

Marie Stopes International Sandwell

Quality Report

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

Summary of findings

Letter from the Chief Inspector of Hospitals

Termination of pregnancy (ToP) refers to the treatment of termination of pregnancy by surgical or medical methods. Marie Stopes International Sandwell is part of the provider group Marie Stopes International (MSI). The service at MSI Sandwell was located within a purpose built neighbourhood health care centre shared with other health care service providers. The services are provided under contract with local clinical commissioning groups for NHS patients. MSI Sandwell also accepts private patients.

The service was registered in November 2010 as a single specialty termination of pregnancy service providing a range of services for medical termination of pregnancy up to a gestation of 10+0 weeks and surgical termination of pregnancy up to 23+6(days). This included: pregnancy testing, unplanned pregnancy counselling/consultation, early medical abortion, abortion aftercare, sexually transmitted infection testing, contraceptive advice and contraception supply and vasectomy services. The Sandwell service had no 'satellite' clinics attached to its registration.

We carried out this announced comprehensive inspection on 8 June 2016, as part of the first wave of our inspection of services providing a termination of pregnancy service. The inspection was conducted using the Care Quality Commission's new methodology.

We have not provided ratings for this service. We have not rated this service because we do not currently have a legal duty to rate this type of service or the regulated activities it provides.

The inspection team included two inspectors and a consultant obstetrician and gynaecologist supporting the inspection by phone.

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

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

Our key findings were as follows:

Are services safe at this service

Staff reported incidents but the systems that supported this were not reliable and investigation and learning was variable. There was sometimes delay in uploading reports to the electronic system, staff could not easily track the progress of incident investigations and some patterns of incident reported were not identified and investigated. Staff did not consistently follow some safety systems such as national guidelines to safer surgery, use of emergency equipment checklists and good hand hygiene practices. Not all staff were up-to-date with their mandatory training including safeguarding, life support skills and supporting anaesthesia. Many staff including local leaders had not undertaken safeguarding training to the level appropriate for degree of vulnerability presented by many patients. Staff followed policies and procedures for safeguarding children and vulnerable adults. Risks to patients were assessed and staff made referrals and emergency transfers to local acute hospitals when it was appropriate for patients. Sufficient numbers of experienced doctors and nurses staffed the service.

Are services effective at this service

Summary of findings

Systems in place that collect information about the effectiveness of the services did not provide the local leaders or staff with a clear picture of how their service was performing against regional and national clinical standards. Clinical audits recommended by the Royal College of Obstetricians and Gynaecologists were not specifically addressed. The results of local audits did not always match with what we observed or the patterns of errors shown on the provider's incident reporting records.

There was no established pathway for effectively supporting women with learning disabilities to give informed consent to treatment. Staff checked patient's medical and health history before treatment and the clinic only carried out procedures for which it was registered and within national guidelines. Other patients were referred to more appropriate services to meet their needs. Patients were given information about contraception and sexually transmitted infection. Nurses and doctors were competent and worked with other healthcare providers locally for the benefit of patients.

Are services caring at this service

Most staff treated patients with respect, kindness, dignity and care. Patients spoke positively about staff attitudes towards them. However we observed some surgical staff showed impatience with one patient with learning disabilities; did not greet or address patients when they entered theatre and clinical staff discussed other patients in the presence of a patient who was under anaesthetic. Patients received a lot of information from staff about their treatment and a 24-hour help line was available to provide additional information and address concerns. Staff checked patients decisions at each stage of the process and went over the options with patients on more than one occasion. Counselling was made available to all patients over the phone or face-to-face by independent counsellors. The provider's policy was this was compulsory for patients under 16 years of age. There was no 'easy read' additional material available to enable patients with learning disabilities to access the information about treatment, treatment options and contraception.

Are services responsive at this service

Services were planned to provide surgical and medical terminations of pregnancy within a purpose built accessible neighbourhood health care centre. Patients accessed services and appointments through a national call centre. This system managed waiting times across clinics to respond flexibly to local demand, legal requirements and targets set by commissioners of the services. Translation services were available to patients from the first point of making contact with the organisation and staff helped patients to access other services for help with domestic violence or drug abuse. Patients could receive counselling prior to receiving any procedures. There were a variety of means by which patients could comment on the service, raise concerns or make a complaint. Waiting times within the clinic was a challenge for the service and patient satisfaction regarding this had fluctuated during 2015/16. There were no specific arrangements to support gaining informed consent from adult patients with learning disabilities.

Are services well led at this service

The provider had a clear philosophical and political vision for the service and all staff were committed to this and highly motivated. The clinic was led by a manager registered with the Care Quality Commission and staff felt well supported by the local leadership team. The views of patients were routinely sought; there was engagement with the wider public and other professionals locally. The organisation aimed to improve by trying out new ways of providing the service. Some clinical staff showed a defensive attitude to critical feedback. This was acknowledged by local leadership; it was reflected in the leadership of the organisation and was a characteristic of the culture of the organisation. Organisational structures in place to ensure legal compliance, manage risk and monitor quality had weaknesses that meant some risks, repeated mistakes and serious incidents were not properly dealt with and learned from.

We saw one area of outstanding practice:

- Reception staff were highly skilled at putting patients at their ease and discretely confirming personal and private details when patients arrived including within areas shared by other service providers.

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

Summary of findings

Importantly, the provider must:

- Ensure all staff treat patients with respect and uphold their dignity at all times including in the theatre environment and when they need extra support over consent.
- Put in place an effective incident reporting system that can provide assurance the provider can consistently learn from incidents and error, notify incidents to the appropriate authorities and exercise its duty of candour requirement.
- Ensure all relevant staff are up-to-date with mandatory training.
- Ensure all appropriate staff undertake safeguarding children and adults training at level three competency.
- Take steps to ensure clinical staff consistently follow good hand hygiene practices.
- Ensure staff follow properly national guidelines to safer surgery.
- Ensure staff use emergency equipment checklist systems effectively.
- Put in place protocols for obtaining consent, pathways and support for all patients who may lack capacity to consent, including those patients with a learning disability.
- Ensure clinical audits recommended by the Royal College of Obstetricians and Gynaecologists for termination of pregnancy are undertaken in order to continuously improve the services offered by the clinics and provide feedback effectively to staff about the services clinical performance.
- Improve the reliability of local clinical and safety audits of the clinics.
- Ensure arrangements are put in place to support the specific needs of patients with learning disabilities to understand the information about the procedures and to support getting informed consent for treatment from learning disabled adult patients.
- Review the governance arrangements in place to provide more effective assurance and auditing systems or processes. These must assess, monitor and drive improvement in the quality and safety of the services provided, including the quality of the experience for people using the service. The systems and processes must also more effectively assess, monitor and mitigate any risks relating the health, safety and welfare of people using services and others. Continually evaluate and seek to improve governance and auditing practice.

In addition the provider should:

- Explore methods of giving patients with learning disabilities access to information about the service and their treatment so they can have a better understanding and be fully involved.

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

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

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

CQC has also undertaken enforcement action for breaches of the following regulations, which are relevant to this location.

Regulation 11 Consent

Regulation 12 Care and treatment must be provided in a safe way for service users.

Regulation 13 Service users must be protected from abuse and improper treatment in accordance with this regulation.

Summary of findings

Regulation 17 Systems or processes must be established and operated effectively to ensure compliance with the requirements in this Part. (Good governance)

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

Professor Sir Mike Richards

Chief Inspector of Hospitals

Summary of findings

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Summary of this inspection

Background to Marie Stopes International Sandwell

Marie Stopes International (MSI) provides services throughout England. It is an international non-governmental organisation providing contraception and abortion services in 38 countries around the world. Founded in 1976, Marie Stopes International grew out of the organisation originally set up by Marie Stopes in 1921.

The MSI mission statement is that choice is fundamental to everything that it does and it gives people the information they need to make their own choices about whether and when to have children. It enables people to prevent or terminate unplanned pregnancies.

The MSI Sandwell clinic opened in October 2010 and was registered to provide surgical termination of pregnancy procedures up to 24 weeks along with medical termination of pregnancy up to 10 weeks gestation. Surgical termination of pregnancy was available under non-anaesthesia, sedation anaesthesia and general anaesthesia. It also provided some family planning services, advice on contraceptive options and provided oral contraception and long acting reversible contraception (LARC) and male sterilisation (vasectomy).

The clinic opened on Mondays for medical termination of pregnancy procedures and consultation only and on Wednesdays for Surgical termination of pregnancy procedures.

Services were provided predominantly to patients referred for funding by local clinical commissioning groups (CCG's) and occasionally privately paying patients.

The Sandwell clinic had two screening rooms, two consulting rooms and one operating theatre. It had four day care beds.

We carried out this inspection under our comprehensive inspection of acute services programme. We inspected termination of pregnancy services. We did not inspect vasectomy services.

The clinic had a manager registered with the Care Quality Commission.

Our inspection team

Our Inspection team comprised two CQC Inspectors and a Consultant Obstetrician and Gynaecologist supporting by telephone.

How we carried out this inspection

Before the inspection visit we asked the provider to send us data and information about the service and we reviewed this.

We visited the Sandwell clinic announced 8 June 2016.

During our visit we followed the care and treatment pathway of and spoke with four patients undergoing

surgical terminations of pregnancy. We spoke with 10 staff members including reception staff, nurses and surgeons and the registered manager and regional clinical operations manager for the service. We looked at six sets of patient notes, policy and procedure documents and electronic records. We looked around the premises.

Summary of this inspection

Information about Marie Stopes International Sandwell

The Sandwell clinic holds a license from the Department of Health as an Approved Place to undertake termination of pregnancy services in accordance with the Abortion Act 1967 and the 1991 regulations.

MSI Sandwell was registered with CQC in October 2010. There was car parking available at the health care centre, and had easy access from nearby public transport services.

MSI Sandwell was contracted by clinical commissioning groups (CCGs) in the Sandwell and Dudley area to provide a termination of pregnancy service for NHS clients predominantly from the these areas but patients may come from further afield through the national contact centre. The service was also available for self-funded patients including from abroad.

MSI Sandwell shared its accommodation with other health care providers within a community health care centre.

The Sandwell clinic had:

- two private consulting rooms
- two screening rooms
- one theatre
- a shared reception area
- four day care beds.

The Sandwell clinic opened Mondays (9am to 5pm) and Wednesdays (7.30am to 5pm).

The following services were provided:

- pregnancy testing
- unplanned pregnancy counselling/consultation
- medical abortion up to 10 weeks of pregnancy
- surgical abortion up to 24 weeks of pregnancy
- abortion aftercare
- miscarriage management
- sexually transmitted infection testing and treatment
- contraceptive advice and contraception supply
- vasectomy services.

A registered manager who was responsible for eight other MSI clinics in Birmingham and the West Midlands and was supported by a team of nurses, health care assistants and administrators managed the service. Doctors provided on site and remote services that included assessment, certification that the lawful grounds for abortion are fulfilled, and prescribing of abortifacient medicines, from other clinics within the organisation (Approved Places).

During 2015, MSI Sandwell carried out 466 (31%) medical terminations of pregnancy (up to 10 weeks gestation) and 1017 (69%) surgical terminations of pregnancy under general, local anaesthetic and conscious sedation. This included eight procedures for terminations in excess of 20 weeks gestation and included children between 13 and 15 years of age but none aged under 13 years in that period. The clinic carried out surgical terminations of pregnancy using manual vacuum aspiration and dilation and evacuation. The service employed two doctors, 10 registered nurses and five administration staff.

Termination of pregnancy

Safe	
Effective	
Caring	
Responsive	
Well-led	

Information about the service

We visited the MSI Sandwell clinic announced 8 June 2016 and we looked at every area of the clinic including treatment and procedures rooms and the theatre.

During our visit we followed the care and treatment pathway of and spoke with four patients undergoing surgical terminations of pregnancy. We spoke with 10 staff members including reception staff, nurses and surgeons and the registered manager and regional clinical operations manager for the service.

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The Sandwell clinic opened Mondays and Wednesdays. There was a surgery list on Wednesdays. Ten nurses, four doctors and five administrative staff were employed by the service. This team moved between the Sandwell clinic and the provider's other registered service at Birmingham Centre clinic (Edgbaston) each week.

Summary of findings

We found staff reported incidents but the systems that supported this were not reliable and investigation and learning was variable. There was sometimes delay in uploading reports to the electronic system, staff could not easily track the progress of incident investigations and some patterns of incident reported were not identified and investigated. There was sometimes delay in uploading incident reports to the electronic system, staff could not easily track the progress of incident investigations and some patterns of incident reported were not identified and investigated.

Staff did not consistently follow some safety systems such as national guidelines to safer surgery, use of emergency equipment checklists and good hand hygiene practices. Not all staff were up-to-date with their mandatory training including safeguarding, life support skills and supporting anaesthesia. Many staff including local leaders had not undertaken safeguarding training to the level appropriate for degree of vulnerability presented by many patients.

Staff followed policies and procedures for safeguarding children and vulnerable adults. Risks to patients were assessed and staff made referrals and emergency transfers to local acute hospitals when it was appropriate for patients. The service was staffed by sufficient numbers of experienced doctors and nurses.

We found systems in place to collect information about the effectiveness of the services did not provide the local leaders or staff with a clear picture of how their service was performing against regional and national clinical standards. Clinical audits recommended by the Royal College of Gynaecologists and Obstetricians were not specifically addressed. The results of local audits did

Termination of pregnancy

not always match with what we observed or the patterns of errors shown on the provider's incident reporting records. There was no established pathway for effectively supporting women with learning disabilities to give informed consent to treatment.

Staff checked patient's medical and health history before treatment and the clinic only carried out procedures for which it was registered and within national guidelines. Other patients were referred to more appropriate services to meet their needs. Patients were given information about contraception and sexually transmitted infection. Nurses and doctors were competent and worked with other healthcare providers locally for the benefit of patients.

We found most staff treated patients with respect, kindness, dignity and care and patients spoke positively about staff attitudes towards them. Most staff treated patients with respect, kindness, dignity and care. Patients spoke positively about staff attitudes towards them. However we observed some surgical staff showed impatience with one patient with learning disabilities; did not greet or address patients when they entered theatre and clinical staff discussed other patients in the presence of a patient who was under anaesthetic. Patients received a lot of information from staff about their treatment and a 24-hour help line was available to provide additional information and address concerns. Staff checked patients' decisions at each stage of the process and went over the options with patients on more than one occasion. Counselling was available to all patients over the phone or face to face. This was compulsory for patients under 16 years of age prior to procedures.

There was no 'easy read' additional material available to enable patients with learning disabilities to access the information about treatment, treatment choices available and contraception options.

We found services were planned to provide surgical and medical terminations of pregnancy within purpose built accessible neighbourhood health care centre. Patients accessed services and appointments through a national call centre and this system managed waiting times across clinics to respond flexibly to local demand, legal requirements and targets set by commissioners of the services.

Translation services were available to patients from the first point of making contact with the organisation and staff helped patients to access other services for help with domestic violence or drug abuse. Patients could receive counselling including from independent counsellors prior to receiving any procedures. There were a variety of means by which patients could comment on the service, raise concerns or make a complaint.

Waiting times within the clinic was a challenge for the service and patient satisfaction regarding this had fluctuated during 2015/16. There were no specific arrangements to support gaining informed consent from adult patients with learning disabilities.

We found the provider had a clear philosophical and political vision for the service and all staff were committed to this and highly motivated. The clinic was led by a manager registered with the Care Quality Commission and staff felt well supported by the local leadership team. The views of patients were routinely sought; there was engagement with the wider public and other professionals locally. The organisation aimed to improve by trying out new ways of providing the service. Some clinical staff showed a defensive attitude to critical feedback. This was acknowledged by local leadership; it was reflected in the leadership of the organisation and was a characteristic of the culture of the organisation.

Organisational structures in place to ensure legal compliance, manage risk and monitor quality had weaknesses that meant some risks, repeated mistakes and serious incidents were not properly dealt with and learned from.

Termination of pregnancy

Are termination of pregnancy services safe?

- The systems in place to report incidents and investigate and learn from them were not effective.
- There was sometimes delay in uploading reports to the electronic system, staff could not easily track the progress of incident investigations and some patterns of incident reported were not identified and investigated.
- A 'never event' although reported by staff was not recognised or investigated. Errors made by staff around record keeping for medication were repeated without action taken to mitigate them.
- Staff did not consistently follow some safety systems such as the checklist for safer surgery practice, hygiene and control of infection and checking emergency equipment. For example, the emergency bag in the recovery room should have been checked weekly but records showed gaps in each of the eleven months preceding our inspection visit.
- Not all staff were up-to-date with their ongoing mandatory training including safeguarding, life support skills and supporting anaesthesia.
- Many staff including local leaders had not undertaken safeguarding training to the level appropriate for degree of vulnerability presented by many patients. Only one staff member, the clinical operations manager had safeguarding training at level three.

However:

- There were systems in place to assess risks to patients and staff made referrals and emergency transfers to local acute hospitals when it was appropriate for patients.
- Sufficient numbers of experienced doctors and nurses worked at and for the service.
- Staff followed policies and procedures in place for safeguarding children and vulnerable adults including for female genital mutilation.
- A system was in place to inform patients appropriately if harm had occurred to them.

Incidents

- The provider reported in data requested by us prior to the inspection, that there were no never events (serious, largely preventable patient safety incidents that should

not occur if the available preventative measures have been implemented) and only one serious incident requiring investigation (SI) at the Sandwell clinic during 2015/16.

- After our inspection visit we asked the provider to send us a record of all incidents reported through the provider's services in their South West and Midland region for 2015/16. The Sandwell clinic, although a separate registered location, was part of the provider's group of services called the 'Birmingham Centre'.
- We noted the provider's matrix of reported incidents identified 'Birmingham Centre' incidents and did not differentiate by clinic or registered location. This made it difficult for the provider to match incident patterns with locations. In correspondence subsequent to the inspection visit the provider told us that it could run reports of incidents by location.
- We noted the provider identified on its incident reporting matrix four incidents within the 'Birmingham Centre' services as needing an investigation in quarter four (Q4) of 2015/16 and two incidents in Q1 of 2016/17.
- However, the information sent to us as requested for inspection of the Sandwell clinic location and for the Birmingham clinic including all satellite clinics ('The Birmingham Centre' which included the Sandwell clinic and its staff team) combined, reported no never events and only one SI in the twelve months preceding our inspection.
- The provider policy on incident reporting was that all incidents, including safeguarding concerns, were reviewed for learning opportunities.
- The provider's procedure included an incident rating matrix which was based on the National Patient Safety model for Incident Rating. It could be used to rate incidents and events that occur within MSI as well as potential risks identified via risk assessments. There was a category of harm and reporting escalation matrix.
- Local leaders told us incident reporting was in paper format. Staff we spoke with said they wrote down what had happened, when and who was involved and pass this on to a senior member of staff who would then report the incident on their computer system and decide if lessons needed to be learned depending on the type of incident. This learning was then disseminated to the operational staff. We noted one incident report form written in May 2016 was not uploaded until three weeks later.

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- The Sandwell clinic reported an incident resulting in harm to the CQC in April 2016 in a timely way. The duty of candour requirement was ticked as triggered on the record. The duty of candour is a regulatory duty that relates to openness and transparency and requires providers of health and social care services to notify patients (or other relevant persons) of certain 'notifiable safety incidents' and provide reasonable support to that person.
- During our visit we looked at the process that followed this and found clinical staff had reported this as a perforated uterus and the patient required transfer to local NHS acute services. The investigation was underway at the time of our visit and was being undertaken by managers from a different regional area. The provider was still within its 45 working days' time target for completion.
- We 'tracked' the process of this incident report on the provider's electronic system and noted it complied with the duty of candour requirement. It was reported by clinicians on 4 April 2016, noted it triggered the duty of candour requirement and also ticked as an event reportable to the Care Quality Commission; a report was completed by the registered manager on 6 April 2016 who assessed the risk level as 'major' and the likelihood 'rare' and an investigation was required.
- We saw copies of a letter to the patient on a duty of candour template that included a sincere apology, a lead contact name and number within the service, assurance an investigation was underway and an offer of a meeting with the clinician and the manager. Statements from some staff were also filed on the system.
- The provider told us 'Incidents are investigated in accordance with MSI Incident Management Policy and a Root Cause Analysis, tabular time line of events along with an appropriate action plan to ensure lessons are learnt and shared across the organisation takes place'.
- We found, from the provider's incident report matrix that in February 2016 staff reported within the 'Birmingham Centre' group of services that included the Sandwell clinic, an incident that would classify as a 'never event' and this was a retained surgical swab.
- We were unable to determine which location in the Birmingham Centre group of clinics this incident occurred at due to the incident records maintained by the service. The provider logged this incident as requiring investigation. However, when we asked the provider for details of this investigation it told us that no investigation had taken place. We were not assured that duty of candour had been triggered for this incident.
- We noted within the 'Birmingham Centre' group of services that included the Sandwell clinic, there were three unplanned returns to theatre reported in February and March 2016 and recorded on the incident log as 'requiring no action'.
- We also noted during March 2016 staff repeated the same three errors relating to administering and recording medication administration. There was also a pattern of record keeping errors repeated in relation to contraceptive implants. However the provider had rated these on the incident system on each occasion as 'no action required'.
- Local leaders told us they were engaged in fostering a reporting culture among clinical staff who may feel too busy to report an incident. We noted from the provider's incident reporting matrix that staff group of services which included the Sandwell clinic did report incidents. The matrix showed 65 incident reports between 23 April and 30 June 2016.
- However, nursing staff we spoke with did not have a clear understanding of what type of incident would be reported through the system. For example, the team meeting agenda for April 2016 we saw reported the clinic ran out of Depo, an injection of a hormone that prevents pregnancy in April 2016, but this did not appear on the provider incident reporting records we saw.
- We found where staff had reported incidents had they were not always properly followed through. This meant the provider could not be confident that its systems for learning from incidents were reliable or effective. For example, we observed an incident with a patient relating to consent for treatment. We subsequently noted from the provider's incident reporting matrix records that staff had not reported this as an incident.
- Staff told us they received feedback from serious incidents in team meetings but did not receive feedback from incident forms they had submitted which were of a less serious nature.
- We observed during our visit in June 2016 three surgical procedures. We noted that although it was four months after staff had reported the retained surgical swab

Termination of pregnancy

incident (a never event), theatre staff were not properly applying the World Health Organisation (WHO) safer surgery checklist in order to prevent the incident recurring.

- This meant the provider had not ensured learning or behaviour change took place to reduce the risk of a retained swab recurring with this team.
- We saw a corporate duty of candour policy and procedure document when we visited the service. This was a comprehensive response to the regulation. However we noted it was dated April 2016 as version 1. Staff confirmed it was a new policy.
- This meant the provider had no policy and agreed procedures in place to comply with the duty for 12 months after it came into force for independent health care providers in April 2015.
- Due to the number of concerns arising from the inspection of this and other MSI locations, we inspected the governance systems at the MSI corporate (provider) level in late July and August 2016.

Cleanliness, infection control and hygiene

- The provider had policies and procedures in place for hygiene and infection control. We noted there were wash basins with no touch taps, hand wash, alcohol gel and paper towels around in consulting and procedure rooms. There were sufficient supplies of soap and hand towels around the clinic.
- The environment was purpose built for ease of effective cleaning with vinyl floor covering. There was no clutter or litter and surfaces were clean. The toilets were clean and well supplied. The treatment and consulting rooms were cleaned by the landlords cleaning contractors.
- We noted staff cleaned the theatre trolley and equipment appropriately between patients.
- We saw staff wore personal protective clothing (PPE) including gloves during procedures with patients and gloves and aprons were changed between patients and were in plentiful supply for staff to use.
- We noted all equipment was single use, wipe clean or auto- clavable. There was a separate dirty utility area that was compliant with regulation, clinical waste was separated appropriately, bins were not overfilled and linen was separated appropriately.
- We observed the theatre nurse, healthcare assistant and surgeon practised appropriate hand washing. The surgeon used appropriate aseptic non touch technique with instruments.

- However, we also observed during the four surgical procedures the anaesthetist although wearing PPE did not wash their hands once although they sited four cannulas during this time.
- A sharp (exposed needle) was left on the work surface between two patient procedures. Staff did not dispose of this immediately after use as they should.

Environment and equipment

- The clinic was within a recently purpose built health centre. The waiting area was spacious and light and patient information and magazines were available for patients to read. Drinking water was available to patients in the theatre changing area.
- The theatre was appropriately lit and arrangements were in place for safe disposal of sharps, the sharps bins were not overfilled, labelled correctly, within date and wall mounted.
- However we noted emergency equipment was not checked consistently. For example, the emergency bag in the recovery room should have been checked weekly but records showed gaps in each of the eleven months preceding our visit.
- Whilst in April 2016 it was recorded as checked five times, most other months showed only one check with February, May and June showing two checks. The continuous sign sheets were also out of date order which makes audit difficult. We raised this with local leaders at the time of our inspection visit and they undertook to review it.
- Portable appliances such as the microwave and blood pressure machine had been tested. This was arranged under contract by the landlord.

Medicines

- The provider had policies and procedures in place for the safe management of medication and we saw during our visits staff follow those procedures.
- The provider told us they did not use patient group directives (PGD's) at the time of our inspection as an organisation although referenced in its medicines management policy it was not practised. This meant nurses did not administer medication that had not been prescribed by registered medical practitioners (doctors). This complied with The Abortion Act and regulations and we observed this was the practice during our visit.

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- We saw the service used electronic prescription charts and this meant prescriptions could be signed remotely by registered medical practitioners in the organisation when necessary. There were two registered medical practitioners on site during our visit.
- We observed staff administered and signed for all medications appropriately and staff checked allergies with patients.
- Medication was stored correctly and fridge temperatures were regularly checked and recorded. There were single use vials for anaesthetic induction agent as there should be to reflect best practice.
- However, we noted liquid or rectal medication was not made available for patients that could not ingest tablets and this caused some distress for one patient whose treatment pathway we observed.
- The provider's audit for control of pharmaceutical supplies in March 2016 found 100% compliance at the Sandwell clinic. The provider had undertaken a risk assessment of availability of key service delivery pharmaceuticals in March 2016 with further controls identified to be put in place by September 2016.
- The provider's medicines management audit for the Sandwell clinic had scored 100% in February 2016. For 2015 the quarterly audit had shown a steady improvement from 94.8 % in February to 97.4% compliance in November 2015.
- However we noted from the provider's incident reporting matrix there were clear patterns of error in medication management. For Q4 2015/16, staff reported 12 medication/administration errors within the Birmingham Centre group of services that included the Sandwell clinic and the same clinical staff team.
- These incidents mostly involved nurses not signing for medicines administration but included one incident of anti D not being administered to a RH negative patient as it should have been. This is in order to protect the mother against a mismatch between her rhesus status and the baby's rhesus status. Staff reported 36 medication/administration errors in Q1 2016/17 (April to June 2016), 27 of which were 'dose not documented'. The provider had rated each incident as 'no action required'. Ten of these incidents were nurses not signing for fitting contraceptive implants to patients. This demonstrated a deterioration from the provider's audit outcome data January to April 2016
- The provider had in place an electronic client record system and this logged patient appointments, stored patient records and enabled those records to be confidentially shared with other staff within the clinic including surgeons and remote doctors on duty within the organisation. We saw staff using this system during our visits.
- Systems were secure for storing patient notes on paper. Notes held electronically securely moved through to the appropriate procedure stream for clinical staff to access for consultations and procedures including surgery. We saw this working for patients undergoing surgical and medical terminations of pregnancy.
- Assessment for risk made during a patient's initial consultation and patient history was put on record. We saw staff completed notes that involved integrated care pathways appropriately and logged any patient's allergies on the electronic patient records.
- The Sandwell clinic audit matrix showed a medical records audit carried out by the provider in February 2016 scored 98.8% compliance. This demonstrated a slight drop from the 2015 bi monthly audits which showed compliance at between 99.7 and 100%.
- We saw systemic gaps during 2016 in records to demonstrate emergency equipment had been checked at the Sandwell clinic.

Safeguarding

- The provider had policies and procedures in place for safeguarding children and vulnerable adults and we noted staff followed them.
- Staff confirmed for example, it was the provider's policy that staff initially saw each patient for a consultation alone regardless of their age. This meant staff could assess that a patient was making her own choice to attend the clinic and discuss the options and procedures without duress.
- The provider reported in the data we asked for about the clinic prior tour inspection visit that three out of ten staff involved in the care of patients less than 18 years old had updated level three, face-to-face safeguarding training for adults and children. Staff on duty on the day of our visits all confirmed they had this level of training. All other nurses had level two safeguarding training and non-clinical staff had level-one training.
- We reviewed the provider's central training matrix for the 'Birmingham Centre' (that also provided the services at the Sandwell clinic). Level two safeguarding training

Records

Termination of pregnancy

compliance was 83% at April 2016. There were two registered nurses who had not yet received training. The provider assured us these two registered nurses were new starters, who were still under observation and supervised at all times as is the provider's policy.

- Only one staff member, the clinical operations manager had safeguarding training at level three.
- Many patients who used the service were vulnerable people but the level of safeguarding competence among staff did not reflect this.
- All staff we spoke with were aware of the safeguarding pathway and policy.

Mandatory training

- All staff we spoke with confirmed they had up-to-date mandatory training and this was provided as a mixture of e learning and face to face sessions.
- Data provided by MSI showed for the Midlands team that included the Sandwell clinic staff for 2015/16 there was 100% compliance with health and safety, fire, COSHH, moving and handling, infection control and prevention, DSE, and IG training. Intermediate life support stood at 71% compliance.

Assessing and responding to patient risk

- Staff confirmed an agreement was in place with a local acute NHS trust for transfer of patients if needed.
- The provider reported the clinic transferred two patients to another health care provider in the 12 months prior to our inspection. The provider's incident report matrix showed in January 2016 one patient was transferred as an emergency as a haemorrhage requiring transfusion; another patient had a suspected perforated uterus (it was not confirmed).
- However the record does not show which clinic these incidents related to because the provider combined the reported incidents for the Sandwell and the Birmingham clinic as 'Birmingham Centre'. In correspondence subsequent to the inspection visit the provider told us that it could run reports of incidents by location.
- The provider reported 100% of patients undergoing surgical termination of pregnancy and 100% of patients undergoing medical termination of pregnancy during 2015 were risk assessed for venous thromboembolism (VTE, a blood clot (thrombus) that forms within a vein). We saw that surgical patient's records contained completed VTE assessment forms.

- The provider told us patients were given the option to receive an initial medical assessment by phone or at the Sandwell clinic. The consultation covered comprehensive medical history checks to identify any existing health conditions.
- Pre-existing conditions (PEC's) were risk assessed in accordance with its PEC policy. With permission, staff would make contact with the relevant medical practitioners to obtain additional medical information and work with the patient's GP or consultant.
- Data provided by MSI showed for 2015/16 Intermediate life support training stood at only 71% compliance within the Midland team which, included the Sandwell clinic staff.
- We observed the treatment of five patients undergoing surgical procedure. We noted a for venous thromboembolism (VTE) risk assessment was present and completed in all their records. Patient notes were detailed and included a risk assessment involving a medical and social history.
- Staff told us the protocol was to check a patient's observations three times during their recovery process. We observed a patient in recovery and noted staff made three sets of observation but they were made almost consecutively. Staff did not use an early warning score chart. This meant they were not monitoring effectively for deterioration in condition.
- There was no place on the electronic patient record to indicate the time observations were taken. The patient was still unconscious and we noted as the observations had been checked three times staff conducted no further observations.
- Our inspection visit was four months after staff had reported the retained surgical swab incident (a never event). We noted the provider used an adapted form of the World Health Organisation (WHO) Five Steps to Safer Surgery checklist, which was suitable for the location. The provider's policy was to follow the national patient safety agency 'how to guide- five steps to safer surgery' 2010.
- Local leaders had undertaken a recent audit of patient's notes and clinical records. This concluded there was compliance with the five steps to safer surgery checklist because they were complete in each patient's file. However we observed procedures and saw the checklist was not properly applied in practice.
- We observed three surgical procedures. We saw health care assistants fully completed this safety check,

Termination of pregnancy

including the post operation instrument, swab count and complications part, before the start of the procedure for each of the three patients. They then added the completed checklist to the patient's file.

- Staff did not count the surgical instruments or swabs as they should. We saw additional swabs were added during one procedure but not counted at the end.
- This was not in keeping with accepted good practice or with the provider's policy. The surgeon and anaesthetist in attendance did not engage with this safety checklist, there was no 'sign off' by the team in attendance after the procedure, it was a tick box exercise carried out by the least qualified and most junior staff member in the team present.

Nursing staffing

- The provider told us the service employed 10 registered nurses, this represented seven full time equivalent staff. We observed there were sufficient nurses on duty at the Sandwell clinic on the day of our inspection visit to support the number of patients.
- The regional clinical operations manager who had day-to-day charge of the Sandwell service was also a nurse and was on duty.
- The provider reported three nursing vacancies during 2015/16 within the 'Birmingham centre' team which included the Sandwell clinic were due to expansion of the service within the region however there was zero use of agency staff.
- Staff confirmed the registered manager was available everyday via telephone if not on site. Each clinic that ran had a lead nurse manager, three nurse practitioners, one in theatre and two in recovery and three healthcare assistants. The staff team worked over different sites run by the provider through the week.

Medical staffing

- The service employed two registered medical practitioners including an anaesthetist who worked for MSI on a sessional basis. They worked 2.4 full time equivalence during the three months prior to our inspection within the Sandwell clinic. Medical staff were present during clinic opening times.
- We noted there were two doctors on duty carrying out the surgery list on the Wednesday we visited the service, one was an anaesthetist.

- The provider reported zero medical staff vacancies and zero use of agency staff during 2015/16. Doctors worked solely for the provider across a number of sites anaesthetists worked on a sessional basis.

Major incident awareness and training

- The clinic was provided within a service level agreement within an NHS health care centre and subject to its fire emergency and major incident arrangements.

Are termination of pregnancy services effective?

- The provider had systems in place to collect information about the effectiveness of its services. Those systems were not effective and did not provide the local leaders or staff with a clear picture of how their service was performing against regional and national standards.
- Local leaders undertook a series of monthly audits of infection control, record keeping and medicines management and the results were passed on to senior leaders for monitoring.
- Patient's medical and health history was checked before treatment and the clinic carried out only procedures for which it was registered and within national guidelines. Other patients were referred to more appropriate services to meet their needs.
- Patients were given information about contraception and nurses gave advice about sexually transmitted infection.
- Nurses and doctors were competent and experienced and worked with other healthcare providers locally for the benefit of patients.

However:

- The results of the monthly audits did not always match with what we observed or the patterns of errors shown on the provider's incident reporting records.
- The provider was not effectively undertaking clinical audits recommended by the Royal College of Obstetricians and Gynaecologists for termination of pregnancy in order to continuously improve the services offered by the clinics.
- Staff without the appropriate training including level of safeguarding competence were taking consent to procedures from vulnerable patients with complex needs.

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- There was no established pathway for effectively supporting women with learning disability to give informed consent to treatment.
- Treatment was offered in line with the requirements of the Abortion Act 1967 and 1991 regulations. Most but not all treatment reflected the Royal College of Obstetricians and Gynaecologists (RCOG) guidelines. For example the clinic was offering a regimen for medical methods up to 63 days gestation that was at a shorter interval time than RCOG recommendations.

Evidence-based care and treatment

- The provider had policies and procedures in place for treatment. Treatment reflected the Royal College of Obstetricians and Gynaecologists (RCOG) guidelines except the clinic was offering a regimen for medical methods up to 63 days gestation that was at a shorter interval time than RCOG recommendations.
- We saw staff followed and complied with this system at the clinic for each patient whose treatment we followed.
- We noted from the provider's incident reporting matrix that staff identified and referred on to other providers, patients whose gestation period was outside of the services' registration criteria for treatment offered.
- We noted staff followed most RCOG guidelines for termination of pregnancy. For example, patients were offered a choice and method of termination of pregnancy; staff offered patients contraceptives including long acting reversible contraceptives (LARC), which we saw staff administering.
- We observed cervical preparation was in line with guidelines and the method of termination of pregnancy the surgeon used was suitable (manual vacuum with a blunt catheter). Surgeons checked aspiration after the procedure and ultra sound was available in the theatre.
- However the clinic was offering a regimen for medical methods up to 63 days gestation that was at a shorter interval time than RCOG recommendations of mifepristone followed 24-48 hours later by misoprostol. The clinic was not offering simultaneous administration of these medications.
- Nurses gave patients information on sexually transmitted infection (STI) at the initial consultation and at discharge and carried out sexual health screening for each patient. This was also in the form of a patient information booklet. Nurses made all methods of contraception available to patients.
- The information booklet identified common symptoms and side effects likely when taking oral abortion medication and details of a 24- hour help line that was available to access any post treatment support they needed.
- However we noted the provider's client feedback report for Q3 and Q 4 2015/16 suggested the service at 76/77% was below its target (of 80%) for ensuring patients left the clinic with contraception.
- We noted all patients were discharged with a pack of two condoms, we also saw nurses administer the contraceptive pill to patients. Contraception was indicated in patient's notes with appropriate consent and the risks and benefits were confirmed with the patient.
- The service treated patients for medical termination of pregnancy where pregnancy was confirmed by abdominal or transvaginal scan to be under nine weeks and four day's gestation. There were varied treatment options available for patients undergoing medical termination of pregnancy.
- Marie Stopes International had started to offer simultaneous administration in the spring of 2016 but had not updated its medical termination of pregnancy policy dated October 2015 to reflect the introduction of simultaneous administration of medicines, engaged with its staff or put in place a national plan to audit and review its administration and effectiveness.
- Marie Stopes International reached the corporate decision three days after, the beginning in April 2016 of the CQC comprehensive inspection of its services nationally, to suspend the practice of simultaneous drug administration to enable a substantiating review to ensure best practice and support both patients and staff.
- We noted patients under 18 were highlighted on the booking system appropriate pathways then put into place to support their needs. There was a specific safeguarding risk assessment in place for young patients. The consent form indicated if the patient had been assessed within Fraser guidelines as competent.

Pain relief.

- Clinicians routinely offered patients pain relief such as non-steroidal anti-inflammatory drugs during surgical termination of pregnancy and alternatives were provided for patients with asthma.

Termination of pregnancy

- We noted surgeons used sedation used for three of four procedures we observed. The patient was unconscious and comfortable.
- Nurses used a pain score to assess patient's pain levels pain in recovery and there was suitable pain relief available to patients in recovery including heat packs. Clinicians discharged patient's with suitable pain relief.

Patient outcomes

- Information about the clinic sent to us by the provider as requested told us, 'We benchmark ourselves against the DH [Department of Health] abortion statistics produced annually. Data on failed procedures is continually collected and analysed using a web based management system. On a quarterly basis, clinical reports are produced e.g. failure rate by surgery and medical treatments, infections, transfers and for what reason. These numbers are also converted into rates which allow us to trend against previous results. We operate a robust Integrated Governance Framework in line with the NHS governance agenda and the CQC Essential Standards of Quality and Safety. The corporate Central Governance committee (CGC) meets four times a year and reports directly to the MSI Board. Local IGC; s meet four times a year. On a quarterly basis MSI UK Governance Support Team produces national clinical governance reports that are shared with the team to ensure best practice is recognised, benchmarks are set and improvement in practice take place.'
- However during our visits we asked regional governance staff how they obtained an effective and accurate picture of outcomes for patients for the Sandwell clinic service at any time. They said the 'overall systems' would 'provide it with internal communications and patient feedback'. This did not sufficiently address our question.
- We asked specifically if, for example, the provider undertook the audits recommended by the RCOG for termination of pregnancy services. Regional governance staff told us it largely did not as 'pathways of care' were mostly CCG controlled so the provider did not audit this; the provider undertook no audit of 'information provision', 'women's choice' or 'pre abortion assessment'. Audit of 'abortion procedures' were not made although there was corporate wide data on surgical verses medical procedures that were responded to by local clinics; 'care after termination of pregnancy' was not audited directly although the post-operative workflow and notes were on the records audit.
- The provider audited patient experience through an external contractor. The survey broke down figures and identified trends and made regional comparisons and comparisons between surgical clinics and medical clinics.
- The provider had a programme of local clinic audits in place. We saw the audit programme for 2016. Regional governance staff told us the audit schedule was the same each year. The provider had introduced a governance dashboard in April 2016 that was informed on a monthly basis by these audits.
- The audit plan covered infection prevention and control (IPC), hand hygiene, medicines management, safeguarding, medical records, regulatory compliance plan and PPM audit tool.
- We noted for example the provider set the hand hygiene compliance target at 95 %. It reported during the 2014/15 cycle the Sandwell clinic scored overall 97% for IPC and 100% for hand hygiene.
- However the March 2016 hand hygiene audit showed a compliance score of only 88.9 %. Local leaders told us the clinic had an IPC lead and link person to drive the audit programme and put in corrective actions where identified.
- During our visit in June 2016 we observed non-compliance with some clinical staff changing their gloves but not washing their hands between procedures. This suggested that the audit programme was not effectively driving improvement.
- The Sandwell clinic audit matrix showed a medical records audit carried out by the provider in February 2016 scored 98.8% compliance. This demonstrated a slight drop from the 2015 bi monthly audits which showed compliance at between 99.7 and 100%.
- Staff we spoke with said they weren't aware of audits being carried out and that senior members did this.
- We noted four incident reports (February, March and June 2016) on the provider matrix for the 'Birmingham Centre' which included the Sandwell clinic and the same staff team, of patients being returned to theatre from the recovery room because they were experiencing higher than expected levels of pain or discomfort or bleeding heavily.

Termination of pregnancy

Competent staff

- Nurses we spoke with said they were up-to-date with their appraisals. The matrix sent to us by the provider confirmed compliance for appraisals at 100% for 2015/16.
- Compliance for appraisals for medical staff was confirmed as 100% for 2015/16 by the matrix the provider sent us.
- Nurses told us they were encouraged to reflect and were supported with their nursing and midwifery revalidation process and continuing professional development within their nursing role. They felt well supported with good supervision with development including their imaging skills and competence.
- The provider sent us data prior to our inspection visit that showed at that time four out of 10 registered nurses and one of the five health care assistants that worked in the clinic had undertaken in house scanning training. The record showed no dates for his training.
- The provider organised periodic meetings in London for its doctors to gather and discuss practice issues. A meeting was taking place on the afternoon of our visit to the Sandwell clinic and the doctors were intending to join it after their surgery list.
- Doctors told us they had support from a named revalidation officer. They could get feedback on their performance but had to request the information.
- A surgeon anaesthetist attended all surgical procedures at the Sandwell clinic. We noted the provider employed a female surgeon as well as male surgeons. Staff told us this surgeon was experienced in treating victims of female genital mutilation (FGM). Staff received training from this surgeon under a local arrangement.

Multidisciplinary working (related to this core service)

- We observed five surgical procedures and noted communication between nurse and surgeon, surgeon and health care assistant in the theatre was minimal. This meant there was no multidisciplinary team working for the World Health Organisation (WHO) Five Steps to Safer Surgery check list and this is not in keeping with accepted good practice and the provider's policy safer surgery policy.
- The clinic had an arrangement in place to refer patients to local NHS acute services in emergencies and to the local NHS acute hospital's early pregnancy advice units (EPAU's).

- There was a service level agreement in place for the transfer of patients to local NHS hospital in the event of complications (including patients from abroad). We noted these events as reported incidents by the 'Birmingham centre' team that included Sandwell clinic staff, on the provider's matrix. Staff told us the clinic had a very good working relationship with the NHS provider.

Seven-day services

- The clinic did not offer treatment seven days a week. It usually opened on Mondays for medical termination of pregnancy procedures and consultations and on Wednesdays for surgical termination of pregnancy procedures.
- The provider ran a 24-hour helpline via MSI One Call that was available out-of-hours.

Access to information

- Staff had access to the provider's policies and procedures to consult through electronic systems. Policies were also available in hard copy. These were updated and accessible to all staff members.
- Staff told us they regularly liaised with other healthcare professionals such as GPs and local social services and safeguarding teams, they felt they had good networks outside of their organisation with social workers and safeguarding leads.
- RCOG guidance sets out in recommendation 8.2 that "On discharge, all women should be given a letter providing sufficient information about the procedure to allow another practitioner elsewhere to manage any complications."
- We noted on discharge nurses gave patients a letter providing sufficient information about the procedure to enable other practitioners to manage complications if required.
- Nurses sought patient's consent to send a copy of the letter to their GP and we noted the GP letter contained adequate information.

Consent, Mental Capacity Act and Deprivation of Liberty Safeguards

- The provider had policies and procedures in place for gaining consent from patients for their treatment. These included procedures for consent from patients less than 18 years old and were linked to safeguarding procedures.

Termination of pregnancy

- We saw that health care assistants (HCA) were taking patient's consent to treatment and signing the forms. Staff told us HCA's completed training to be able to complete this task. The provider sent us certificates of in house e-learning attainment on informed consent for these staff dated 2013.
- However we subsequently noted from information submitted from the provider's head office, the content of this training was not effective in providing the appropriate knowledge, skill and understanding to carry out this task.
- However the provider's training matrix shows health care assistants were safeguarding competent only up to level two training and this is not sufficient for the complex needs and vulnerability of many patients accessing the service.
- For example during our inspection visit we saw staff carried out consent taking appropriately for three of the four patients whose treatment we observed. The fourth patient we observed was a woman with a known learning disability.
- The patient had noted on their record from the telephone consultation that they had learning disabilities. 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 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.

Are termination of pregnancy services caring?

- Patients we spoke with and those who responded to the provider's patient feedback surveys spoke positively about staff attitudes towards them.
- Patients received a lot of information from staff about their treatment and there was a 24- hour help line available to provide additional information and address concerns.
- Staff checked patients decisions at each stage of the process and went over the options with patients on more than one occasion.
- Counselling was made available to support all patients over the phone or face -to-face. This was compulsory for patients under 16 years of age.

However:

- We observed one incident where a doctor was impatient and disrespectful to a vulnerable patient who had not received the support they needed to properly consent before entering the theatre. One patient became upset because they did not fully understand the procedure and were anxious. This situation was further escalated by the attitude and behaviour of the surgeons.
- There was no 'easy read' additional material available to enable patients with learning disabilities to access the information about treatment, treatment options and contraception.

Compassionate care

- During the inspection visit, we observed most staff were kind and caring towards patients. For example we observed compassionate care from nurses and health care assistants (HCA) who supported a patient having a procedure without anaesthetic; they offered constant reassurance and support to the patient.
- However we also observed surgeons did not acknowledge the patients' arrival in theatre even when the HCA introduced them; surgeons kept their back to the arriving patient and continued completing notes.
- One patient became upset because they did not fully understand the procedure and were anxious. We observed this situation was further escalated by the attitude and behaviour of the surgeons. We raised this with local leaders and after our visit with the provider organisation and they assured us they had taken action.

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- We also heard the medical team in theatre discussing other patients in front of an unconscious patient.
- The provider had generally organised the environment at Sandwell clinic to promote the greatest possible privacy for patients. However the reception area was shared with other clinics.
- We observed reception staff at the Sandwell clinic were skilled at maintaining patient's confidentiality and privacy within a reception area shared by other provider's clinics in the health centre.
- We noted the clinic score rates of patient satisfaction for dignity and respect had improved from 94% for Q3 to 100% for Q4 2015/16 against a target of 100% in the provider's feedback survey.

Understanding and involvement of patients and those close to them

- Patients received 'Your Treatment Information' booklets through the post or staff gave them to patients on arrival at the clinic. This also included details of the 24-hour helpline and additional information was also available on the Marie Stopes website for patients to access.
- We noted posters on display in the clinic about chaperones and when patients booked appointments staff encouraged them to bring a companion to accompany them home.
- Patient's we spoke with during our visit told us they felt well supported and satisfied with their treatment, they said the staff were supportive.
- However staff confirmed there was no 'easy read' additional material to enable patients with learning disabilities to access this information.
- We observed clinicians made no adjustment for a patient who could not take medication in tablet form.
- The provider audited patient experience through an external contractor. We saw a copy of the Q4 2015/16 report for the Sandwell clinic. The percentage of respondents was 40% and showed the overall rating of care for the clinic at 92% as 'very good' or 'excellent' compared with 95% nationally with other MSI clinics.

Emotional support

- The provider made counselling available to all patients either over the telephone or face-to-face prior to any procedures and available following procedures. This was arranged through the MSI Birmingham clinic system for Sandwell clinic patients and included independent local counsellors.

- We observed nurses checked the patient was 'sure' about their decision before the surgery.
- The provider offered post-operative care complications and advice through a 24-hour help line following termination of pregnancy.
- The provider offered mandatory counselling for patients less than 16 years old. Local leaders told us this face-to-face counselling was undertaken by an external counsellor as the provider did not offer this training to nurses.

Are termination of pregnancy services responsive?

- Services were planned to provide surgical and medical (up to 10 weeks) terminations of pregnancy for the Dudley and Sandwell area within a neighbourhood health centre.
- Patients accessed services and appointments through a national call centre. This system managed waiting times across clinics to respond flexibly to local demand, legal requirements and targets set by commissioners of the services.
- Translation services were available to patients from the first point of making contact with the organisation.
- Staff helped patients to access other services they needed such as help for domestic violence or drug abuse.
- Patients were offered choices about disposal of the remains of their pregnancy and there were proper procedures in place for the dignified disposal of pregnancy remains.
- There were a variety of means by which patients could comment on the service, raise concerns or make a complaint. These included participating in the 'client feedback survey' before leaving the clinic, telephoning the call centre or by e mail through the MSI website. Complaints were raised and discussed at the clinic team meetings.
- Access to the Sandwell clinic was good for people with physical and sensory disability.

However:

- Waiting times for patients within the clinic was a challenge for the service and patient satisfaction with this had fluctuated during 2015 but improved in early 2016.

Termination of pregnancy

- There were no arrangements to support the specific needs of patients with learning disabilities to understand the information about the procedures or to support getting informed consent for treatment from learning disabled adult patients.

Service planning and delivery to meet the needs of local people

- We saw the Department of Health 'Certificate of Approval' to carry out terminations of pregnancy on the premises was displayed within the clinic.
- The Sandwell clinic opened Mondays for consultations and medical termination of pregnancy procedures only and on Wednesdays when there was also a list for surgical terminations of pregnancy.
- The Sandwell clinic was part of the provider's 'Birmingham centre' in its administration and we saw the whole staff team supporting the Sandwell clinic also provided the services at its Birmingham clinic (Edgbaston) location each week.
- The provider had contractual arrangements with local clinical commissioning groups (CCGs). The majority of patients received treatment funded by the NHS. Some patients paid privately including patients from abroad.
- Patients from outside of the West Midlands region could receive treatment at the clinic. Under these circumstances, the clinic reception staff had to contact MSI 'One Call' to add the patient onto the records system for them.
- The provider offered patients a choice of clinic dates, times and locations and patients we spoke with on the day of our visit confirmed this.
- We saw the MSI wait times report that was sent through to the clinic daily. The provider added extra clinics to lists if there was a risk of not meeting target times against demand locally.
- Local leaders told us the main challenge they faced was the control over the patient location list for surgical and medical terminations of pregnancy.
- Staff felt they were not able to accommodate some patients especially those close to their 23 weeks gestation. This meant at times they had to postpone appointments of other patients to be able to accommodate those who needed an emergency appointment.
- Staff confirmed the clinic's diaries were constantly reviewed and adjusted to ensure access and full availability for the clinic. The provider told us; during 2015, patients who waited more than 10 working for days for consultation were accounted for by those who requested to wait for personal reasons for example, they were undecided.
- We noted from the provider's patient feedback survey report (40% response rate) for the clinic patients reported a 90% satisfaction (target 95%) in Q4 2015 with 'the process of booking your appointment'. This rose to 96% satisfaction rate for Q1 2016.
- On the day of our visit to the Sandwell clinic we noted the surgery list seemed rushed. This led in part to surgeons' unsympathetic response to one patient when the procedure was delayed because staff had to revisit the consent process.
- Administration staff told us there was pressure on the service's ability to meet the provider's five day target for waiting times for patients with pregnancies above 14 weeks gestation. The provider told us this target ensured a safety net to allow it to meet the national target for waiting time which is 10 days. The provider was meeting the 10 day national target.
- This included using the electronic patient records system to access remote registered medical practitioners for agreeing independently 'in good faith' decisions for a patient. Also to sign the HSA1 forms and prescribe termination of pregnancy medication.

Access and flow

- Patients could access treatment privately by self-referral or could be referred directly by their GP in which case a GP referral form was kept on the patient record file.
- The provider had systems in place to manage appointments to ensure short waiting times and access to all of the services at the clinic. The provider was required to regularly send data on waiting times to the CCG's.
- The provider's UK business support team in London monitored and flagged target times for the clinic.

Meeting people's individual needs

- We noted the provider website gave patients direct access to translation services to make contact with the organisation.

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- Telephone translation services were available for patients whose first language was not English. Staff contacted an external company telephone translation service with which the provider has a contract. Information was also available on the MSI website in over 90 different languages through the translate feature.
- A face- to-face interpreter was available if required and could be booked through 'One Call' when the patient made the appointment. These were organised through a local CCG funded organisation. Staff confirmed they used an interpreter phone line for patients who did not speak English.
- We noted the clinic was located in a new purpose built health care centre that had good access for people with disabilities and parking facilities.
- The provider told us treatment options were presented to the patient determined by their specific needs and requirements. During the consultation their reasons were discussed along with their contraception requirements.
- Staff also signposted clients with specific requirements where needed, for example women suffering domestic abuse or drug abuse.
- A lead nurse told us that if a patient under 18 attended they could have a friend or relative to support them in the recovery area if they requested.
- We noted staff checked fasting arrangements before surgery commenced and clear information had been given to the patient prior to day of surgery. Staff offered patients drinks and snacks once recovering on the ward and in the discharge lounge and gave advice about eating and drinking following discharge, this was also in the patient information leaflet.
- However we found the service had no arrangements in place to support the specific needs of patients with learning disabilities to access information about the medical or surgical procedures. Nor did it have pathways to address consent from learning disabled adult patients. Local leaders confirmed there was no pathway in place to support adult patients with learning disabilities including no signposting to independent advocacy services.
- If requested, staff gave patients information about the options available for the disposal of pregnancy remains. They said they were aware patients expectations had to be appropriately managed. We saw the leaflet that supported this.
- The 'management of pregnancy tissue' MSI Policy detailed the process of disposal of pregnancy remains conducted by an external clinical waste disposal company. MSI had a national contract with a clinical waste company that was renewed centrally. The waste disposal contractors collected samples on non-surgical days in order to avoid upset to patients.
- Staff told us the majority of patients expressed no preference regarding the disposal of pregnancy material. Where a patient did not request a specific method, the clinic used the recognised disposal routes in accordance with national guidelines.
- Staff told us because of lack of demand; the provider had no arrangements in place with local undertakers.
- However, the clinic could support patients in making these arrangements if required and also took into account the religious requirements of the local population. Staff facilitated patients who wished to keep pregnancy remains and there was a pathway in place for this.
- If pregnancy products needed to be retained for the purpose of a criminal investigation or were required for DNA testing a separate clinical storage container was used and labelled appropriately.

Learning from complaints and concerns

- The provider had a system in place for patients to raise concerns, make a complaint or just provide feedback. Patient feedback was formally analysed and reported on a quarterly basis by an external contractor. The provider told us the service had received two complaints during 2015.
- The complaints record showed one was about the service generally and the provider up held this and refunded the patient, the other was about a failed medical termination of pregnancy and this complaint was not upheld.
- Staff we spoke with in the Sandwell clinic told us they could not recall any recent complaints or actions that followed.
- However we saw a team meeting agenda for May 2016 that showed the common themes of complaints from patients as being leg positioning during surgical procedure and pre and post-operative patients being in the same waiting room.

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- Staff told us a complaints manager based in London had recently given a talk at a team meeting about reviewed complaints and lessons learned across the organisation.
- We followed the process of one complaint through the provider's electronic records system. Staff helping us had difficulty accessing this as it was separate to the incident reporting system and had limited access.
- We noted the correct procedure had been followed to respond to this complaint about 'general care and treatment' and within the agreed time frame. The response letter sent by the provider addressed each point raised by the complainant and offered an apology and a refund of fees for their expectations not being met.
- However, there was no improvement plan on record. A regional governance lead explained to us that the issues raised couldn't be changed or learned from because they were providing the service out of a host clinic. This could have put on the record as an outcome to be noted and signed off.

Are termination of pregnancy services well-led?

- The provider had a clear vision for the service and all staff were committed to this and highly motivated.
- The clinic was led by a manager registered with the Care Quality Commission and staff felt well supported by the local leadership team.
- The service routinely sought the views of patients and ran programmes of engagement with the wider public and other professionals locally.
- The organisation aimed to improve by trying out new ways of providing the service and increasing its presence in new locations.
- The organisation had structures in place to provide the service within the Abortion Act 1967 and the 1991 regulations.

However:

- Quality assurance systems had weaknesses locally and organisationally. This meant some incidents were not reported and some risks, repeated mistakes and serious incidents that staff reported were not properly dealt with and learned from.

- Some clinical staff were defensive to external scrutiny of their practice; local leaders did not manage this effectively and senior leaders accepted a defensive organisational culture as inevitable.

Vision and strategy for this this core service

- All staff we spoke with were aware of and personally committed to the provider's vision of 'children by choice not chance'. Staff told us the provider's strategy was to expand its services to make them accessible locally within as many communities as possible.
- We saw posters and publications available to patients communicating the provider's vision and purpose.
- We noted the provider displayed the certificate of approval (the license issued by the Department of Health to carry out terminations of pregnancy) in a prominent position within the clinic.

Governance, risk management and quality measurement for this core service

- The provider told us it had put in place a UK assurance framework governance structure. This set out that 'centre integrated' governance meetings reported to the health systems committee, reporting to the central governance committee and then to the UK executive.
- The health systems committee oversaw clinical leads and operations plus resuscitation, the committee structure for infection prevention and control (IPC) and safeguarding.
- The provider had created a new post of regional governance officer. The UK health systems director was supported by a director of governance, lead surgeon and lead anaesthetist who led the operational staff.
- We noted the provider had put in place arrangements for compliance with the Abortion Act 1967 and 1991 regulations and with its conditions of CQC registration. We saw that most procedures in place were adequate to reflect the required standard operating procedures (ROSP's) for a Department of Health licence for termination of pregnancy.
- We looked at the clinic risk register but noted the risks identified were generic to the organisation and its clinics. We saw no link between clinical risks identified locally for the Sandwell clinic and rated through the incident investigations process, and the risk register.
- Leaders told us they had already identified the incident reporting system used by the provider was not effective.

Termination of pregnancy

We were told a new system was to be installed by the end of 2016. However the provider had put in place no interim measures to mitigate the risks in incident capture and duty of candour compliance.

- The provider responded to some incidents in a manner that underestimated their gravity. This indicated a poor understanding of what was required for effective governance of the service.
- For example the provider had failed to recognise a reported incident that was a 'never event' within the 'Birmingham centre' of which the Sandwell clinic was part and includes the same staff team. It failed to ensure the investigation was undertaken although its own procedure identified one was required; it therefore failed to report it to the clinical commissioning group as is required and failed to exercise its duty of candour in respect of this incident.
- We raised an issue of concern with local leaders about the behaviour of surgeons over consent to treatment with one particular patient we observed. Given our concerns about learning from incidents, after our inspection visit we asked for an account of how the incident had been taken forward by the local leaders. We also requested up to date incident report data for the services' region.
- We noted from the incident data the provider sent us that local leaders did not appear to have reported this as an incident. We received no further information about how local leaders responded to the incident. However, subsequent correspondence with the provider demonstrated local leaders acted promptly and appropriately.
- The provider's incident reporting matrix showed patterns of repeat error within the 'Birmingham centre' which included the Sandwell clinic and staff team, and the provider's systems of governance had not addressed this. This indicated a weakness in systems. The provider has subsequently told us it can run reports on individual locations.
- The provider told us, 'patients may either opt to have a telephone consultation carried out by its 'One Call' team, or face to face consultation within a clinic. During the consultation the patient is assessed for eligibility under the Abortion Act criteria. This is clearly documented on the provider's electronic centralised record system that can be viewed by the clinicians before prescribing any treatments. The HSA1 form [the legal document that certifies two registered medical

practitioners have agreed 'in good faith' one of the criteria for which termination of a pregnancy is legal] is only completed once a full medical history and criteria had been established. Two doctors, either the surgical team at the clinic or the remote doctors signed the form and the copy was held in the medical record to be checked prior to any treatment being initiated.'

- We observed the clinic used the system in place to fulfil the legal requirements under the Abortion Act 1967 and Abortion Regulations 1991 to certify an agreed 'good faith' independent opinions against criteria for a termination of pregnancy (completion of a HSA1 form). Also to notify the Department of Health with details of each termination of a pregnancy (completion of a HSA4 form).
- We saw that HSA1 forms for each patient whose treatment we followed and also the sample of records we looked at, were properly completed and signed and dated by two registered medical practitioners as required. We followed the care and treatment pathway of five patients undergoing surgical termination of pregnancy during our inspection visit. We saw the HSA1 form was completed for each patient and signed by the two registered medical practitioners present when the patient came to the theatre.
- The provider's 'live' patient record system directly gathered information on each procedure and automatically populated the HSA4 form. The clinicians who authorised the HSA1 form signed the HSA4 forms as required by law.
- At the point of patient discharge the administrator checked the HSA4 for completeness before pressing 'send' to the Department of Health. When the electronic process was not available local leaders told us the provider kept hard copies on site. These were to be completed by the registered medical practitioners once the procedure had taken place and sent by post in the appropriate Department of Health envelopes.

Leadership / culture of service

- A manager registered with the CQC oversaw the clinic along with a number of other services within the provider's South West and Midland region. They were also the regional manager. A lead nurse was on duty in the Sandwell clinic whenever the clinic was open.
- Staff told us they felt the service was well led by the management team in place. They confirmed our

Termination of pregnancy

observations of good relationships between reception staff and clinical and senior staff. Staff told us that the senior staff team were approachable and would listen to any issues or concerns they had.

- Local leader told us they were engaged in fostering a reporting culture among clinical staff including of near misses. We saw the clinic staff team meeting agenda for May 2016 that included an item on the importance of incident reporting including of 'near misses'.
- However we found some medical staff defensive in their response when we spoke with them about a serious incident (SI) we were tracking through the provider's reporting and investigation procedures.
- Local leaders explained this as an organisation wide sensitivity to criticism, as the organisation was often under attack for its activity and purpose.
- The provider did not respond in a timely way to the Care Quality Commissions request for further information after the inspection visit. Senior leaders excused the issue of concern we raised about the behaviour of surgeons over consent to treatment with one particular patient we observed by asserting it was caused by the presence of an inspector in theatre.

Public and staff engagement

- The provider's governance structure included a communication and engagement committee (CEC). Staff confirmed this committee included some staff from the Birmingham and Sandwell clinics and it held quarterly meetings which could be attended by any member of staff.

- The provider published papers and under 16s 'Share Your Story' articles were made available on its website.
- We noted the provider had published a UK community engagement plan for 2016. Arrangements for public engagement were made centrally in line with this plan. The provider also engaged with the public through social media.
- Staff told us locally some senior staff from the clinic had given talks at GP surgeries and held debates/talks at the universities. In addition the service worked closely with national charities such as Women's Aid who had provided a representative to attend a recent team meeting.
- Staff in all roles told us they were proud to work for MSI and the service they provided to people. All staff we spoke with in every role were knowledgeable about and committed to the providers values and vision. They were highly motivated to provide the service.
- The provider had a reward and recognition scheme for staff and they spoke to us about the 'meal out' they had recently earned.

Innovation, improvement and sustainability

- Local leaders recognised the challenges in the future such as, increasing patient demand and a more flexible approach needed for early medical terminations of pregnancy services situated within local communities. They stated that the plan was for continuous improvement through increased leadership support and staff development to manage increasing demands for the services going forward.

Outstanding practice and areas for improvement

Outstanding practice

Reception staff were highly skilled at putting patients at their ease and discretely confirming personal and private details when patients arrived, including within a shared reception area.

Areas for improvement

Action the provider **MUST** take to improve

Action the clinic **MUST** take to improve

- Ensure all staff treat patients with respect and uphold their dignity at all times.
- Put in place an effective incident reporting system that can provide assurance the provider can consistently learn from incidents and error, notify incidents to the appropriate authorities and exercise its duty of candour requirement.
- Ensure all relevant staff undertake mandatory training.
- Ensure all appropriate staff undertake safeguarding children and adults training at level three competency.
- Take steps to ensure clinical staff follow good hand hygiene practices consistently.
- Ensure staff follow properly national guidelines to safer surgery.
- Ensure staff use emergency equipment checklist systems effectively.
- Put in place protocols for obtaining consent, pathways and support for all patients who may lack capacity to consent including those patients with a learning disability.
- Ensure clinical audits recommended by the Royal College of Obstetricians and Gynaecologists for

termination of pregnancy are undertaken in order to continuously improve the services offered by the clinics and provide feedback effectively to staff about the services clinical performance.

- Improve the reliability of local clinical and safety audits of the clinics.
- Review the governance arrangements in place to provide effective assurance and auditing systems or processes. These must more effectively assess, monitor and drive improvement in the quality and safety of the services provided, including the quality of the experience for people using the service. The systems and processes must also more effectively assess, monitor and mitigate any risks relating the health, safety and welfare of people using services and others.
- Continually evaluate and seek to improve governance and auditing practice.

Action the provider **SHOULD** take to improve

- Explore methods of giving patients with learning disabilities access to information about the service and their treatment so they can better understand and be fully involved.

Requirement notices

Action we have told the provider to take

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

Regulated activity	Regulation
Termination of pregnancies	<p>Regulation 10 HSCA (RA) Regulations 2014 Dignity and respect</p> <p>Health and Social Care Act (Regulated Activities Regulations 2014</p> <p>Regulation 10- Dignity and Respect</p> <ol style="list-style-type: none">1. Service users must be treated with dignity and respect.2. Without limiting paragraph (1), the things which a registered person is required to do to comply with paragraph (1) include in particular—<ol style="list-style-type: none">a. ensuring the privacy of the service user;b. supporting the autonomy, independence and involvement in the community of the service user;c. having due regard to any relevant protected characteristics (as defined in section 149(7) of the Equality Act 2010) of the service user. <p>In that:</p> <p>Some surgeons did not display sympathetic behavior toward a distressed disabled patient; did not acknowledge patients when introduced to them as they entered the theatre; theatre staff spoke about other patients in front of a patient who was under sedation.</p>