

# BPAS - Cannock

## 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

BPAS Cannock is part of the provider group British Pregnancy Advisory Service (BPAS).

The service is registered as a single specialty termination of pregnancy service. BPAS Cannock provides a range of termination of pregnancy services for early medical abortion (EMA) up to nine weeks pregnancy, medical abortions (MA) between weeks 9-10 pregnancy and surgical abortions up to 15 weeks and 6 days gestation. Surgical terminations are carried out using general anaesthetic and vacuum aspiration. The service also provides pregnancy testing, unplanned pregnancy counselling/consultation, abortion aftercare, sexually transmitted infection testing, contraceptive advice, contraception supply and vasectomies.

We carried out this announced comprehensive inspection on 14 May 2016, as part of our independent healthcare inspection programme. The inspection was conducted using the Care Quality Commission's new methodology. The inspection team included three inspectors.

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.

Our key findings were as follows:

### **Are services safe at this service?**

- There were appropriate arrangements in place to highlight incidents and patient safety concerns. The provider had established systems to ensure that learning from incidents was shared throughout the organisation and staff group. Staff understood the principles of being open with patients when things went wrong.
- The service had sufficient numbers of suitably trained staff available to care for patients. However, due to some mandatory training being completed within the NHS, BPAS did not always have formal records of completion.
- The service used the World Health Organisation (WHO) Five Steps to Safer Surgery to minimise risks to patients having surgical operations.
- There were reliable systems, processes and practices in place to highlight and safeguard patients from abuse.
- Arrangements were in place to manage emergencies and transfer patients to another health care provider where needed.

### **Are services effective at this service**

- Staff generally provided care in line with national best practice guidelines.
- The provider monitored complication rates. Between January and April 2016, BPAS Cannock recorded zero complications for surgical treatments. Out of 171 simultaneous medical abortions, seven minor complications were recorded. Of the five non-simultaneous medical abortions, zero complications were recorded for this time period.
- There were appropriate arrangements in place to record patients' written consent including patients less than sixteen years. However, we saw that information regarding the slightly raised risk of complications arising from simultaneous administration of abortifacient medication was not verbally discussed when patients' chose this treatment.
- The service employed medical doctors including surgeons and anaesthetists under practice privileges at BPAS Cannock. Doctors provided evidence of General Medical Council (GMC) registration, indemnity insurance, qualifications and evidence of annual appraisal / revalidation to the provider. This ensured doctors were suitably experienced and qualified to undertake procedures at BPAS Cannock.

### **Are services caring at this service**

- We observed that staff treated patients in a very caring, compassionate and supportive manner. Staff responded to patient's individual needs in a visibly person centred way.

# Summary of findings

- Patients consistently reported that the care they had received had been to a very high standard and staff were kind, helpful and non-judgemental.
- The service used a patient satisfaction survey called 'Your Opinion Counts'. Analysis of feedback from the survey between April 2015 and December 2015 showed an overall satisfaction with care of 9.7 out of ten. The survey identified that 99% of patients surveyed would recommend the service (225 patients).

## **Are services responsive at this service**

- Patients could book appointments through the BPAS telephone booking service, which was open 24 hours a day throughout the year. This also enabled patients to choose the location they attended.
- There was a fast track appointment system for patients with a higher gestational age or complex needs.
- There were appropriate systems in place to raise and act upon concerns and complaints within the organisation.
- BPAS Cannock used Big Word, a telephone interpretation service, for those patients who did not speak English.

## **Are services well led at this service**

- Staff displayed the values and expected behaviours of the service.
- The culture within the service was caring, non-judgemental and supportive to patients.
- Staff felt supported by the manager and regional operations director.
- There were effective corporate governance arrangements to manage risk and quality. This included an audit programme and an established system to cascade learning. The provider did not always identify local risks such as the raised risk of retained products of pregnancy associated with simultaneous administration of EMA medications. However, following the inspection we were assured that the treatment manager had received training, and was maintaining a local risk register.
- We observed in medical records checked that terminations were only carried out following agreement of two doctors in line with the Abortion Act 1967.
- The provider ensured that services were monitored and audited in line with Required Operating Procedures (RSOP) 16. This included monitoring waiting times, rates of complications, failure rates, patient experience and complaints and critical incidents.

We saw there were areas where the provider needed to make improvements.

- The provider must ensure that explicit information about the effectiveness of medicines to induce abortion given at the same time (also called 'simultaneous' abortifacient medicines) is identified during the consent process to ensure that patients were able to provide 'informed consent'.

In addition the provider should:

- Ensure that, when staff receive mandatory training from another provider, there is confirmation of this available.

**Professor Sir Mike Richards**  
**Chief Inspector of Hospitals**

# Summary of findings

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# Summary of this inspection

## Background to BPAS - Cannock

BPAS Cannock is part of the provider group British Pregnancy Advisory Service (BPAS). BPAS Cannock has been registered with the CQC since 2011. The service is located within an NHS Hospital in a suite of rooms leased by BPAS on a sessional basis.

BPAS Cannock provides a range of termination of pregnancy services for early medical abortion (EMA) up to a gestation of nine weeks, medical abortions between nine and ten weeks and surgical abortions up to 15 weeks

and 6 days gestation. The service also provides pregnancy testing, unplanned pregnancy counselling/consultation, abortion aftercare, sexually transmitted infection testing, contraceptive advice and supply, and vasectomies. Services are provided under contract with local clinical commissioning groups for NHS patients.

BPAS Cannock termination of pregnancy services has no patient minimum age restrictions.

## Our inspection team

The inspection team included three inspectors.

## How we carried out this inspection

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?

Before visiting, we reviewed a range of information we held about the service.

We carried out this announced comprehensive inspection on 14 May 2016, as part of our independent healthcare inspection programme. The inspection was

conducted using the Care Quality Commission's new methodology. We talked with patients and members of staff including regional managers, the registered manager, nursing staff, medical staff, and support staff. We observed how staff cared for patients and reviewed patient's clinical records.

We spoke with 15 members of staff in the registered, including a midwife, patient care coordinators, nurse practitioners, administrative and clerical staff, the registered manager and regional operations director. We reviewed 12 treatment records. During our inspection, we spoke with four patients, observed nine surgical procedures and four patient consultations and observed how staff interacted with those patients. We also received 19 comment cards responses.

## Information about BPAS - Cannock

The British Pregnancy Advisory Service was established as a registered charity (Registered Charity Number 289145) in 1968.

The registered holds a license from the Department of Health (DH) to undertake termination of pregnancy services in accordance with the Abortion Act 1967.

CQC registered BPAS Cannock in July 2011. It is registered as a single specialty service for medical and surgical

# Summary of this inspection

termination of pregnancy services to NHS and private patients predominantly in Staffordshire and surrounding areas. Although treatment is also available for private patients; the registered manager confirmed all patients were funded through the NHS. The registered is open on Wednesday 09:30 to 13:00, Thursday 16:30 to 21:00 and Friday 16.30 to 21:00 and Saturday 08:00 to 14:00. Women choose their preferred treatment option subject to their gestation (weeks and days of pregnancy) and medical assessment.

The following services are provided at BPAS Cannock:

- pregnancy testing
- unplanned pregnancy counselling/consultation
- surgical abortion up to 15 weeks and 6 days of pregnancy
- medical abortion up to 10 weeks of pregnancy
- abortion aftercare
- vasectomies
- sexually transmitted infection testing
- contraceptive advice and contraception supply.

The service is located within a day case ward of an NHS Hospital, which is leased by BPAS on a sessional basis. BPAS Cannock has a reception and waiting areas and offices, five screening rooms, three consultation rooms, a theatre and an eight bedded ward area. The registered does not provide overnight stays. The service carried out 405 early medical abortions, 1090 surgical abortions, and 119 vasectomies between January and December 2015.

A treatment unit manager was also the registered manager and responsible for the management of two BPAS treatment units in Staffordshire (BPAS Cannock and BPAS Tamworth). Employed staff included 18 nurses and 16 clinical care coordinators/administrators who support the registered manager. Some of this staff group also work at BPAS Tamworth. In addition, a number of doctors work at the clinic under practising privileges. 'Practising Privileges' is a term that is defined in the Health and Social Care Act 2008 (Regulated Activities) Regulations 2010 as: 'the granting, by a person managing a hospital, to a medical practitioner of permission to practise as a medical practitioner in that hospital'. The registered manager was also the accountable officer for controlled drugs.

## Detailed findings from this inspection

# Termination of pregnancy

Safe	
Effective	
Caring	
Responsive	
Well-led	

## Summary of findings

- There were appropriate arrangements in place to report incidents and patient safety concerns. There were established systems in place to ensure that learning from incidents was shared throughout the organisation and staff group.
- The premises were clean and systems to minimise risk of infection were in place.
- Records were securely stored, well maintained and completed with clear dates, times and name of the person documenting.
- The service had sufficient numbers of suitably trained staff available to care for patients. The service employed medical doctors including surgeons and anaesthetists under practice privileges at BPAS Cannock. Doctors who worked at the registered were suitably experienced and qualified to undertake procedures.
- Care was generally provided in line with national best practice guidelines.
- Information about the effectiveness of 'simultaneous' abortifacient medicines was not identified or discussed during the verbal consent process to ensure that patients gave 'informed consent' with this additional knowledge.
- We observed that staff treated patients in a very caring, compassionate and supportive manner. We saw staff respond to the individual needs of patients in visibly person centred way.
- Patients could access appointments through the BPAS telephone booking service, which was open 24 hours a day throughout the year.

- There were effective corporate governance arrangements to manage risk and quality. This included an audit programme and an established system to cascade learning. However, the provider did not always identify local risks.



# Termination of pregnancy

## Are termination of pregnancy services safe?

### Summary:

- There were appropriate arrangements in place to report incidents and patient safety concerns. BPAS had established systems in place to ensure that it shared learning from incidents throughout the organisation and across staff groups.
- Appropriate systems were in place to identify and minimise potential patient risk.
- The premises were visibly clean and the required systems to minimise risk of infection were in place.
- There were appropriate and safe arrangements for medicines.
- Records were securely stored, well maintained and completed with clear dates, times and the name of the person documenting.
- There were reliable systems, processes and practices in place to keep people safeguarded from abuse.
- Arrangements were in place to manage emergencies and the transfer of patients to another health care provider where needed. These arrangements were known to staff as identified through staff interviews during the inspection.
- Staff generally had the required mandatory training or plans were in place, however, documented confirmation that staff had received training outside the organisation was not always provided.

### Incidents

- The system for reporting clinical and non-clinical incidents was paper based using an incident reporting book, that was held by the registered manager. The registered manager escalated incidents to the corporate risk and safety team who would record them on a central electronic register.
- The registered manager told us and we saw meeting notes which confirmed that 'never events' (serious incidents that are wholly preventable as guidance or safety recommendations that provide strong systemic protective barriers are available at a national level and should have been implemented by all healthcare providers) and serious incidents with any subsequent learning were discussed within the Regional Quality and Improvement Forum (RQuAIF).

- Learning from incidents was shared locally. Staff told us about learning following an incident of a patient who had a post-partum haemorrhage. As a result, Bakri balloons (equipment used to stop bleeding) were now included within emergency kits.
- The registered manager reported safety incidents, which included failed early medical abortions which required further treatment, and ectopic pregnancy. Staff said that in the registered manager's absence they would complete an incident report and escalate to an alternative manager.
- We looked at the records of safety incidents held at the registered location at the time of our visit. There was one safety incident reported between January 2015 and December 2015.
- Staff told us and we observed that when an incident is reported, three copies of the incident report were made, one remained in the patient notes, one remained in the book and one was sent to head office.
- There were no serious incidents at BPAS Cannock between January 2015 and December 2015.
- Never events and serious incidents were investigated by senior manager. Staff told us that the manager shared investigation reports for 'never events' and serious incidents and they had to sign to confirm they had read it. The regional manager and registered manager told us that the confirmation signature list was returned to the regional office to evidence that staff were aware of any learning from the incident.
- There have been no 'never events' reported at BPAS Cannock from January 2015 and December 2015.
- From April 2015, duty of candour with regard to adverse events is a statutory requirement for independent healthcare providers registered with the Care Quality Commission (CQC). Duty of candour is a regulatory duty that relates to openness and transparency and requires providers of health and social care services to notify patients (or other relevant persons) of certain 'notifiable safety incidents' and provide reasonable support to that person. The BPAS Clinical Safety Incident Policy identifies that duty of candour applies when a 'notifiable incident' occurs. For BPAS, notifiable incidents are: major complications, extreme (red) and high risk (amber) rated clinical incidents, serious incidents requiring investigation (SIRIs), including 'never events' and 'not at BPAS events' (NABEs), any other

# Termination of pregnancy

exceptional incident or complication that the Medical Director or the Director of Nursing and Operations determines should fall within the BPAS definition of a notifiable incident.

- Duty of candour arrangements to meet with the patient and/ or their representative and write to them with the findings of the investigation and an apology was undertaken by the regional director. Staff understood the principles of “being open” and had received information about the “Duty of Candour”. BPAS Cannock reported no duty of candour incidents.

## Cleanliness, infection control and hygiene

- The premises appeared visibly clean and uncluttered. The ward bays, waiting rooms, toilets, and bathrooms were clean and tidy.
- We saw that hospital domestic staff had completed cleaning schedules, checklists and cleanliness audits for patient areas and within the theatre areas. The hospital management had shared cleaning records with BPAS Cannock registered manager. An infection prevention and control audit dated May 2016 identified 100% compliance with all measures.
- Handwashing sinks, soap, and alcohol hand rubs were in good supply and we saw instructions for their use clearly displayed. We observed staff washing hands and using gel appropriately and were bare below the elbow to enable good hand washing and reduce the risk of infection.
- We observed that protective personal equipment (PPE) such as disposable gloves and aprons were readily available, correctly stored, and were worn by staff.
- The registered manager submitted results of all audits such as infection prevention and control audits which were then included on a dashboard as a performance indicator. The Cannock unit had a performance rating of green, which meant that IPC compliance was above 90%. Between January 2015 and April 2016 all “essential steps audits” identified 100% compliance.
- We saw that there were appropriate policies and procedures in place for the safe disposal and removal of clinical waste and foetal tissue. We saw that there were appropriate arrangements in place for the segregation and disposal of waste materials.
- There were no reported health acquired infections or Methicillin Resistant Staphylococcus Aureus (MRSA) and Clostridium Difficile (C. Diff) from January 2015 to December 2015.

## Environment and equipment

- The service was provided in a NHS hospital within a day case facility, which was leased by BPAS on a sessional basis.
- We saw that electrical safety testing of equipment was undertaken.
- Records showed that staff checked resuscitation equipment and drugs daily. This provided assurance that appropriate equipment and drugs were available in an emergency.
- We observed clinical waste was separated appropriately, and clinical waste bins were not overfull.
- Sharps arrangements were appropriate. Sharps bins were not overfull, were labelled correctly, were seen to be in date and wall mounted.
- BPAS Cannock was located within a NHS hospital; there was no specific security staff on the ward where the clinic was based; however the reception desk was situated so staff could see all people entering. We observed that if the staff member working on reception had to leave their post, another member of staff would stand in.
- Should a patient undergoing surgical termination wish to keep foetal remains for personal disposal, the remains were placed in a separate appropriate container for the patient to take home, along with instructions for appropriate disposal methods.

## Medicines

- There was a designated person for the ordering of drugs with the national purchasing department. A registered nurse signed to accept delivery of drugs. There were local and national records of drug ordering and receipt.
- There was a comprehensive medicine management policy in place and staff had access to a BPAS employed pharmacist whom they could contact by email if needed.
- The registered manager was responsible for auditing of medicines and reporting to the local intelligence network. The clinical dashboard for April to June 2015 indicated medicines management requirements were ‘achieved’.
- We found that the service had appropriate arrangements in place for the safe storage, and competent administration of medicines.
- The unit dispensed prescriptions for analgesia, antibiotics and contraceptives.

# Termination of pregnancy

- We found that controlled drugs, which require special storage and recording arrangements, were stored and administered in line with good guidance procedures.
- During the inspection we looked at 12 medical records. We saw that staff clearly recorded allergies to medicines on patient's medicine records.
- Resuscitation medications were available on the resuscitation trolleys; these were in date and ready for use.
- We observed contraceptive implants and injections were given in accordance with good medicine administration guidance.
- We saw that staff recorded fridge temperatures which showed that medicines were safely and appropriately stored in line with good medication guidelines.
- A doctor prescribed all abortifacient medicines following completion of HSA1 forms (legal documents which must be agreed and signed by two doctors prior to prescribing abortion inducing medication and nurses provided some non-abortifacient medicines under Patient Group Directions (PGDs). Patient group directions provide a legal framework which allows some registered health professionals to supply and/or administer specified medicines, such as painkillers, to a predefined group of patients without them having to see a doctor.
- The PGDs were in line with national guidance. Accountable officers were clearly named and they had signed PGDs correctly. All PGDs were within review date and staff undertook training to administer medicines by PGDs.
- Doctors prescribed drugs that induced abortion. This was done after a nurse led face to face consultation. Two doctors were required to agree for these drugs to be prescribed, as demonstrated by them signing a HSA1 form. We observed doctors appropriately completing HSA1 forms which confirmed the doctors agreed the abortion was being requested as per The Abortion Act 1967.
- We observed the discharging nurse or midwife provided antibiotics pre-prescribed by doctors, and contraceptive medications. The nurse checked the patient understood what the medications were for and the importance of taking them as prescribed.

## Records

- Patient records were paper based. Patient information and records were stored safely and securely in lockable cabinets in line with the data protection act. Medical records stayed on site for six months then were archived at the BPAS head office.
- We looked at 12 sets of records across various pathways and found them to be up to date, complete and legible. Records indicated risk assessments were completed, and follow up of any medical concerns or issues identified were well documented and reviewed following appropriate interventions.
- Patient records we looked at all included risk assessments for venous thromboembolism (VTE) and sexual health.
- Monthly audits of patient consultation notes were undertaken. Information provided by the service identified 100% compliance with case note audits undertaken in January, February, March and April 2016.

## Safeguarding

- Staff told us how they would access the safeguarding policies and demonstrated a good understanding of the processes involved for raising a safeguarding alert. The BPAS policies and processes reflected up to date national guidance on sexual exploitation of children and young people, and female genital mutilation (FGM). Staff we spoke with confirmed these principles had been included in their most recent safeguarding training.
- Staff carried out safeguarding risk assessments when there was any suspicion of abuse and they made safeguarding referrals to the local safeguarding team.
- Staff told us and we observed that the booking system highlighted patients under 18 to ensure that appropriate pathways were in place to support them and meet their needs.
- Organisational policy stated that if a girl under 13 years old used the service staff would always make a safeguarding referral. For young people aged up to 18 years, staff would complete a safeguarding risk assessment. Staff would discuss the outcome of the assessment
- We reviewed a record of a young person aged less than 16 years that showed staff had followed organisational policies and procedures.

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- All staff had received vulnerable adult and children's safeguarding training, up to level 3, in line with The Royal College of Paediatrics and Child Health intercollegiate document.
- Staff told us and we observed that all patients received a private initial consultation without anyone else present to safeguard against possible coercion or abuse and give them the opportunity to disclose information in a safe environment.
- The registered manager was the designated safeguarding lead for BPAS Cannock. Staff knew who the safeguarding lead for the service was to seek advice.
- We saw that the safeguarding risk assessment included questions around consent and coercion to sexual activity and lifestyle to identify possible coercion, overt aggression, suspicion of sexual exploitation, grooming, sexual abuse and power imbalances. In addition, potential domestic abuse was highlighted within the patient assessment, which asked if they felt safe at home. This gave nurses an opportunity to discuss possible concerns if needed.

## Mandatory training

- BPAS mandatory training covered a range of topics: life support, fire safety, health and safety, safeguarding, moving and handling, infection control and information governance. Staff told us that all staff were trained in basic life support (BSL) and the surgeons and doctors were trained in advanced life support (ASL).
- The registered manager told us that staff could undertake e-learning training within the unit. Staff told us that the manager closed the unit for one session every two years for staff to undertake required training. If staff were unable to attend this session they could access training sessions at other treatment units and staff confirmed this. One staff member told us they were on annual leave when the training day was taking place and there were arrangements for them to attend another registered.
- The registered manager told us that the lead nurse was an advanced life support trainer and was able to update staff on life support and resuscitation annually.
- The organisational target for completing mandatory training was 100%. Staff told us they had all completed mandatory training. We saw that records mainly supported this for level 3 safeguarding adults and

children, infection control, health and safety. However, some training was completed within NHS establishments and no confirmation of completion of such training was kept in BPAS staff files.

- We noted that although staff should have fire evacuation training every six months it was last undertaken in May 2014. Information provided identified that further training was planned for July 2016.

## Assessing and responding to patient risk

- We saw that prior to, during and after surgery, a modified version of the World Health Organisation audit was in use. The clinic used the Five Steps to Safer Surgery procedures and checklists. Internal observational audits of the "safer surgical checklist" showed recent compliance rates of 100%.
- We observed during the inspection that theatre staff appropriately met the required standards of 'safer surgery' to minimise the risk of potential patient harm.
- Anaesthetic risk was assessed during the medical consultation part of the patient's pathway. Any identified medical risks were addressed prior to the patient attending for their procedure.
- We observed that the surgeon and anaesthetist reviewed all patients on the morning of clinic before they provided treatment.
- Risk assessments, medical follow up, interventions and preoperative reviews were evident in patient's records we looked at.
- Staff performed blood tests on all patients to establish those patients who had rhesus negative blood group. Records we looked at confirmed that women received treatment with an injection of anti-D when required to protect against complications should they have future pregnancies.
- Theatre staff were observed to be competent. They handed patients over to recovery staff postoperatively. Patients were observed post general anaesthetic every five minutes for 20-30 minutes. We saw that a formal early warning system was not used; however observations were taken and recorded.
- We observed that staff acted appropriately to seek additional medical attention for a deteriorating patient. The surgeon then reviewed the patient and they were taken back to theatre for further treatment.
- Staff in the ward area were aware of their roles in relation to blood loss monitoring and recording of patient observations.

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- An agreement was in place with the local NHS acute hospital to facilitate the emergency transfer of patients.
- Staff gave patients advice and information regarding accessing emergency medical health services should they suffer heavy blood loss following discharge. Staff also provided patients with a letter that detailed the treatment they had received should they require emergency care when they had left the clinic.
- Aftercare and helpline numbers were included in the BPAS guide, which was given to all patients who had a termination of pregnancy.
- All patient records we looked at included risk assessments for venous thromboembolism (VTE). Information provided by the service identified that recent audits had identified 100% compliance with VTE risk assessments.
- The anaesthetist, who was trained in advanced life support (ALS) stayed on the premises until all patients were fully recovered from their anaesthetic. Patients were discharged the same day.
- If an emergency transfer was required then staff would contact the obstetrics and gynaecology registrar at the local NHS acute hospital. The service had an agreed service level agreement to transfer patients when required.

## Nursing staffing

- The clinic used the BPAS safe staffing policy, which outlined minimum staffing levels. The performance dashboard for BPAS Cannock for staffing was identified as green indicating no breaches of the minimum staffing level between May 2015 and December 2015.
- The clinic used a skill mix of registered midwives, nurses and healthcare assistants. We observed that sufficient and appropriate staff were available to provide patient care pre operatively and within the recovery and ward areas.
- The registered manager told us they mainly provided nurse cover within the staff group. They also said that they used 'preferred agencies' which provided nurses with required competencies. We saw the clinic had used the same agency nurse for several years. Upon interview with the agency nurse during the inspection, they confirmed they had received an orientation to the service and were able to access training.

## Medical staffing

- The provider employed surgeons and anaesthetists under practising privileges at BPAS Cannock.

- Treatment unit doctors were up to date with relevant training such as advanced life support for anaesthetists. All doctors had disclosure and barring checks (DBS) and child protection training to level 3.
- The provider had a process in place for checking and updating medical staff information every two years. DBS checks were repeated every three years.

## Major incident awareness and training

- BPAS had a corporate Emergency Contingency plan which included loss of electricity, major plant failure and disruption to service delivery. The registered manager told us that in the event of a major incident such as a power failure, they would stop the operating list and they would rebook the patients' treatment. This was to ensure that generator power was used for essential services at the hospital, as the registered provider did not provide urgent surgery or treatment.

## Are termination of pregnancy services effective?

### Summary:

- The service employed suitably qualified and competent staff. However, there was a need to ensure regular and ongoing checks of nurse personal identification numbers (PIN) were recorded in staff files.
- Care was generally provided in line with national best practice guidelines
- All care records we reviewed contained signed consent from patients. However, verbal information about the effectiveness of 'simultaneous' abortifacient medicines was required to ensure that the patient has given fully informed consent.

## Evidence-based care and treatment

- Staff had access to up-to-date policies and procedures through the BPAS intranet.
- Staff told us that when policies or guidelines were updated, these were cascaded via email and conference calls, which staff could dial in to. The registered manager told us that BPAS recorded the conference calls for staff to access later if unable to dial in during the live presentations.
- All doctors prescribing medication for medical terminations adhered to the Royal College of Obstetricians and Gynaecology (RCOG) guidelines, The Abortion Act and abortion legislation for the treatment



# Termination of pregnancy

of women for termination of pregnancy as observed within patient files. BPAS Cannock prescribed simultaneous administration of medicines for early medical abortion (EMA) which is currently outside of RCOG guidelines. However, following pilot studies, BPAS have found it appropriate to use this method of treatment for early medical abortions.

- Policies relating to termination of pregnancy and professional guidance were developed in line with the Department of Health (DH)'s "Required Standard Operating Procedures" (RSOP). All staff, including agency staff had access to BPAS policies.
- Staff followed best practice guidelines for the counselling of patients prior to termination of pregnancy; following RSOPs and RCOG clinical guidelines, for medical abortions and surgical abortions. This included following RSOP 12 which relates to sexually transmitted infection testing and the provision of contraception including long acting reversible contraception (LARC). We observe that chlamydia testing was offered to patients, and the clinic was able to provide a range of contraception including LARC.
- There was a programme of clinical audit both at local and national level, which included audits of patient pathways. BPAS reported audit results centrally for benchmarking and made recommendations for action where necessary. Audits of patient records showed that staff followed appropriate treatment pathways.

## Pain relief

- We saw that BPAS used a nationally recognised pain score assessment tool to assess pain and its severity and noted this in client records.
- We observed that pain relief was available for patients and staff offered it on a regular basis post procedure.
- We observed that staff offered all women appropriate pain relief to take home following both surgical and early medical abortion (EMA).

## Patient outcomes

- BPAS monitored and compared patients outcomes such as; pathways of care were followed, pre abortion assessment was undertaken, care after abortion. In addition complication rates such as retained products of conception, on-going pregnancy, post procedure and post-operative infections and haematomas following vasectomy were compared with other BPAS clinics, all results were within an expected range.

- The unit had screening targets for Chlamydia. Staff offered all patients screening for sexually transmitted infections (STIs). If a positive result was returned, processes were in place to track partners and offer treatment.
- Staff asked patients undergoing medical abortion to ensure that a pregnancy test was completed two weeks post treatment to ensure that the treatment was successful. Patients would contact the BPAS Aftercare Line and were invited back to clinic if there were any concerns.
- Staff told us that in order to monitor patient complications they relied on other organisations reporting to them (if a patient attended another hospital) or patients using BPAS Aftercare Line. If the clinic was informed that there had been a complication, a form would be completed and a record kept in patients' notes to ensure that the information was captured. The quality leads monitored all complications and any learning was cascaded through governance and regional meetings. We were provided with minutes that confirmed this; the minutes were printed off for staff to read.
- Abortifacient medicines were administered using two options. Either staff could administer these over a two-day period, returning to a BPAS registered clinic the following day, or both the medicines could be administered simultaneously in one visit. Simultaneous administration was presented as the option for EMA. We observed that delaying the second medication for EMA for 6-72 hours was not discussed or offered within consultations; although this method of administration was offered within the BPAS booklet.
- The service monitored the outcomes of simultaneous administration of abortifacient medicines, which were reported to the clinical governance committee. We saw minutes of the Clinical Governance Committee meeting held in June 2015 that there had been an increase in complications since the introduction of simultaneous administration of mifepristone and misoprostol for early medical abortion (EMA) but that these were within what was quoted in the BPAS guide, given to all patients.
- The registered kept a log of patients that were referred to NHS hospitals with suspected ectopic pregnancy We saw that staff actively followed up the outcomes for these patients by direct communication with the early pregnancy assessment unit (EPAU) or with the patient.

# Termination of pregnancy

- Between January 2015 and December 2015, BPAS Cannock transferred one patient to another healthcare provider for further treatment.
- Between 1 January and 31 December 2015 two out of 119 vasectomy patients suffered a minor complication of the procedure; a haematoma, which is a small collection of blood causing a swelling.

## Competent staff

- BPAS had introduced a 12 week competency based training programme for newly employed staff which included all the mandatory training topics, along with patient support skills training, and topics including sexually transmitted infection training, and HIV training. Staff records evidenced completion of job specific induction programmes for registered staff and healthcare assistants. Staff records also evidenced where competency assessments were completed.
- When skills gaps were identified or when staff wanted to develop in their role, staff were encouraged to access additional training. We saw that staff had received additional training and role development in clinical practice such as supporting patients emotionally and scanning.
- Nurses and midwives performing scans needed to have completed 150 supervised procedures before they were able to perform and interpret scans independently. Nurses also told us that they had a two yearly review when they sent further scans to an assessor who checked them for accuracy.
- Midwifery staff received supervision from a named supervisor of midwives at the local NHS hospital who was contactable at any time for advice or support with practice.
- All nursing staff were aware of revalidation requirements and they had been asked by the organisation to produce a portfolio. The provider had changed the structure of 1:1s and appraisals to include a section on revalidation and the registered manager had a register of when staffs revalidation was due.
- Data from January 2015 to December 2015 showed that at BPAS Cannock, 100% of nursing staff and administrative staff had received an appraisal.
- We saw that nurse personal identification numbers (PIN) were checked. On the day of our inspection records we

looked at identified that two staff did not have a record of a valid PIN. We shared this information with the manager who then checked the PINs electronically and was able to show they were valid.

- To obtain practising privileges doctors had to provide evidence of General Medical Council (GMC) registration, indemnity insurance, qualifications and evidence of annual appraisal / revalidation.
- We confirmed that doctors had met these above requirements. The registered manager had appropriate records in place to ensure that doctors remained eligible to practice at BPAS.
- All medical staff working at BPAS Cannock had annual appraisals with their main employer. The registered manager at BPAS had a copy of these appraisals. The regional clinical lead was responsible for overseeing medical staff in terms of competence. The regional director told us that there was a structured process in place for following up on concerns about a doctor's practice or performance. This included action planning to improve performance.

## Multidisciplinary working

- We observed that medical staff, nursing and midwifery staff and other non-clinical staff worked well together as a team and respect for each other's roles was evident.
- There were clear lines of accountability that contributed to the effective planning and delivery of care.

## Seven-day services

- The BPAS Cannock clinic was open Wednesday (9.30 – 13.00), Thursday (16.30 – 21.00), Friday (16.30 – 21.00) and Saturday (8.00- 14.00).
- If women needed to use services on other days, they could be signposted to alternative BPAS clinics.
- Required Standard Operating Procedures (RSOP) 3: Post Procedure sets out that patients should have access to a 24-hour advice line, which specialises in post abortion support and care. BPAS Aftercare Line was available 24 hours per day and seven days a week. Callers to the BPAS Aftercare Line could speak to a registered nurse or midwife who performed triage and gave advice. The dedicated team of nurses and midwives had received training for the role from BPAS.

# Termination of pregnancy

## Access to information

- Patient notes were paper based and were kept onsite for six months following discharge. If any complications occurred this allowed easy access to notes within this time. Records were archived at a central store following this time but staff could retrieve them easily if needed.
- Staff had access to relevant guidelines, policies and procedures in relation to termination of pregnancy.
- Staff confirmed they were able to access diagnostic tests/blood results in a timely manner.
- RSOP 3: Post Procedure recommends that wherever possible the patient's GP should be informed about treatment. Staff asked patients if they wanted their GP to be informed by letter about the care and treatment they received. Staff recorded patients' decisions and they respected their wishes. We observed patients were given a post treatment letter to be given to other medical professionals in case of an emergency.

## Consent, Mental Capacity Act and Deprivation of Liberty Safeguards

- All care records we reviewed contained signed consent from patients.
- We observed that staff consistently and repeatedly checked consent was in place prior to treatment taking place.
- Within the reference guide to consent for examination or treatment produced by the Department of Health (DoH) it is stated "it is therefore advisable to inform the person of any 'material' or 'significant' risks or unavoidable risks, even if small, in the proposed treatment; any alternatives to it; and the risks incurred by doing nothing".
- The treatment consent form referred the patient to the BPAS booklet ('My BPAS Guide'), which detailed information about complications. Within the 'My BPAS Guide', it was stated "We will explain the known risks and complications of any treatment that is offered to you. All of your questions will be answered. You will need to sign a consent form to say that you understand the potential risks of your treatment". However, we saw that information regarding the slightly raised risk of complications arising from simultaneous administration of abortifacient medication was not verbally provided or discussed during appointments when patients chose this treatment.
- Staff we spoke with were aware of Fraser Guidelines to obtain consent from young people regarding

contraception and treatment. We observed that consent forms indicated that the young person had been assessed as having the capacity to understand the treatment and its impact.

- Staff were able to provide examples of how they assessed competence of a young person using Fraser Guideline principles, which allow staff to assess patient competency to consent to sexual health related treatment should the patient be under 16 years.
- There was access to guidance and policies for staff to refer to concerning Mental Capacity Act (MCA).
- Staff had received training in the Mental Capacity Act 2005 (MCA) and Deprivation of Liberty Safeguards (DoLS); data provided by BPAS reported 100% staff compliance with this training. Staff told us that patients with learning difficulties would have this identified on initial face to face consultations and be recorded in the patient record, however this was not picked up so well during telephone consultations.

## Are termination of pregnancy services caring?

### Summary:

- We observed staff treating patients in a very caring, compassionate and supportive manner. We saw staff respond to the individual needs of patients in a visibly person centred way.
- Patients consistently reported that the care they had received had been to a very high standard and staff were kind, helpful and non-judgemental.
- Ongoing emotional support was provided as part of the care and treatment such as through pre and post termination counselling services delivered outside of the clinic.

### Compassionate care

- We observed that staff were consistently polite, helpful and very caring towards patients and their supporters. Staff greeted patients in a courteous and respectful manner when arriving at reception, and treated patients with kindness and dignity throughout appointments.
- Patients were actively encouraged to complete feedback forms 'Your Opinion Counts'. Information



# Termination of pregnancy

provided by BPAS as a whole company reported that between January and April 2015, 99% of 10,162 respondents would recommend the service. This is better than the NHS average of 65%.

- As part of the inspection process, 19 patients completed CQC comment cards in May 2016. All of these comments referred positively to the caring, supportive and professional nature of the staff they had encountered at the clinic. Patients we spoke with during the inspection consistently reported that nursing staff had been kind and supportive.
- Relationships between staff and patients were strong. We observed the discharge nurse accompanied the patient from the clinical area to the reception area where partners, friends or family members were waiting to take home. We saw on one occasion, a nurse physically supported a patient who was less able to walk unaided at this point to their waiting family members.
- We saw nurses considered patients' privacy and dignity, such as offering a quieter waiting area following treatment that may cause pain, and giving the option of self-administration of intimate medication.

## Understanding and involvement of patients and those close to them

- We saw during appointments staff communicated clearly with patients and encouraged them to refer to a BPAS booklet, so that they fully understood the care and treatment to be undertaken. During every appointment observed, staff offered patients numerous opportunities to ask questions.
- Nurses took the time to provide full explanations of procedures and processes and ensured that the patient had time to ask questions. During one appointment, a patient became visibly upset and distressed. The nurse responded in a compassionate and timely way; allowing the patient to express their concerns and explored options with them to reduce distress and worries.
- We saw a nurse asked a patient about social support and discussed the patient's preference for sharing information with family members. Staff respected the patient's choice not to inform family members and they made notes in their record to ensure other staff were aware.

## Emotional support

- Patients reported, and we saw during appointments staff discussed post termination counselling options

and provided relevant telephone numbers within the BPAS booklet. Staff discussed other support options, such as a 24-hour BPAS helpline, and highlighted relevant contact numbers to the patient.

- We saw, and patient comment cards reinforced, that staff were supportive prior to and during the pre-surgery and anaesthetic procedures. Comments made by patients included: "Everyone has been lovely, reassuring me and talking to me to calm my anxiety. Everything was explained and I never felt unsafe. Thank you so much."
- We saw good examples of support given to patients. For example, a healthcare assistant who aided patients to the anaesthetic room prior to surgery provided appropriate verbal support to reduce distress and calm down any anxious patients.
- During patient interviews, we heard further evidence of the emotional support given by staff.

## Are termination of pregnancy services responsive?

### Summary:

- Patients could book appointments through the BPAS telephone booking service, which was open 24 hours a day throughout the year. This also enabled patients to choose the location they attended.
- There was a fast track appointment system for patients with a higher gestational age or complex needs.
- Patients were provided with information to help them to make decisions.
- There were appropriate systems in place to raise and act upon concerns and complaints. Learning from complaints was shared within the organisation.

## Service planning and delivery to meet the needs of local people

- Patients could book their appointments through the BPAS telephone booking service, which was available 24 hours a day throughout the year. The electronic triage booking system offered patients a choice of appointment ensure they were able to access the most suitable appointment for their needs as early as possible.

# Termination of pregnancy

- Women were able to receive various options in relation to termination of pregnancy including medical and surgical techniques. For surgical terminations, women were offered general anaesthetic or local anaesthetic procedures.
- BPAS were planning to develop the service offered to patients at the unit to include conscious sedation to provide wider anaesthetic options for those undergoing surgical terminations.
- During times of peak demand, the service was able to provide additional or longer clinics.
- Treatment was offered at other BPAS treatment units within the region for patients who had complex medical conditions, preferred a different location, or where a convenient appointment time was not available at BPAS Cannock.
- The service was planning to open an additional 'satellite' clinic that provided early medical abortions in Stafford in response to local demand.

## Access and flow

- Referrals for treatment were received via GPs and self-referrals.
- Staff told us that there was a fast track appointment system for patients with a higher gestational age or complex needs.
- Between October 2015 and December 2015, 69% of patients had their consultation within five working days of referral. BPAS also measured the number of patients who waited longer than 10 working days from their first appointment to their treatment. Thirty-six percent (549) of patients had waited longer than 10 working days from their first appointment to treatment within the same reporting period. A patient spoken to during the inspection reported they had waited longer than ten working days, however this was due to them consuming liquid too close to the time they were due to have general anaesthetic therefore the treatment was rearranged for the earliest possible time following this.
- BPAS staff told us some women may choose to be treated at a different unit or need extra time in which to make a decision about whether to proceed with treatment. They were able to choose to do this at various stages of their treatment.
- The percentage of women treated at less than 10 weeks gestation is a widely accepted measure of how

accessible abortion services are. In 2015/16, 79% of women treated by the clinic have been less than 10 weeks pregnant, which is comparable with the national average of 80%.

## Meeting people's individual needs

- BPAS Cannock was accessible to wheelchair users and accessible toilets were available.
- Staff told us that a telephone interpreter service was available to enable staff to communicate with patients whose first language was not English.
- BPAS Cannock treated fit and healthy patients without an unstable medical condition. For patients who did not meet these criteria a specialist placement team completed a referral form for treatment elsewhere. This was a seven-day service. Patients were referred to the most appropriate NHS provider to ensure that they received the treatment they required in a timely and safe way.
- A general guide for patients attending any BPAS clinic was available called 'my BPAS guide'. This provided information about different options available for termination of pregnancy and the associated potential risks. The guide also provided relevant information about disposal of pregnancy remains. Staff told us that they would discuss patients' expectations and choice about sensitive disposal of pregnancy remains on an individual basis.
- Leaflets were given to patients to inform them what to expect after treatment. This included the 24-hour telephone number of where patients could seek advice if they were worried.
- Midwives and nurses undertaking assessments had a range of information leaflets that they could give to patients as required. This included advice on contraception, sexually transmitted infections, miscarriage and services to support patients who were victims of domestic abuse and how to access sexual health clinics.
- We saw that staff discussed aftercare following treatment clearly. Staff provided a BPAS booklet at every initial consultation; and we saw staff encourage the patients to refer to relevant pages within this booklet during appointments. Emergency and non-emergency help and advice lines were contained within this booklet, and staff showed patients where to find these. Staff provided aftercare packs containing items such as condoms, medication if appropriate and information

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leaflets. For early medical abortion treatment, the patient was required to undertake a pregnancy test two weeks following the treatment. If necessary, staff gave a pregnancy test at the appointment, and offered to send a reminder text message to ensure the patient remembered to take the test and inform the clinic of the results.

- Patients were told about telephone counselling services available for emotional support. This service was delivered by appropriately trained counselling staff.
- Discussion regarding respectful disposal of pregnancy remains was not routinely documented. There was a checklist / prompt to remind nursing staff to talk to patients about this sensitive issue.

## Learning from complaints and concerns

- Staff told us that the registered manager was the first point of call for any complaints about the service.
- There was a local complaints register to record informal complaints or concerns. There were no informal complaints on the register at the time of our visit.
- The BPAS patient engagement manager was responsible for all unresolved informal complaints and written complaints. It was their role to undertake a full investigation of the complaint and provide feedback to everyone concerned.
- Between January 2015 and December 2015, BPAS Cannock received two formal written complaints. The first complaint related to a patient not receiving anti D treatment due to an error, this was being investigated at the time of our inspection. The other complaint related to a treatment complication the patient felt they had not been appropriately informed about relating to surgical termination. We saw that in both cases a letter of apology had been sent by BPAS to the complainant and information about the complaint had been shared with the staff group to ensure future learning.
- Information on how to make a complaint was included in the 'my BPAS guide' and on the BPAS website. Comment cards were given to all patients undergoing surgical treatments within which concerns or complaints could be noted. We did not observe explicit instructions on how to make a complaint displayed on walls. When asked, administration staff were able to locate complaint cards, however a patient would need to ask for this rather than them being readily available.

## Are termination of pregnancy services well-led?

### Summary:

- Staff displayed the values and behaviours of the organisation.
- The culture within the service was caring, non-judgemental and supportive to patients.
- Staff felt supported by their registered manager, who led the service locally, and regional operations director.
- There were effective corporate governance arrangements to manage risk and quality. This included an audit programme and an established system to cascade learning. However, local risks were not always identified.

### Vision and strategy for this core service

- BPAS Cannock was led by the clinic manager who was also the registered manager.
- The vision for the service was to provide safe, effective and non-judgemental care for termination of pregnancy. The registered manager discussed these values with new staff through the induction process and training.
- We observed that staff displayed the values and behaviours of the organisation.
- The registered manager told us, and staff records we looked at, confirmed that the values of the service were supported by the recruitment of staff.
- The organisation's ethos was to treat all patients with dignity and respect, and to provide a caring, confidential and non-judgemental service. The provider supported staff to promote the organisations values through training and ongoing support.
- BPAS policies and procedures reflected the patient's right to influence and make decisions about their care, in accordance with BPAS quality standards of confidentiality, dignity, privacy, and individual choice.

### Governance, risk management and quality measurement for this core service

- The organisational structure chart supplied by the provider showed clear lines of accountability to the chief executive officer and the board of trustees.
- The BPAS Regional Quality Assessment and Improvement Forum (RQuAIF) met three times a year and maintained oversight of all services in the region. The forum consisted of a lead nurse, a patient care

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manager, doctor, nurse, clinical lead and associate director of nursing. At each meeting, members of the forum reviewed complaints, incidents, serious incidents, audit results, complications and patient satisfaction. We saw that information was shared with a focus on learning. This forum reported to the organisation's clinical governance committee.

- Minutes from RQuAIF were shared at the regional management meetings, which were attended by regional operations director and the registered managers. Managers attending then held team meetings within their clinics to ensure that learning was shared amongst their staff team. Staff told us and we saw records which confirmed that regular team meetings were held at BPAS Cannock.
- We saw notes from the most recent North Regional Management meeting held on 24 February 2016 that confirmed learning about complaints and serious incidents had been discussed, and action points agreed.
- BPAS launched key policies via a conference call, which was accessible to all staff. These were also recorded and available for a month to enable staff to access them. A recent example of issues discussed in this was the duty of candour.
- BPAS had a central risk register, which listed various areas of generic risks across all treatment units. The provider identified risks and a recorded action taken to reduce the level of risk. However, we asked to see the local risk register and the manager confirmed that one was not in place. Since the inspection the provider has confirmed that all BPAS treatment managers have received training around the completion and maintenance of risk registers. We were assured that BPAS Cannock was using a local risk register following this training.
- Legislation requires that for an abortion to be legal, two doctors must each independently reach an opinion in good faith as to whether one or more of the legal grounds for a termination is met. They must be in agreement to same reason for the abortion to be lawful (HSA1 forms). In the 12 patient records we looked at, we found that all forms included two doctor's signatures and the reason for the abortion.
- BPAS treatment units completed monthly audits of completion of HSA1 forms to ensure and evidence

compliance with the BPAS policy. BPAS Cannock demonstrated 100% compliance with accurate completion of HSA1 forms in accordance with legal requirements between January 2016 and April 2016.

- We observed that the surgeon and anaesthetist reviewed all patients on the morning of clinic before treatment was provided; they both signed The Abortion Act paper work (HSA1 form) for surgical and medical abortions before they commenced the list for that day.
- The Department of Health (DH) requires providers undertaking termination of pregnancy to notify them by the completion of HSA4 forms. The HSA4 notifications were completed and uploaded to the DH electronic reporting system. Doctors working under practising privileges at BPAS treatment units across the UK completed HSA4 notifications for those patients for whom they had either prescribed medication or performed a surgical termination of pregnancy. Staff made a record within the patient's notes that the HSA4 form was completed and submitted. The DH sent out an automatic reminder after two weeks
- Staff provided all vasectomy patients information on post-vasectomy testing. Semen samples were sent for testing and successful outcomes were confirmed to the patients.

## Leadership / culture of service

- The certificate of approval (issued by the Department of Health) to confirm that the location was approved for the purpose of carrying out termination of pregnancies was displayed during the clinic sessions.
- Clinic staff told us that the registered manager was supportive.
- Staff told us the senior management team were visible and had a regular presence at BPAS Cannock. Managers were supportive and available for advice and support for clinical or professional issues.
- BPAS held a bi-annual national day for all managers. The provider held bi-annual clinical forums for all staff and clinics were closed to facilitate attendance. Staff told us that the recent clinical forum had discussed the use of conscious sedation (a combination of medicines to help patients to relax: sedative) and to block pain (an anaesthetic) during the procedure, nurses' revalidation and scanning.

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- Staff spoke positively about the care and services they provided for patients and were proud to work for BPAS. They described BPAS as a good place to work, and felt they could approach managers if they felt the need to seek advice and support.
- Staff had access to a free counselling/support telephone service that they could call in relation to any work related or personal problems. We saw that details of the service were accessible through the staff intranet.

## Public and staff engagement

- Patients using BPAS Cannock completed a survey to complete entitled 'Your opinion counts'. Staff told us and we saw that the surveys were in the sitting area where patients were offered a hot drink and biscuits after surgical treatments. Staff told us that they found patients were more likely to complete the surveys in this environment. However, we saw that patients who had a medical abortion did not go into this room and did not have the opportunity to complete a survey. We highlighted this to the manager who told us they would ensure surveys were available for all patients to complete.

- The analysis of feedback from the patient satisfaction survey for April 2015 to December 2015 showed an overall satisfaction with care of 9.7 out of ten. This survey identified that 99% of Cannock patients surveyed would recommend the service (225 patients).
- Staff surveys were completed to gain staff opinion of working at the registered location. The staff survey results reported on the BPAS website for the BPAS organisation during July 2016 were generally positive: 100% of staff across the organisation stated they were proud to work at BPAS and over 50% of staff had been employed with BPAS for over five years.

## Innovation, improvement and sustainability

- The provider has reviewed treatment programmes and when possible introduced new regimes to provide women with greater choice such as the simultaneous administration of abortifacient medicine.
- The provider and service had a 24-hour telephone appointment service for patients.

# Outstanding practice and areas for improvement

## Areas for improvement

### Action the provider **MUST** take to improve

- Ensure that during the consenting process, all patients are explicitly told about the slightly elevated risk of complications and continuing pregnancy associated with the simultaneous administration of abortifacient drugs for early medical abortion (EMA).

### Action the provider **SHOULD** take to improve

- Ensure that when staff receive mandatory training from another provider, documented confirmation is made available.
- Ensure there are regular and ongoing checks of nurse's personal identification numbers (PIN).

This section is primarily information for the provider

## Requirement notices

### Action we have told the provider to take

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

Regulated activity	Regulation
Termination of pregnancies	<p>Regulation 11 HSCA (RA) Regulations 2014 Need for consent</p> <p><b>Regulation 11 (1):</b> Care and treatment of service users must only be provided with the consent of the relevant person.</p> <p>How the Regulation was not being met:</p> <p>Information regarding the slightly raised risk of complications arising from simultaneous administration of abortifacient medication was not verbally discussed during appointments when patients' chose this treatment.</p>