI staff. The provider undertook an audit of the process which demonstrated that 95% of audited forms were signed prior to the administration of abortifacient medication. However, there was no evidence of on going monitoring of the new processes.
- The provider had no process through which it could be assured that HSA 4 forms were submitted to the Department of Health within the legal timeframe of 14 days. Following CQC raising this as a concern the provider is currently working with the Department of Health to ensure that all HSA4 forms are submitted in a timely manner.
- We saw evidence that a number of policies had recently been updated when we carried out our inspection. When we asked how these were ratified we were told that they had not been

Summary of findings

ratified. This meant that the organisation was utilising policies which it had not ratified. We also saw that a number of policies were out of date or did not contain the most recent information. The director of governance told us that there was no policy review group.

- The resuscitation policy referred to having a resuscitation committee in place. Resuscitation committees are recommended by the Resuscitation Council (UK) so that they can oversee the risks associated with resuscitation. This is part of having good governance arrangements around patient safety issues. The lead anaesthetist told us on 3 August 2016 that there was no resuscitation committee anymore and that it had been subsumed into the clinical leads' meeting. We found no evidence to indicate that issues relating to resuscitation had been discussed at this meeting. The policy had not been ratified and referred to roles and responsibilities that were no longer in the MSI structure.
- There was a lack of learning from incidents and complaints. Staff within eight locations inspected told us that they did not receive information on incidents they had reported. However local systems were in place at four locations for the dissemination of feedback. We saw evidence that there were delays in reporting safeguarding alerts to the appropriate authorities. This potentially impacted upon the care received by these patients.
- An "Inadequate reporting system, which has previous red RAG risk assessment" was identified as a major risk to the organisation at quarter 1 2016 and given a risk rating of 20. Despite the fact that MSI's policy requires risks stratified at that level to require immediate action, no immediate action was taken to mitigate this risk, other than taking steps to replace the incident reporting system in November 2016. The corporate risk register dated 30 June 2016 did not include any entry relating to the incident reporting system risk; a risk which was scored as a major risk in the Q1 report.
- There was no evidence of a system in place to monitor that incidents were being reported and managed according to MSI's policy or how the provider planned to mitigate the identified risk until the new reporting system was due to be implemented.
- There was a lack of training and monitoring of competency across the organisation in England. This meant that the provider could not assure themselves that they were providing a quality service.
- The systems and processes that were established did not operate effectively to safeguard children and young people from abuse and improper treatment. Following our concerns

Summary of findings

the provider had taken steps to ensure that children and young people were consented by staff that were trained in level three safeguarding. The provider began weekly audits to ensure that this process was in place. However, the first audit showed that despite putting this process in place, there remained instances where children and young people were not consented by staff with level three safeguarding training as per recommendations. The provider increased training provision to ensure that 80% of the workforce would be trained in level three safeguarding by the end of August, with the remainder to have been trained by the end of September. However, whilst this training is in place there is no assurance that children and young people will be assessed, managed and cared for by staff with the appropriate skills and competency to identify any potential safeguarding concerns. There was no evidence that the provider had taken active steps to mitigate known risks of failing to ensure the timely identification and reporting of potential safeguarding incidents in order that the safety of children and young people is assured.

- Following the inspection the provider undertook a number of roadshows to staff to roll out new policies and provided training to staff during September and October 2016. CQC were updated in this respect and met with the provider ahead of the proposed recommencement of services to assure CQC that systems and processes had been put in place to reduce the risk of immediate harm to patients using the service.

Leadership of the service

- There was an absence of clinical leadership across MSI. There had been a gap in nursing leadership of six months between October 2015 and March 2016. There had been a director of nursing post, however this post was made redundant in October 2015 and there was no lead for nursing within the organisation until a head of nursing position was recruited to in March 2016. At the time of inspection the head of nursing post was vacant, after the post holder left on 20 May 2016.
- During our inspection, we asked the senior directors how they were assured there was adequate nursing leadership. They told us they would be recruiting to this role but in the meantime the director of governance and the new UK health systems director had a nursing background. However, neither post had responsibility for providing nursing leadership and one of these post holders was not currently registered with the Nursing and Midwifery Council.

Summary of findings

- There was a lead surgeon and lead anaesthetist in place. The surgical lead was a retired professor of obstetrics and gynaecology. They had been retired for around 18 months. There was no succession planning in place for this post.
- The lead anaesthetist was not on the General Medical Council (GMC) Specialist Register. The lead anaesthetist was responsible for providing clinical leadership and oversight of the One Call centre. We were not assured how the provider ensured the lead anaesthetist was clinically competent.
- Both of these roles were part time. The lead surgeon was employed for half a session a week with MSI and we raised concern regarding the level of oversight that would be possible which such limited time on site. Following us raising concerns, the provider immediately doubled the input from the lead surgeon.
- The lead surgeon, as responsible officer (RO), was responsible for medical staff revalidation. Information regarding doctors' appraisals were held by the RO and not stored on the central electronic system as per the policy.
- There were no appropriate systems and processes in place to be assured that all nurses are registered with their regulatory body. Assurance could not be provided that competency of nurses, doctors and anaesthetists was monitored effectively.
- The provider had no system or process in place to monitor compliance against the Required Standard Operating Procedure (RSOP) standards. There was a lack of knowledge amongst the senior management team at the headquarters regarding the standards.
- On 28 July 2016 we interviewed the head of human resources who was unaware of the duties under the fit and proper person's regulation. They stated that would not be their responsibility as they were unaware of the regulation. However, subsequent information stated that they were responsible for the implementation of this regulation.
- We were concerned that the leaders of the organisation did not have the skills, experience or competence to fulfil their roles. Examples of these concerns are outlined above and in other sections of the report.
- On 15 August 2016, MSI stated that they had recruited a new member of staff, with the "remit to fully review MSI governance and present recommendations". The letter also stated that MSI "will be appointing 2 further posts, ideally this week, firstly a project manager to oversee implementation of our recovery plan as above and also a Governance Manager". Following this letter these posts were appointed to by the provider.

Summary of findings

Culture within the service

- We were concerned about the turnover of staff within the provider level function.
- We found that staff within the corporate team raised concerns but limited action was taken to address these concerns. Some issues such as the inconsistency of reporting safeguarding incidents and the failures noted at the Norwich centre were known to the senior team for many months before action was taken.
- When we initially raised concerns, the senior team were unable to provide evidence to assure CQC that systems and processes were in place. This demonstrated that they did not have a safety and quality improvement culture.

Fit and Proper Persons

- Regulation 5 of the Health and Social Care Act 2008 Regulated Activities Regulations 2014 requires providers to ensure that all those with director level responsibility are fit and proper to carry out their role.
- MSI confirmed that at the time of our inspection they did not have a policy in place regarding the fit and proper person's regulation (FPPR). Without a formal policy in place, MSI was unable to demonstrate how it ensured its directors were fit to carry out their roles. None of the senior staff we interviewed as part of our inspection considered compliance with FPPR to be part of their role. This included the head of HR and head of governance. During interview, the head of HR stated that they were unaware of the fit and proper person regulation.
- Furthermore, during a review of staff files held by MSI we found that key documentation, which providers should ensure are acquired and available to the Commission under FPPR, was missing.
- During our inspection, we reviewed 10 staff files. We found that two staff had no record of Disclosure and Barring Service (DBS) checks on file.
- None of the 10 files reviewed contained evidence of occupational health clearance, evidence of capacity to lead assessments or evidence to demonstrate that compliance with the principles of the regulation had been considered.
- Only one of the 10 members of staff had a record to demonstrate searches of insolvency and bankruptcy registers had taken place.
- Furthermore, MSI had employed directors without taking sufficient steps to ensure employees had the relevant qualification, competencies, skills and experience for the post.

Summary of findings

- There were concerns regarding the quality of references held on file on MSI. One staff file had no references. They had been recruited through an agency but there was no evidence that MSI had gained sufficient assurance as to their fitness to carry out their role.
- Another member of senior staff had references on file which significantly predated their employment (15 and 20 months) and were not addressed to MSI. Despite references making note of the terms of a dismissal from a previous employer, there was no evidence on file to demonstrate that MSI carried out appropriate checks (including contacting the previous employer) to inform the suitability of appointment.
- Another member of staff (who is no longer in post) was recruited to a role which required a “fully qualified Medical Doctor, with post-qualification experience”. There was no evidence available on file to demonstrate that MSI had taken appropriate steps to ensure the individual met these requirements. No record was held on file with details of their qualifications (or professional registration) and their CV did not provide details regarding medical education.
- The risk regarding failure to comply with FPPR regulations, including the absence of a policy to address the regulation and the lack of assurance regarding the suitability of some appointments was not captured on the MSI risk register.
- Additional evidence supplied by MSI on 15 August 2016 confirmed that no audit activity was in place regarding compliance with FPPR regulation and no audit activity was planned for 2017 in relation to the regulation.
- Follow up information, submitted on 30 August 2016, included a draft FPPR policy and assurances that missing information would be acquired. Subsequently assurances were obtained from the provider that outstanding items were obtained.

Outstanding practice and areas for improvement

Areas for improvement

Action the trust MUST take to improve

- Ensure that staff taking consent have the appropriate knowledge, skills and competence and have a full understanding of the procedure for which they are taking consent.
 - Ensure that vulnerable patients are able to give informed consent.
 - Ensure that there is an effective counselling system for children and young people, and vulnerable patients, to assist in enabling informed consent.
 - Ensure that effective oversight systems and processes are in place to service and maintain all equipment.
 - Ensure that there are effective systems in place for timely reporting and management of incidents and safeguarding concerns.
 - Ensure that all risks are assessed, monitored and that mitigations are in place to reduce the risk of harm.
 - Ensure that all medical and nursing staff are competent to ensure the safety of patients using the service.
 - Ensure that effective systems and processes are in place to monitor and improve services.
- 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 the World Health Organisation (WHO) Five Steps to Safer Surgery checklist is completed accurately and used appropriately at each phase of the surgical procedure.
 - Ensure audits undertaken in relation to the World Health Organisation (WHO) Five Steps to Safer Surgery checklist include observational audit to assess the quality of the check and embedded practice.
 - Ensure that there are effective processes in place to ensure that the certificate(s) of opinion HSA1 forms are signed by two medical practitioners in line with the requirements of the Abortion Act 1967 and Abortion Regulations 1991.
 - Ensure that there is an effective process for submission of HSA 4 forms to the Department of Health within the legal timeframe of 14 days.
 - 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 Treatment of disease, disorder or injury	<p>Regulation 12 HSCA (RA) Regulations 2014 Safe care and treatment</p> <p>Staff did not complete the World Health Organisation (WHO) Five Steps to Safer Surgery checklist accurately or appropriately at each phase of the surgical procedure.</p> <p>Staff were observed at MSI Essex and MSI Norwich to complete this documentation prior to the surgical procedure commencing.</p> <p>The checklist was completed in advance by a healthcare worker without the involvement of any clinicians present at MSI Sandwell and MSI Birmingham.</p> <p>There was inconsistent and incomplete use of the checklist at MSI Maidstone.</p> <p>Some staff had limited understanding of the checklist and were unaware of MSI policy.</p>
Diagnostic and screening procedures Termination of pregnancies Treatment of disease, disorder or injury	<p>Regulation 17 HSCA (RA) Regulations 2014 Good governance</p> <p>There was no effective system for monitoring and auditing the appropriate completion of the certificate(s) of opinion HSA1 forms.</p> <p>There were no effective qualitative audits in place to ensure that the World Health Organisation (WHO) Five Steps to Safer Surgery checklist was completed correctly.</p>

This section is primarily information for the provider

Requirement notices

Staff undertaking ultrasound scanning were trained internally. The course was not accredited. There was no assessment of staff understanding at conclusion of the course and no effective monitoring system to ensure on-going maintenance of competency. The scope of the USS Policy v7 included an element of diagnosis that did not reflect the level of training undertaken.

“Reveal the presence of any pelvic conditions, which could influence the choice of surgical approach”.

There was no policy in place, no training for staff and no auditing of when the statutory duty of candour was to be implemented within the organisation. A policy has now been written but evidence of staff training and an effective process for monitoring needs to be in place.

Regulated activity

Termination of pregnancies

Regulation

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

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

There was evidence of bulk signing of HSA1 forms and no evidence that MSI had changed practice to provide doctors access to sufficient information to reach an opinion in good faith and provide a signature of opinion. There was a lack of assurance that two signatories had been obtained before prescribing abortifacient medication.

The provider had no process through which it could be assured that HSA 4 forms were submitted to the Department of Health within the legal timeframe of 14 days.

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
Termination of pregnancies	<p>Regulation 11 HSCA (RA) Regulations 2014 Need for consent</p> <p>We found that, as at May 2016, only 38.5% of staff had received consent training.</p> <p>Not all staff had received the appropriate training to undertake an assessment of the competency of children and young people.</p> <p>Training provided did not equip staff to take effective consent from patients who had a learning disability or children and young people and to recognise the needs of these groups of patients.</p> <p>Taking consent was not always delegated to a person with knowledge of the procedure to be undertaken.</p> <p>There was confusion within the organisation as to the provision of counselling services to children and young people to ensure that they were enabled to give informed consent.</p>
Diagnostic and screening procedures Termination of pregnancies Treatment of disease, disorder or injury	<p>Regulation 12 HSCA (RA) Regulations 2014 Safe care and treatment</p> <p>There was a policy for the management of anaesthesia and sedation however this was due for review in 2013 and had not been reviewed. The policy did not address the management of difficult airways. At location level the staff told us that there was no policy in place.</p>

Enforcement actions

There was a lack of consideration of managing a difficult intubation within the draft policy.

There was no effective system in place whereby the competence of anaesthetists administering general anaesthesia and conscious sedation was assessed.

The provider had not ensured that there was a system in place to ensure that nursing staff were trained and competent to assist an anaesthetist to administer anaesthesia and monitor patients undergoing conscious sedation or general anaesthesia.

There was no documentation to assure the provider that equipment was fit for purpose.

There was no policy in place with regard to the management of deteriorating patients.

There was a risk assessment for the management of the deteriorating patient dated November 2016. The risk assessment did not consider the full extent of risks associated with this issue.

There was no policy in place to set out the expectations for nursing and health care assistant staff on what to look for and what action to take with a deteriorating patient.

There were no Patient Group Directions (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.

There was no evidence as to how the staff are to be trained in the use of the National Early Warning Score (NEWS) scoring tool due to be implemented.

This section is primarily information for the provider

Enforcement actions

The resuscitation policy was not ratified and contained inconsistencies.

There was no evidence provided that all clinical staff had received the appropriate level of training in life support.

There was a lack of effective governance around simulation drills. No themes or actions were identified.

There was no evidence of resuscitation being discussed at the clinical governance committee.

Regulated activity

Diagnostic and screening procedures

Termination of pregnancies

Treatment of disease, disorder or injury

Regulation

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

Training has not been in place and safeguarding incidents not reported in a timely manner due to the original stipulation in MSI policy that only staff with level three children's safeguarding training could report.

On 8 August 2016 the provider did not have sufficient staff trained at this level to comply with the Intercollegiate Document for Healthcare staff (2014) guidance.

Level three safeguarding training was undertaken by one or two members of staff at each location. This meant that there were insufficient numbers of appropriately trained staff to appropriately assess, plan, intervene and evaluate the needs of children and young attending the service.

The original training provided to staff to date did not address the issue of child sexual exploitation. We found that there was no evidence to demonstrate that any training had been given to staff on this issue.

This section is primarily information for the provider

Enforcement actions

Training information and slides sent to CQC on 26 August 2016 did not have particular relevance to termination of pregnancy and the age groups likely to be managed at MSI.

On review of the training matrix sent by the provider on 9 August 2016, we found that 37.4% of staff either were out of date in accordance with the policy or had not received level one safeguarding training within three years.

The safeguarding minutes reviewed from July 2015 to June 2016 showed that the people attending these meetings were aware of problems with “delays and inconsistent reporting of safeguarding incidents”. This issue was on the risk register. However, there were no actions highlighted to mitigate this risk apart from “Change to information.”

The list of safeguarding incidents, sent by the provider to CQC, showed that nine of the 22 referrals were referred within 24 hours, nine within a week, two at nine days and three over 15 days.

Whilst the provider is putting in place auditing systems to assure itself that staff competency is maintained, it has failed to address the known risks in relation to the inconsistency and delays in the reporting of incidents and referrals to local safeguarding teams in a timely manner.

Regulated activity

Diagnostic and screening procedures
Termination of pregnancies
Treatment of disease, disorder or injury

Regulation

Regulation 17 HSCA (RA) Regulations 2014 Good governance

The clinical leadership at a corporate level at MSI to oversee clinical decisions was limited in August 2016. There was a vacant post for the head of nursing and in addition, a retired surgeon provided the clinical

Enforcement actions

leadership for doctors during eight hours per week. The clinical lead for anaesthetics was suspended from clinical facing duties at that time due to falsifying a set of patient records.

There was no nurse lead in post to direct and lead MSI's nursing workforce.

There was no policy in place regarding the fit and proper persons' regulation (FPPR) for directors at Regulation 5 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014.

None of the senior staff we interviewed as part of our inspection on 28 July 2016 considered compliance with FPPR to be part of their role. This included the head of HR and head of governance. During interview, the head of HR stated that they were unaware of the fit and proper person regulation.

During a review of staff files held by MSI we found that key documentation, which providers must ensure are acquired and available to the Commission under FPPR, were missing.

MSI had employed directors without taking sufficient steps to ensure employees had the relevant qualification, competencies, skills and experience for the post that they held.

MSI on 15 August 2016 confirmed that no audit activity was in place regarding compliance with the FPPR regulation and no audit activity had been planned for 2017 in relation to the regulation.

The flagging system alert when nursing registration dates were expiring was not effective as it was reliant on the data being entered in the correct field and this was found not to occur.

Enforcement actions

The provider had no system or process in place to monitor compliance against the Required Standard Operating Procedure (RSOP) standards. There was a lack of knowledge amongst the senior management team at the headquarters regarding the standards.

There has been an ineffective governance process in place with regard to incidents.

MSI had a limited overview of training across the organisation. When data has been available, compliance with training has been low and, in some cases, the quality of training was inadequate.

There was a lack of oversight of the ongoing competence of doctors in that there was no formal policy in place which details how doctors' competencies should be monitored by MSI.

MSI did not have effective oversight of situations when concerns are raised regarding the fitness to practice of their clinicians, including having oversight of the responsible officer's correspondence with the General Medical Council, regarding doctors employed by MSI.

MSI had an additional policy in place for revalidation of doctors. However, MSI were not acting in line with that policy.

The Annual RO Report (July 2016) failed to provide sufficient oversight to board and fulfil the duties stated in the MSI policy.

The Professional Registration Policy had not been updated in light of the introduction of the NMC's revalidation requirements for nurses (approved by NMC council in October 2015, introduced in April 2016).

Enforcement actions

MSI did not have a policy in place for the revalidation of nurses. No information was provided to the board regarding oversight of nursing revalidation.

The corporate risk register dated 30 June 2016 did not include any entry relating to the incident reporting system risk; a risk which was scored as a major risk in the Q1 report. We did not find any evidence of how the provider is assured that incidents are being reported and managed according to policy or how they are mitigating the identified risk until a new reporting system is in place, due in November 2016.

There was potential false assurance that there was a positive reporting culture in place. We have found no evidence in the reports to the MSI board, the central governance committee (CGC) or the clinical leads' meeting that any trends in incidents, themes and any learning from incidents have been discussed.

During our location inspections, it was found that the incident process was ineffective. Staff consistently told us they did not get feedback from incidents. Clinic leads found it difficult to extract information from the incident system in terms of what incidents had been reported, what stage of the investigation process they were at and if they were closed.

It was not clear how figures for the complication rate were determined, given that the data on clinical complications provided in CGC minutes had such a high number of clinical complications with no value recorded.