BPAS Leicester City

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

Overall summary

BPAS Leicester City is operated by British Pregnancy Advisory Service (BPAS). BPAS is a not-for-profit organisation with 73 treatment units across the UK. Services are commissioned to provide termination of pregnancy services, support, information, treatment and aftercare for patients seeking help with regulating their fertility and associated sexual health needs.

BPAS Leicester City has contracts with three clinical commissioning groups to provide a range of services to patients living in Leicestershire. These include;

- Pregnancy testing
- Unplanned pregnancy counselling/consultation
- Medical abortion
- Surgical abortion under local anaesthetic/conscious sedation
- Abortion aftercare
- Miscarriage management
- Sexually transmitted infection testing and treatment
- Contraceptive advice
- Contraception supply

Most patients are funded by the NHS, whilst some patients choose to pay for services themselves.

We inspected this service using our comprehensive inspection methodology. We carried out the announced inspection of BPAS Leicester City on 19 July 2018. We did not inspect the satellite location at BPAS Solihull.

To get to the heart of patients' experiences of care and treatment, we ask the same five questions of all services: are they safe, effective, caring, responsive to people's needs, and well-led? Where we have a legal duty to do so we rate services' performance against each key question as outstanding, good, requires improvement or inadequate.

Throughout the inspection, we took account of what people told us and how the provider understood and complied with the Mental Capacity Act 2005.

Services we do not rate

We regulate termination of pregnancy services but at the time of announcing the inspection we did not have a legal duty to **rate** them when they are provided as a single specialty service. We highlight good practice and issues that service providers need to improve and take regulatory action as necessary. At out next inspection of this service we will have the legal duty to rate.

We found the following areas of good practice:

Summary of findings

- There were clearly defined systems and processes to keep patients protected from avoidable harm, including appropriate levels of staffing, infection control and the use of a surgical checklist.
- Staff understood their roles and responsibilities regarding safeguarding vulnerable adults and children, had received appropriate levels of safeguarding training and could tell us about examples of where they had identified and raised concerns.
- Staff kept appropriate records of patients' care and treatment. Paper and electronic records were clear, up to date and available to all staff providing care.
- Staff were trained to use the emergency equipment which was readily accessible and ready for use.
- The treatment unit provided care and treatment based on latest evidence and national guidance and within the requirements of relevant legislation and monitored outcomes and audit data by use of a quality dashboard.
- Staff were supported to develop and maintain their knowledge, skills and competencies.
- Staff understood their responsibilities under the Mental Capacity Act 2005 and gained informed consent from patients at each stage of the patient's care.
- Staff with different roles worked together as a team to benefit patients. Midwives, nurses and support staff supported each other to provide good care for patients.
- Staff understood and respected the personal, cultural, social and religious needs of patients and those important to them. Patients and their escorts we spoke with told us they were treated with dignity, kindness and respect.
- Staff provided emotional support to patients to minimise their distress and always respected patients' privacy and dignity.
- Staff gave patients detailed verbal and written information to ensure they were well informed about their care and treatment.
- The services provided reflected the needs of the population served and mostly ensured flexibility, choice and continuity of care.
- Staff assessed patients' individual needs and made adjustments for patients with complex needs.
- Complaints were reviewed in accordance with BPAS policies and timescales.
- There was a clear leadership structure. Regional managers were accessible and visible and regularly visited the treatment unit.
- Local leaders understood the performance, risks and priorities of the service.
- Staff were proud of the service they offered and there was a visible patient-centred culture.

However, we also found the following issues that the service provider needs to improve:

- The admission process for patients attending the treatment unit was not robust.
- Although medicines were generally managed in a way that kept people protected for avoidable harm, there was no system of monitoring the temperature within the room where medicines were stored.
- Patients who used the service described the initial part of the process as slow and not all patients were happy with the choice of treatment they were able to access.

Heidi Smoult

Deputy Chief Inspector of Hospitals (Central Region), on behalf of the Chief Inspector of Hospitals

Summary of findings

Our judgements about each of the main services

Service	Rating	Summary of each main service
Termination of pregnancy		We regulate this service but at the time the inspection was announced we did not have a legal duty to rate when it is provided as an independent healthcare single speciality service. We highlight good practice and issues that the service providers need to improve and take regulatory action as necessary. At out next inspection we will have the legal duty to rate the service.

Summary of findings

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Background to BPAS Leicester City

BPAS Leicester City is part of the provider group British Pregnancy Advisory Service (BPAS). BPAS is an independent healthcare charity running for 50 years, which has provided treatment for patients and couples who decide to end a pregnancy, offering care to more than 70,000 patients a year in 73 treatment units nationwide.

BPAS Leicester City was registered with the Care Quality Commission in 2017. It is a private treatment unit in Leicester, Leicestershire. The treatment unit has had a registered manager in post since 2017.

The service holds a license from the Department of Health to undertake termination of pregnancy (TOP) services in accordance with the Abortion Act 1967. TOP means abortion by surgical or medical methods. We saw this licence was in date and displayed in the main reception area of the treatment unit.

BPAS Leicester city is registered for the following services:

- Diagnostic and screening procedures
- Family planning services
- Treatment of disease, disorder and/or injury
- Termination of pregnancy
- Surgical procedures

The service is commissioned by three clinical commissioning groups to provide termination of pregnancy services, support, information, treatment and aftercare to patients living in Leicestershire. Most patients are funded through the NHS; however, some patients choose to pay for the service themselves.

There were no special reviews or investigations of the hospital ongoing by the CQC at any time during the 12 months of this inspection. This was the first CQC inspection of the location since registration.

Our inspection team

The team that inspected the service comprised a CQC lead inspector and one other CQC inspector. Both inspectors had expertise in midwifery and TOP services. The inspection team was overseen by Simon Brown, Inspection Manager.

Information about BPAS Leicester City

BPAS Leicester City is located on the outskirts of Leicester City and is easily accessible by car and public transport. All regulated activates are provided in a self-contained suite of rooms situated within a GP practice. The suite comprises of two screening rooms, two consultation rooms and one treatment room. There was also a seating area for patients and their escorts within the treatment unit. There was secure access into the treatment unit and patients and visitors gained access through an intercom system.

BPAS Leicester City is open Monday to Thursday from 8am to 4.30pm (6pm on Mondays and Tuesdays). The treatment unit provides early medical abortions (EMA) and medical termination of pregnancy (MTOP) up to 10 weeks gestation, and surgical termination of pregnancy (STOP) up to 13 weeks and six days gestation. Surgical TOPs can be performed under local anaesthetic or conscious sedation.

BPAS Leicester City also operates a small satellite service from BPAS Solihull, which we did not inspect. BPAS Solihull is open two days a week on Wednesdays 8.30am to 6pm and Fridays from 8.30am to 4pm and provides EMAs only.

Summary of this inspection

From 1 August 2017 to 30 April 2018, BPAS Leicester City carried out 1242 EMAs (including medical terminations) and 179 surgical TOPs. BPAS Solihull carried out 238 EMAs. In the same period BPAS Leicester City treated seven young patients aged between 13 and 15 years old and BPAS Solihull treated one. No young patients under 13 years were treated during this period.

Track record on safety for 2017/18

- No never events
- There were 15 incidents reports by BPAS Leicester City, of which eight were classified as low harm and seven as moderate harm. There were two moderate harm incidents reported for BPAS Solihull.
- There was one formal complaint.
- There were no major medical or surgical complications.

During our inspection, we spoke with 11 staff including BPAS directors, managers, medical staff, registered nurses and midwives, administrators and health care support workers. We observed staff interactions with patients and those close to them, reviewed the environment and equipment and spoke with five patients and three relatives. We reviewed seven care records.

Summary of this inspection

The five questions we ask about services and what we found

We always ask the following five questions of services.

Are services safe?

Are services safe?

We found the following areas of good practice:

- There were clearly defined systems and processes to keep patients protected from avoidable harm, including appropriate levels of staffing, infection control and the use of a surgical checklist.
- Staff understood their roles and responsibilities regarding safeguarding vulnerable adults and children, had received appropriate levels of safeguarding training and could tell us about examples of where they had identified and raised concerns.
- Staff kept appropriate records of patients' care and treatment. Paper and electronic records were clear, up to date and available to all staff providing care.
- Staff were trained to use the emergency equipment which was readily accessible and ready for use.

However, we also found the following issues that the service provider needs to improve:

- The admission process for patients attending the treatment unit was not robust.
- Although medicines were generally managed in a way that kept people protected for avoidable harm, there was no system of monitoring the temperature within the room where medicines were stored.

Are services effective?

We found the following areas of good practice:

- The treatment unit provided care and treatment based on latest evidence and national guidance and within the requirements of relevant legislation and monitored outcomes and audit data by use of a quality dashboard.
- Staff were supported to develop and maintain their knowledge, skills and competencies.
- Staff understood their responsibilities under the Mental Capacity Act 2005 and gained informed consent from patients at each stage of the patient's care.
- Staff with different roles worked together as a team to benefit patients. Midwives, nurses and support staff supported each other to provide good care for patients.

Summary of this inspection

Are services caring?

We found the following areas of good practice:

- Staff understood and respected the personal, cultural, social and
- Staff provided emotional support to patients to minimise their distress and always respected patients' privacy and dignity.
- Staff gave patients detailed verbal and written information to ensure they were well informed about their care and treatment.

Are services responsive?

We found the following areas of good practice:

- The services provided reflected the needs of the population served and ensured flexibility, choice and continuity of care.
- Staff assessed patients' individual needs and made adjustments for patients with complex needs.
- Complaints were reviewed in accordance with BPAS policies and timescales.

However, we also found the following issues that the service provider needs to improve:

- Patients who used the service described the initial part of the process as slow and not all patients were happy with the choice of treatment they were able to access.

Are services well-led?

We found the following areas of good practice:

- There was a clear leadership structure. Regional managers were accessible and visible and regularly visited the treatment unit.
- Local leaders understood the performance, risks and priorities of the service.
- Staff were proud of the service they offered and there was a visible patient-centred culture.

Detailed findings from this inspection

Termination of pregnancy

Safe	
Effective	
Caring	
Responsive	
Well-led	

Are termination of pregnancy services safe?

Mandatory training

- All staff working at the treatment unit were required to complete mandatory training modules at the initial induction and received updates on a regular basis. Data provided by the treatment unit prior to our inspection specified the regulatory training requirements for staff based on their role. Modules covered included infection prevention and control, safeguarding adults and children, moving and handling, information governance, adult resuscitation, fire safety and health and safety.
- Mandatory training was provided through face to face sessions and e-learning. Completion of training was logged, which allowed managers to monitor compliance. We reviewed training records whilst on inspection and saw all staff had completed (17 out of 18) or were booked (one staff member) onto training sessions. All staff we asked about mandatory training confirmed they were up to date with training.
- We saw there was a BPAS sepsis screening and action tool which was based on national guidance. (Sepsis is a life-threatening condition caused by the body's response to infection.) Lead nurses across BPAS completed training, including practical sessions, on sepsis and the use of the modified early warning score (MEWS). This learning was cascaded to staff at the treatment units. All other staff completed an e-learning training module training for sepsis, and we saw staff had signed to confirm they had completed the training apart from staff who were away on long term sickness absence. Service leads told us they were currently undertaking a knowledge assessment to ensure this training had been fully embedded.

Safeguarding

- Safety and safeguarding systems, processes and practices were developed, implemented and communicated to staff through mandatory training. Patients who used the service were protected from the risk of abuse as the service had taken reasonable steps to identify and mitigate the risks where possible.
- Policies, procedures, protocols and frameworks relating to safeguarding were in line with national guidance. BPAS Leicester City complied with the Department of Health Required Standard Operating Procedure (RSOP) 7 (2014), which states that services must have policies and systems in place to promote the safety of people using the service, including patients under 18 years of age.
- All 18 staff had completed the 'Safeguarding Vulnerable Groups' training module within three months of starting employment with the organisation and then every two years as part of their mandatory training. This module included level 3 children protection training and protection of vulnerable adults. Mandatory safeguarding training included child sexual exploitation (CSE), female genital mutilation (FGM), modern day slavery and PREVENT (anti-terrorism) training.
- There was an organisation wide lead for safeguarding. In addition, staff had access to support and advice from the corporate safeguarding team, who were all trained to Level 4, through a safeguarding alert email group. Staff told us they would usually try to send emails whilst the patients was still on site and would normally receive a quick response. The registered manager was the local safeguarding lead for the treatment unit. Their responsibilities included co-ordinating safeguarding actions for the unit, reporting to the corporate

safeguarding lead and liaising with external agencies such as the local authority safeguarding boards, as necessary. The safeguarding lead monitored the number of referrals for the organisation as a whole.

- All staff we spoke with had a good understanding of their responsibilities to safeguard patients and their families. Staff we spoke with understood their mandatory responsibilities to report FGM and other forms of abuse. This was included in the BPAS domestic abuse policy, which we reviewed and which we saw staff followed. Patients could be referred to the local multi-agency safeguarding hub (MASH) if concerns were identified.
- BPAS electronic booking records had an age tag system, which highlighted any patient under 18 years of age. This system included mandatory additional information sections to be completed before the booking could be completed.
- Staff told us they received safeguarding supervision as part of their clinical supervision every few months.
- From 1 August 2017 to 30 April 2018, BPAS Leicester City and the satellite at BPAS Solihull treated eight young patients aged between 13 and 15 years old. No young patients under 13 years were treated during this period. Staff told us children under the age of 13 would always be referred to local safeguarding agencies. Children aged between 13 and 15 years would be assessed on a case by case basis. Staff told us if any patient under 18 years did not attend for a planned appointment they would try to contact them by phone and make a safeguarding referral if there were still concerns.
- Staff told us a patient's partner would not be present for the initial part of the consultation for any form of treatment, to ensure the patients was happy with the decision and there was no evidence of coercion.
- We reviewed the Safeguarding Assurance Tool for 2017/18, which was submitted to the three local clinical commissioning groups (CCGs) for Leicester and Leicestershire in October 2017. The tool was RAG (red, amber, green) rated to demonstrate the organisation's compliance with the CCGs standards. The CCG had RAG rated the service as green (the requirement is met consistently across the organisation) for Prevent training and all other areas as amber (the requirement is met in part; there may be pockets of excellence or areas of improvement required) where additional information or assurances was required. Following this, in January 2018 a further self-evaluation assurance tool was completed was rated as green across all areas.

Cleanliness, infection control and hygiene

- There were reliable systems in place to prevent and protect people from a healthcare-associated infection.
- During the inspection we observed the clinical environment was visibly clean. Staff had access to a range of infection prevention and control policies, procedures, guidelines, cleaning checklists and audits. We saw staff adhere to these policies in relation to hand hygiene and infection control. For example, we saw staff observed the 'bare below the elbow' rule in the clinical environment.
- Staff had access to suitable personal protection equipment such as gloves and aprons and we saw staff wore them as appropriate when providing care and treatment. There was a sufficient supply of hand sanitising gels and sinks throughout the clinical area with handwashing prompts for staff, patients and visitors. We observed staff completing hand hygiene between patient contacts. This was in line with National Institute for Health and Care Excellence (NICE) Quality Standard 61, which states that healthcare workers should decontaminate their hands immediately before and after every episode of direct contact care.
- Staff wore appropriate clothing and footwear for the treatment room environment to protect people from a healthcare associated infection. We saw staff maintain the sterility of the environment prior to surgical procedures.
- The three couches in the recovery area were separated with disposable curtains, which meant they could be disposed of and replaced if they were soiled. The curtains were visibly clean and dated so staff knew when they needed to be replaced.
- Each area of the treatment unit had a cleaning schedule and a daily cleaning checklist for staff, who completed cleaning tasks as required throughout the day. In addition, the service employed an external cleaning

company to clean the office and clinical areas at the end of each working day. Cleaning staff signed the cleaning schedule to confirm the area had been cleaned and used it to highlight any issues.

- Surgical equipment was single use and was disposed of appropriately within the clinical waste.
- The service monitored infection prevention and control measures through the monthly 'essential steps' audit tool for the dashboard. For the six months prior to our inspection we saw the audit score was 100%, and we saw staff were continually reviewing performance. The most recent audit included a comment around obtaining a staff information poster for sharps injuries.

Environment and equipment

- The design and maintenance of the environment within the treatment unit kept people protected from avoidable harm. All areas were free from clutter and corridors were kept clear. Store cupboards were well organised and we saw good use of notice boards for patients and staff information.
- The treatment centre was in a self-contained suite of rooms situated on the first floor a GP practice. External signage was discrete to minimise patients distress or embarrassment. The GP practice was responsible for the weekly fire checks and staff told us the fire alarm was regularly tested.
- The 'Required Standard Operating Procedure (RSOP) 22: Maintenance of Equipment' (DOH) states all providers should minimise risks and emergencies through a programme of regular checking and servicing of equipment. We examined eight pieces of equipment in the treatment unit. The equipment was clean and well maintained and seven out of the eight had recent evidence of service testing or medical engineering dates. The one piece of equipment that did not have evidence of testing was a new piece of equipment recently purchased. This meant that equipment was maintained in line with relevant safety standards and RSOPs.
- There was restricted access to the treatment unit by means of a digital key pad and intercom system. Patients and other visitors could not enter the treatment unit without authorisation from the unit staff. Within the treatment unit, there was digital key pad access to clinical area.
- Staff had access to emergency equipment, including emergency airway equipment which was stored in the clinical area. We saw equipment also included an automated external defibrillator (AED) which is a portable electronic device used to diagnose life threatening cardiac conditions and enable treatment with controlled electric shocks to re-establish a normal heart rhythm. We saw an oxygen cylinder was available which was full and correctly stored. Staff completed daily checking of the emergency equipment, and signed a checklist to confirm it was complete, and all items were present and in good working order. We reviewed the checklist and saw there no missing entries for daily checks.
- Staff told us they had sufficient equipment to provide a safe service for patients. We were told service leads were receptive to suggestions from staff for additional equipment. For example, the lamp within the small treatment room environment was wall mounted and impacted on safety within the room and therefore managers purchased a new mobile lamp. Staff told us a business case was being written to purchase a new treatment couch which would more easily support patients being placed head down in the event of vasovagal syncope (collapse following a clinical procedure). The current couch could provide a head down position but it involved moving the patients along the couch.
- There were clear processes for staff to follow for the management and disposal of clinical waste. Staff segregated clinical and non-clinical waste using colour-coded bins. Staff safely disposed of used sharps in designated sharps boxes. We saw these were labelled and not over filled.

Assessing and responding to patient risk

- Staff assessed and responded appropriately to the changing risks of patients who used the service including deteriorating health and wellbeing and medical emergencies.

Termination of pregnancy

- During procedures performed under conscious sedation, staff trained to immediate life support were always present to support the surgeon.
- We reviewed patients' records and saw staff asked patients at their initial consultation about their medical history to assess their suitability for treatment. This review included a height and weight measurement and questions about medicines and allergies.
- All patients had an ultrasound scan to confirm the gestation of their pregnancy. We saw evidence of the scan and gestation recorded in all the records we reviewed. Trained staff also completed a scan during each surgical procedure to reduce the risk of retained products of conception. In addition, the surgeon visually checked pregnancy remains following each procedure to confirm all products had been removed. If there was any doubt the surgeon would rescan the patient and take appropriate action.
- There were reliable processes in place to maintain the safety of surgical patients. A surgeon with practising privileges worked for one day a week to carry out surgical termination of pregnancy either using local anaesthetic or under conscious sedation. Conscious sedation is an alternative to local anaesthetic whereby medication is given intravenously (into a vein) which makes people feel drowsy and relaxed but still be awake. There were no procedures carried out under general anaesthetic at BPAS Leicester City. The surgeon had received training to carry out conscious sedation and we saw suitable monitoring of patients both during and after the procedure to check for any serious side effects of the medicine and to monitor sedation levels. Deep sedation was not used for procedures.
- We reviewed the BPAS corporate clinical guidelines which were comprehensive and which stipulated the exclusion criteria for the different types of procedure they offered. These exclusions related to previous medical, reproductive allergy and immune system history. Other factors considered included body mass index (BMI), history of drug misuse, inadequate venous access (poor veins) and the refusal of blood transfusions. Patients who were suitable for and chose surgical termination under conscious sedation were required to bring an escort with them, who would be able to travel home with them and monitor potential side effects. Staff told us, and we saw, they would not provide conscious sedation to any unaccompanied patients.
- When patients arrived at the treatment unit, nursing staff would take them to a private consultation room to discuss the treatment with them, check they were still happy to proceed and ensure all paperwork had been completed correctly. We were not assured this process was robust as during our inspection we saw there were four issues that should have been identified and picked up but were missed. Three of these four issues were identified prior to the procedure by staff performing pre-procedure checks and included a consent form not signed, confusion around the type of contraceptive coil to be fitted, and a BMI not calculated although the patient had been weighed. The missing check related to a patient not being given cervical preparation prior to the surgery even though she fitted the criteria for the pre-operative treatment. This was not identified until after the procedure was completed and reported as an incident.
- During our inspection we observed a surgical termination of pregnancy list. All staff involved in the procedure list participated in the 'safety huddle' at the start of the day, including the surgeon, recovery and treatment room nurses and health care assistant. Discussions were held around the number of patients expected and any potential concerns and issues. On the day of our visit staff shared that one patient had a raised BMI, another might require the services of an interpreter and one patient would require an ultrasound scan prior to the treatment to ensure the gestation of the pregnancy met the threshold for treatment. During the 'safety huddle' staff confirmed emergency trolleys and equipment was available and had been checked.
- Before starting the surgical procedure, we saw the surgeon read through the patients' notes to check the medical and obstetric history, consent, blood group and chosen method of contraception. Patients were weighed as part of the assessment process, and the level of medicine given as part of the conscious sedation process was varied according to weight. This meant patients were less likely to suffer any serious complications from having too much sedative.

Termination of pregnancy

- In 2010, the National Patient Safety Agency recommended that the World Health Organisation (WHO) and 'five steps to safer surgery' checklist should be used for every patient undergoing a surgical procedure. BPAS had developed its own surgical safety checklist, modelled on the WHO version but modified to be fit for purpose within the specialist BPAS care environment, which was to be used for every surgical procedure. During our inspection, we observed staff at BPAS Leicester City fully completed the surgical safety checklist and used a white board within the treatment room to record when medication was given together with swab and instrument counts We reviewed the BPAS Annual Clinical Governance Report 2017, and saw staff were undertaking audits of the surgical safety checklist. Themes of errors across the organisation were identified and highlighted for improvement, for example reading out the details from the surgical safety checklist in front of the patient.
- Prior to the surgical procedure, staff took patients' observations, such as pulse, blood pressure, temperature and oxygen saturations to ensure they were well prior to the treatment and these were used as a baseline for subsequent observations. During the surgical procedures we saw staff monitored the patients' sedation levels by asking the patients to maintain eye contact and respond to questions. Staff also monitored oxygen saturation levels during the procedure, we saw staff asking one patients with risk factors to take deep breaths to maintain her oxygen saturation levels.
- Following the procedure, staff assisted patients to walk into the recovery area, where they stayed for approximately 45 minutes following conscious sedation. During this time, staff recorded observations every 15 minutes and plotted them on a MEWS tool. Plotting any deviation from the baseline observations or normal parameters would help staff identify patients whose health was deteriorating. Staff also recorded scores for sedation, pain and nausea and there were pictorial aids to help staff assess acceptable blood loss. We saw staff recognised when one patient's blood pressure had deviated from normal and repeated the reading after five minutes rather than waiting for 15 minutes. We saw the surgeon remained within the treatment unit until the last patient was discharged from the recovery area and were safe to go home.
- There were clear policies and procedures for staff to follow to ensure patients who became unwell during or after medical or surgical procedures were transferred to the local NHS hospital. We saw protocols and flowcharts displayed within the treatment room for staff to follow in the event of a patient emergency. These included anaphylactic or allergic reaction, use of reversal agents for conscious sedation and basic life support. There was also clear guidance for the management of a major haemorrhage (bleeding) together with a haemorrhage trolley in the treatment room, including emergency drugs which were removed from the fridge and placed on the trolley for each session. We saw all the equipment and drugs on the trolley were within expiry dates.
- We saw there had been two patients transferred to the NHS between August 2017 and April 2018. Staff told us they had requested emergency ambulance transfers for these patients, who were both experiencing heavy bleeding, which was an appropriate course of action and in line with BPAS guidelines.
- Prior to discharge, staff completed the discharge checklist which included checking patients' pain, level of bleeding and ability to pass urine. Each patient was given a 'My BPAS guide' booklet, which gave patients detailed information about after care. Nursing staff discussed the signs and symptoms of possible complications of the procedure, for example bleeding or infection. The patients' partner or escort were included in this discussion in case the patients might still feel somewhat drowsy and might not be able to recall the information.
- Data provided to us before the inspection showed that between August 2017 and April 2018, 179 (100%) patients who had surgical termination of pregnancy were assessed for their risk of developing venous thromboembolism (VTE). VTE are blood clots in the deep veins of the leg. All the care records we reviewed contained completed VTE risk assessment prior to the patients' treatment. The risk assessments indicated if patients should receive prophylactic treatment.
- Prior to any form of termination of pregnancy (TOP), all patients should have a blood test to identify their blood group. Any patients with a rhesus negative blood type should be offered treatment with an injection of Anti-D, which is a medicine used in preventing antibody

formation in rhesus negative patients who have a rhesus positive baby. Anti-D is given to the mother to reduce the chances of these antibodies being formed which could lead to complications with a different pregnancy at a later stage should the woman become pregnant again. From the records we reviewed, we saw all patients had a blood test prior to their TOP and were offered Anti-D accordingly.

Staffing

- The Department of Health 'Required Standard Operating Procedures (RSOP) 18: staffing and emergency medical cover' requires that providers of TOP services should ensure there is enough staff with the right competencies, knowledge, qualifications, skills and experience to safeguard the health, safety and welfare of all who use the service and meet their routine and non-routine needs. RSOP 18 also requires there should always be a registered nurse or midwife on duty in the clinic when there are patients who need their care.
- BPAS had an Operational and Clinical Policy for Minimum Clinical Staffing Levels (November 2017) which we reviewed. This policy clearly set out minimum nursing and medical staffing levels dependant on the type of treatment being carried out at any location. We saw staffing levels at BPAS Leicester City were in line with this policy.
- Safe staffing levels were audited as part of the unit dashboard. We reviewed the most recent audit report from April 2017 to March 2018 and saw both BPAS Leicester City and BPAS Solihull were compliant with the safe staffing minimum levels, apart from December 2017 where no data was submitted for BPAS Solihull.
- Data provided by the service prior to the inspection, for the period August 2017 to April 2018, showed there was a full time treatment unit manager and lead midwife plus five registered nurses or midwives (3.05 whole time equivalent (WTE)) employed at BPAS Leicester City. There was also one patients care coordinator and two administrative staff (1.69 WTE). There was one additional registered nurse and one health care assistant who covered the part time opening hours at BPAS Solihull. There was a vacancy for a qualified nurse or midwife for 16 hours per week (0.43 WTE).
- BPAS Leicester City did not use any agency staff. Staff worked flexibly to cover shortfalls in the rota due to sickness or annual leave and staff from other locations would also cover additional shifts as 'bank' staff.
- Medical staffing cover was provided by doctors who worked both at the treatment unit and remotely. All doctors were either employed by BPAS or engaged under practising privileges. Practising privileges is a well-established process within independent healthcare whereby a register practitioner is granted permission to work in an independent hospital or clinic or in independent private practice.
- The doctors working remotely were based at other BPAS premises with a Department of Health licence. Their role was to review patient case notes and medical histories prior to signing the HSA1 forms and prescription forms for medicines. The Abortion Act 1967 requires two doctors to complete HSA1 form before any termination of pregnancy is performed.
- BPAS Leicester City BPAS Leicester had a surgeon with BPAS practising privileges working one day a week, to carry out surgical procedures. If medical cover was required for the surgical clinics due to annual leave, this would be requested from doctors working at other units who had the same practicing privileges and experience to work at BPAS Leicester City. Alternatively, the clinic would be cancelled and patients offered appointments at the next available clinic or other locations in line with the BPAS Contingency plan.

Records

- Patients' individual care records were written and managed in a way that kept them protected from avoidable harm. Information needed to deliver safe care and treatment was available to relevant staff in a timely and accessible way.
- We reviewed the BPAS operation/clinical policy and procedure for record keeping (February 2016) which detailed the principles of good record keeping and outlined staff responsibilities for recording and keeping information.
- BPAS used a combination of paper and electronic records, however all clinical records were paper based. Service leads told us there were plans to move to an all-electronic system in the future. We reviewed seven

sets of paper records. All the records we reviewed were legible and completed in full. One of the records contained loose papers that might become detached from the main records, however most of the records we reviewed had pages that were securely attached.

- Staff used comprehensive booklets to record patients' information, which differed dependant on the nature of procedure. In all the records we reviewed, we saw details of every attendance made by the patients at the treatment unit, together with details of ultrasound scans with gestation, blood results, assessment and plan of care and consent to treatment. Staff used the booklets to record details of the surgical procedure, including the treatment room documentation such as swab counts, audit trail stickers for the equipment used, MEWS and operative notes completed by the surgeon. The surgeon's records were legible and dated and a stamp with the General Medical Council (GMC) number was placed beside their signature, so they could be easily identified, which is in line with best practice.
- Staff completed monthly record keeping audits against the BPAS standard, and data was collated as part of the treatment unit dashboard. Compliance with the standard was by review of 1% (or a minimum of five) case notes which should achieve a score of 90% or more. We reviewed the most recent audit report from April 2017 to March 2018. BPAS Leicester City was compliant for the whole year. BPAS Solihull was compliant apart from June 2017. No data was submitted for BPAS Solihull in December 2017.

Medicines

- Medicines were generally managed, transported, stored and disposed of safely and securely.
- The organisation had a medicines management policy and procedure, dated February 2017, which we reviewed. This guideline was easily accessible to staff and gave clear guidance in relation to the management of medicines for termination of pregnancy, pain relief, contraception and antibiotics. Arrangements for controlled drugs (CD) (a medicine that is controlled under the Misuse of Drugs legislation 2001) were also included within this policy. Staff could also access the most up to date British National Formulary (BNF) from the organisation's intranet.
- We checked the drug cupboard and found it to be locked and secure. Medicines were kept within their original packaging and were within the expiry date. Intravenous fluids were stored in the locked clinical room which minimised the risk of them being tampered with. The temperature of the fridge used to store medicines was regularly checked. This meant staff could be assured medicines were being stored at the correct temperature.We saw CDs were stored appropriately in a locked cupboard and the keys held separately from the main keys. We checked the physical stock of the CDs against the stock level recorded in the register and saw evidence of daily checking by two registered staff. However, we observed the clinical room in which medicines was being stored appeared to be very warm and there was no mechanism for monitoring temperatures within the room. Staff could not be assured the medicines were being stored in line with manufacturer's recommendations. We escalated this to managers who told us they would purchase a thermometer.
- Staff told us the delivery of medicines for BPAS Solihull was managed and overseen by the treatment unit manager for BPAS Leicester. Medicines including CDs were signed for on arrival in line with the medicines management policy and procedure.
- Staff we spoke with were aware of their responsibilities for the management of medicines. We saw there were five pre-drawn syringes of fentanyl and midazolam (used in conscious sedation) for the surgical list. The syringes were covered with a sterile bung, clearly labelled, timed and dated and were under constant supervision of the surgeon, which was in line with the BPAS medicines management policy.
- We saw there were suitable arrangements for the disposal of unused medicines where staff checked the medicines and signed to confirm they had been disposed of in line with the drug disposal flow chart in the medicines management policy.
- Medicines including contraceptives were supplied and administered against a doctor's prescription or by a patient group directive (PGD). PGDs 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

organisation's clinical governance committee had approved a range of PGDs, which included medicines used for cervical preparation for surgical termination of pregnancy. We saw up to date versions of all PGDs were printed in a file so that all staff had easy access to the information and all qualified staff were required to read and sign when PGDs were issued or amended

- NICE QS 61 recommends that people are prescribed antibiotics in accordance with local antibiotic formularies. We saw nursing staff administered prescribed antibiotics to reduce the risk of infection during and after the procedure. In all the patients records we reviewed, we saw staff had recorded patient allergies. We observed staff double checked with patients about their allergies before given them antibiotics to take home.
- The organisation monitored compliance with medicines management policies through the unit dashboard which incorporated an early warning scorecard. The treatment unit manager completed a monthly audit of stock levels of medicines, CD daily checks, medicines fridge daily checks and correct receipt of medicines against orders. From April 2017 to March 2018, BPAS Solihull was compliant every month apart from April. There was no audit submission in December. For the same period for BPAS Leicester was 100% compliant.

Incidents

- Staff understood their responsibilities to raise concerns, to record safety incidents, concerns and near misses and to report them where appropriate. Staff reported incidents to the treatment unit manager, who then submitted them through the organisation's electronic incident reporting system.
- From the time of first registration up to the inspection, the treatment unit had not reported any never events. Never events are serious incidents that are entirely preventable as guidance, or safety recommendations providing strong systemic protective barriers, are available at a national level, and should have been implemented by all healthcare providers. Each never event type has the potential to cause serious patient harm or death, but neither need have happened for an incident to be a never event.
- Data provided by the service for the period September 2017 to April 2018 showed there were 15 incidents reports by BPAS Leicester City, of which eight were classified as low harm and seven as moderate harm. Most moderate harm incidents related to 'lab error' relating to samples either not received or incorrectly labelled, but also included one identified safeguarding incident. There were two moderate harm incidents reported for the same period for BPAS Solihull. One related to a patient transferred with a possible ectopic pregnancy and the other related to equipment failure.
- Staff we spoke with could give examples of incidents they had reported, for example failed treatment and told us learning was shared by email, at team meetings, during clinical supervision or at clinical forums conferences.
- Service leads monitored themes and trends of incidents at the treatment unit, across the region and at organisational level. We reviewed the minutes of the clinical governance committee and saw all serious incidents were discussed, together with themes and trends of other reported incidents. We reviewed the Clinical Incidents and Near Misses Summary Report for January to April 2018 and saw the largest number of incidents reported across the region were laboratory errors. This report was reviewed by the regional quality assurance and improvement forum (RQuAIF), however service leads told us this process had recently changed and in future would be reviewed by the quality and risk committee.

Are termination of pregnancy services effective?

Evidence-based care and treatment

- Staff at BPAS Leicester City assessed patients's physical, mental health and social needs and provided care, treatment and support in line with legislation, standards and evidence based guidance.
- All non-NHS providers of termination of pregnancy (TOP) services must operate under licence from the Department of Health (DOH) and comply with the 'Required Standard Operating Procedures' (RSOP) 2014. We saw the treatment unit was compliant with all of the RSOPs. RSOP 10: Professional Guidelines states that providers should have regard to relevant clinical and professional guidance such as the National Institute of

Health and Clinical Excellence (NICE) and the Royal College of Obstetricians and Gynaecologists (RCOG). We saw staff could access a range of evidence based policies and guidance which referenced latest professional guidelines.

- We saw staff advising and supplying reversible methods of contraception including long acting contraception (LARC) in accordance with RSOP 13. Contraception and Sexually Transmitted Infections Screening.
- Clinical guidelines, policies and procedures were disseminated to staff in several ways. Minor changes were sent to staff by email. More significant changes, such as termination for fetal anomaly, and conscious sedation were publicised at a 'roadshow' of events. This included internal and external speakers, or through a series of conference calls which were recorded. Service leads used the two-yearly BPAS Clinical Forum to which all registered staff were invited to publicise new guidelines and policies (dependant on the timing of the publication). In addition, there were minutes distributed to staff from the RQuAIF.
- BPAS had strict criteria for treatment within the treatment units, dependant on the type of procedure, to ensure the safety of the patients treated. There was clear guidance for staff to follow in the BPAS clinical guideline: 'Suitability for Treatment at BPAS', which was in line with the American Society of Anaesthesiologists (ASA) Physical Classification system. Patients were given the option of surgical abortion by local anaesthesia or conscious sedation. Conscious sedation was introduced following recommendations by the RCOG, the World Health Organisation (WHO) and the Department of Health and has several advantages over other anaesthesia including the potential of no fasting or long recovery and reduced pain and anxiety when compared to local anaesthetic. General anaesthetic was not available at this location.
- BPAS Leicester City offered surgical TOPs for patients with a confirmed ultrasound gestational date of up to 13 weeks and 6 days. Early medical abortion (EMA) was offered to patients who were up to 10 weeks gestation and was by administration of two abortifacient (causing an abortion) medicines. Patients were offered two options for EMA which was explained fully to them during the consultation and was also clearly explained in the 'My BPAS Guide', given to every patient. One option was simultaneous administration, where both medicines were taken on the same day and patients would not need to make another visit to the treatment unit. The second option was a 24 to 48-hour period between administration of the medicines and would require another clinic visit. The risks, failure rates and side effects of each option were clearly explained in the guide.
- Some aspects of treatment offered by BPAS were outside of current RCOG guidance. For example, the use of simultaneous administration of medicines used for EMA and not using cervical preparation for all patients undergoing surgical TOP.However, a structured governance system including risk assessments was in place and had been followed to introduce these processes.
- We reviewed the BPAS Clinical Audit Plan for 2018 and saw there was a comprehensive plan for local quality and safety audits. These included quarterly cleaning and monthly infection control audits, evaluation of guidelines and policies, provision of support and training for nurse practitioners, outcome data for the two EMA treatment options, quality assurance and case note audits. Local treatment units were also required to audit the completion of HSA1 forms (a legal requirement).

Nutrition and hydration

- Patients were given information about when to stop eating and drinking prior to surgery. This information was also included in the 'My BPAS guide'.
- We saw staff offering patients a light snack prior to their discharge home after surgical procedures. Patients were given a choice of drink and biscuits.
- We saw there was a cold-water fountain and a hot drinks machine in the waiting area of the treatment unit for use by patients and their escorts whilst waiting for appointments or treatment.

Pain relief

- We saw patients were routinely offered pain relieving medicines during surgical and medical procedures. Staff followed RCOG guidance by offering non-steroidal anti-inflammatory drugs (NSAIDs) such as ibuprofen rather than paracetamol to reduce pain.

- Staff recorded post-surgical pain scores as part of the modified early warning score (MEWS) assessment tool and could administer additional pain relief if required.
- The 'My BPAS Guide' gave clear information and advice for patients to follow prior to their surgical procedure and to manage their pain at home.

Patient outcomes

- From 1 August 2017 to 30 April 2018, BPAS Leicester City carried out 1242 EMAs and 179 surgical TOPs.BPAS Solihull carried out 238 EMAs.
- The service monitored the number of complications from both surgical termination of pregnancy and early medical abortion (EMA). Data provided by the treatment unit for the six-month period September 2017 to April 2018 for BPAS Leicester City showed there were no recorded complications from surgical procedures. For the same period there was one major complication of EMA related to a haemorrhage that required blood transfusion (0.1% of all cases),17 minor complications recorded within 63 days of simultaneous treatment (1.7%) and five minor complications between 64 and 70 days of non-simultaneous treatment (4.7%). For the same period for BPAS Solihull, there were four recorded minor complications of treatment for EMA within 63 days of treatment (4.3%).
- Staff completed monthly treatment audits against the BPAS standard, and data was collated as part of the treatment unit dashboard. Compliance with the standard was by review of 1% of each treatment type which should achieve a score of 90% or more. We reviewed the most recent audit report from April 2017 to March 2018. BPAS Leicester City was 100% compliant. BPAS Solihull were compliant with the treatment audit, apart from January 2018. No data was submitted for BPAS Solihull in December 2017.
- We reviewed BPAS's Annual Clinical Governance Report 2017 (published March 2018) and saw audit data from the organisation as a whole had been collated and analysed in order to identify themes and trends, this included national waiting times, annual safeguarding audits and NHS Quality Indicators.
- Waiting times was highlighted as an area for improvement in 2017 through the previous quality report. The service took national actions to reduce waiting times such; as additional appointments, additional locations, expansion of the telephone consultations and the creation of more same day consultation and treatment appointments.

Competent staff

- Staff had the right skills and knowledge to meet patients' needs, preferences and choices.
- 'RSOP 18: Staffing and Emergency Medical Cover' specifies that providers should ensure there is sufficient number of staff with the right competencies, knowledge, qualifications, skills and experience to safeguard the health safety and welfare of all who use the service and meet their routine and non-routine needs.
- BPAS provided nurses and midwives with a revalidation portfolio in line with the Nursing and Midwifery Council (NMC) guidance which helps staff to work through their revalidation process. Whilst it was the individual nurse of midwife's responsibility to revalidate, BPAS was required to ensure staff had up to date registration. As part of the inspection process, we checked the staff files of three nurses and midwives and saw evidence of current registration in all of them.
- To ensure that any surgeon undertaking surgical TOPs had the essential skills and training necessary to safely perform the procedures, they had an annual appraisal and were monitored through the practicing privileges process. The annual appraisal process reviewed evidence of registration with the General Medical Council (GMC), indemnity insurance and completion of mandatory training. We reviewed the staff file of the surgeon working at BPAS Leicester City and saw evidence of an appraisal undertaken by an NHS trust within the previous year together with certificates of training completion including immediate life support (ILS).
- The treatment unit employed registered nurses and midwives. New staff completed a 12-week training programme which covered all aspects of the service. Staff we spoke with told us it was a very thorough course and they were well supported to complete it. Additional training was provided for ultrasound scanning and consent. Nurse and midwife practitioners were not allowed to carry out ultrasound scanning on their own without completing the training and demonstrating competence. There was an ongoing

process of assessment to ensure staff maintained their competence. Data provided by the unit demonstrated staff performing scanning and insertion of long acting reversible contraception had completed the competency assessments.

- Staff told us they felt confident and competent to complete tasks assigned to them and would not carry out any task before supplying evidence of competence, for example safely inserting or removing intravenous cannulas (a needle going directly into the vein).
- Bank staff from other treatment units could work in BPAS Leicester City to cover for annual leave or sickness. We saw these staff had a 'clinical passport', a document which provided details of their training and competencies. In this way, treatment unit managers could be assured staff covering shifts in their area were suitably qualified to carry out care and treatment as required.
- We saw evidence in staff files and staff told us they received annual appraisals which were meaningful and useful. Once the initial training programme had been completed, staff could access additional training courses, such as in contraception. The treatment unit manager kept records on staff who had accessed additional training such as an event or a conference call and this information was used as part of the appraisal.
- Staff could access clinical support and advice from a variety of sources. Each treatment unit had a lead nurse or midwife. The northern region had a regional clinical lead and each area within the region had a clinical nurse or midwife specialist who worked in a supportive and flexible role. We saw the regional nurse specialist was supporting a newly appointed lead nurse at BPAS Leicester City and was able to provide cover for annual leave or sickness if required.
- Staff told us they received clinical supervision from the regional nurse specialist every few months. Service leads monitored compliance with clinical supervision as part of the unit Dashboard. For the period April 2017 to March 2018, BPAS Leicester City was compliant for most months apart from February and March 2018. BPAS Solihull was complaint apart from February 2018, no data was submitted in December 2017.
- Service leads told us staff who provide post abortion counselling would have completed the BPAS client support skills, counselling and self-awareness courses, and be fully competent with the client care co-ordinator (CCC) competencies framework. A CCC we spoke with confirmed they had completed the competencies.

Multidisciplinary working

- All necessary staff, including those in other teams, services and organisations were involved in assessing, planning and delivering care and treatment.
- Patients' care was delivered by the surgeon and nurse or midwife practitioners, with support from administrative staff and client care co-ordinators. We saw staff working collaboratively to provide safe care for patients and to improve services where possible. For example, we saw all staff participate in a safety huddle prior to starting the surgical list to improve communication and ensure staff were informed about any potential issue. At the end of the list we saw staff held a 'post-list debrief' to share learning about what had gone well and what could be improved.
- Some patients were referred into the service by their own GP. Staff asked patients for consent to share information with their GP. Printed discharge summaries were given to the patient to pass to her GP if she wished to.
- Staff gave examples of working with other agencies and services such as the local safeguarding board, early pregnancy unit at the local NHS acute hospital, mental health services and learning disability support workers.

Health Promotion

- 'RSOP 12: Information for Patients' specifies patients must be given impartial and evidence based information (verbal and written) delivered neutrally and covering: abortion method and alternatives to abortion, what to expect during and after the abortion including emotional responses, contraception options and sexually transmitted infection (STI) testing.
- 'RSOP 13: Contraception and Sexually Transmitted Infection Screening' specifies that providers should be able to supply all reversible methods of contraception, including long acting reversible methods (LARC) which are the most effective and offer testing for STIs as appropriate.

- Patients were given clear information in the 'My BPAS Guide' about STI testing and contraception methods. In all the care records we reviewed, we saw staff had documented discussions around STI testing and contraception. We saw staff had previously discussed contraception with the patients who were having surgical procedures during our inspection and contraceptive devices were fitted during the procedure where possible.
- Health promotion materials were displayed in the waiting area of the treatment unit. Subjects covered included smoking cessation, drug and alcohol use and healthy body mass index (BMI) in relation to weight management.

Consent and Mental Capacity Act

- Staff understood the relevant consent and decision-making requirements of legislation and guidance including the Mental Capacity Act (MCA) 2005 and other relevant national standards and guidance.
- BPAS had a consent to examination and treatment policy, dated June 2016, which we reviewed and which was easily accessible to staff.Written consent was required for all medical abortions, surgical procedures, any method of contraception fitted, removed or administered whether under conscious sedation or when awake. In all the care records we reviewed, we saw patients had signed to consent to treatment according to the policy.
- Staff told us they explained the process to patients at every stage and made sure patients understood the implications of all treatment, including side effects and complications. We observed staff asking patients for consent at all stages of the process and checking their understanding of the process. Patients who were booked for surgical procedures were asked for consent at the initial consultation and again prior to the surgery. This was to ensure the patient had sufficient time to decide, in line with guidance from the Royal College of Surgeons. During our inspection we saw one occasion where a patient had not signed a consent form prior to the surgery. This was picked up by staff in the treatment room completing the surgical check list and we saw staff checking her understanding and willingness to proceed before asking her to sign her consent. We also saw an occasion where a patient changed her mind about having a surgical procedure on the day, despite already having signed a consent form. We saw staff supported her to decide about the other options available to her.
- Staff told us if a patient was under 16 and wished to consent to their own treatment, for example if they wished to undergo a termination of pregnancy, staff followed Gillick Competency assessments and Fraser guidelines to assess whether the young person would have the maturity and intelligence to understand the risks and nature of treatments. The young person would be given time to consider all the options. (Gillick competency and Fraser guidelines are used to help assess whether a child under the age of 16 has the maturity to make their own decisions and to understand the implications of those decisions.) Staff understood the legal framework that a young person aged 16 or 17 can give valid consent without also obtaining consent from an adult with parental responsibility.However, staff told us they would always try to involve an adult with parental responsibility in the decision-making process, which is good practice.
- Staff gave us a specific example of where they had worked in partnership with a care worker to provide treatment for a patient who lacked capacity which was in her best interests in accordance with the BPAS policy and the MCA.

Are termination of pregnancy services caring?

Compassionate care

- During this inspection, we saw staff took the time to interact with patients who used the service and those close to them in a respectful and considerate manner. We observed staff delivering care in the treatment centre and speaking to patients on the phone and they always introduced themselves and spoke to patients with kindness and compassion. Without exception, the patients and those close to them we spoke with described the staff as caring, thoughtful and non-judgemental, which was important to them.
- Staff made sure that patients' privacy and dignity needs were understood and respected. We observed staff protecting patients' dignity by covering them as much

as possible before, during and after the treatment. After surgical procedures, patients were transferred to the recovery area, where curtains were used to protect their privacy. Staff handover from treatment room to recovery staff was kept as quiet and private as possible, and the radio was kept on maintaining background noise to help maintain the patient's privacy.

- All patients were given a client satisfaction survey to complete before leaving the treatment unit called 'Your opinion counts'. Patients were asked questions about waiting times, involvement of their escorts, privacy and dignity and involvement in the decision making about their care. We reviewed the survey results for both BPAS Leicester City and BPAS Solihull for September 2017 to April 2018. During this period, 100% of patients would recommend BPAS to someone they knew who needed similar care.

Emotional support

- Staff understood the impact of care or treatment on a person's wellbeing and those close to them.
- Staff we spoke with were proud of the care they could give to patients, to make them feel relaxed and confident about the treatment or procedure. We saw staff reassured patients throughout the procedures. Patients and those close to them described good support and information to help them cope with their care and treatment.One patient we spoke with told us "Staff here are so amazing, made me feel relaxed, I was worried and they were reassuring, I even had a good laugh with them".
- We saw specific examples of where staff gave exceptional care to patients who were distressed or in pain during the procedures. This included making allowances to the usual rules around the pre- operative and recovery area to allow patients to receive additional support from their partners.

Understanding and involvement of patients and those close to them

- We saw staff gave patients both verbal and written information to support the patients to make an informed choice about their options and their treatment and care. We saw specific examples of where staff provided additional support to patients who were unsure of their decision.
- We saw every patient was given a comprehensive information booklet called "My BPAS guide", which offered neutral information about all aspects of the options and treatments, and clear instructions and recommendations for the treatments and possible side effects or complications. We saw staff explained the contents of the booklet to patients. This was in line with 'Required Standard Operating Procedures 12 – Information for Patients' (Department of Health) which states that patients must be given impartial, accurate and evidence based information (verbal and written) delivered neutrally. One patients we spoke with told us "they gave me all of the choices".
- At every stage of the surgical procedure, we saw staff checked patients' understanding and gave explanations of what would be happening and the next steps. Staff told us they tried to make the patients feel comfortable and did not like to rush them in any way. We saw patients were discharged in a timely but unhurried manner, patients could stay longer in the waiting room for additional support from staff if they wished following the treatment.
- Staff explained the process to those accompanying patients for the treatment. They checked they understood the possible side effects of the treatment. Staff showed concern for partners, relatives and friends and offered advice about parking, waiting times and places they could go whilst waiting.

Are termination of pregnancy services responsive?

Service delivery to meet the needs of local people

- The services provided by BPAS Leicester city reflected the needs of the population served and mostly ensured flexibility, choice and continuity of care.
- The premises and facilities were appropriate for the services being offered. The BPAS Leicester City treatment unit was located within a GP practice, in a first-floor suite of rooms which was solely occupied by BPAS. A lift and disabled toilet facilities were available in the building. The location was well served by local transport.

- There were private consulting rooms where patients could talk privately at the initial consultation and when being attending for treatment. These rooms could also be used for counselling or if patients were anxious or too distressed to wait in the main waiting area.
- There was limited space in the waiting area within the suite of rooms therefore patients were only able to bring one escort with at any time.However, there was additional seating outside the unit where additional escorts could wait.
- The recovery area was small and had three recovery beds separated by curtains, however we saw staff tried hard to maintain patients' privacy and dignity always.
- Admission criteria were in place to reduce the risks of treatment for patients who might be higher risk and not suitable to be treated at this treatment unit. Patients would be referred to other treatment units within the BPAS organisation if they did not meet the admission criteria or referred outside of BPAS to NHS services if specialist services were required. In these circumstances, staff would complete a specialist placement form which would be coordinated by the specialist placement team within the BPAS contact centre and a copy placed within the patient's records.
- Commissioners worked closely with the Leicester unit staff and held quarterly contract review meetings to evaluate the service provided.

Meeting people's individual needs

- Staff assessed patients' individual needs and planned their care and treatment accordingly.Staff told us adjustments and arrangements could be made to accommodate patients with complex needs or learning disabilities and we were given specific examples of such arrangements.
- BPAS website gave information highlighting disabled patients' difficulties in accessing contraception and pre-conception care. Links to other support services were also available.
- We saw the BPAS website was easy to navigate and provided the full range of information and advice patients might need. The website contained information leaflets translated into 18 other languages, which staff told us they could download and print for patients for whom English was not their first language. Patients who had hearing difficulties could also access sign language videos from the website. Staff could access translation services as required for face to face consultations.
- Whilst the service mostly provided treatment paid for by the NHS or directly by the patient, staff told us due to their charity status, BPAS could fund some treatment for patients who would find it difficult to access treatment, and gave the example of funding treatment for an asylum seeker who had only been in the country for one week and who required an urgent referral.
- Client care coordinators were employed and trained by BPAS to support patients to make decisions about their care and treatment but did not have formal counselling qualifications. Staff could signpost or refer patients to other services if more in depth counselling was required, in line with 'Required Standard Operating Procedure (RSOP) 14: Counselling. Service leads told us patients could contact BPAS through a dedicated phone line to make an appointment for post-abortion counselling. This was a free service to all BPAS clients and would be accessed at any time following the procedure, whether the same day or many years later.
- Staff disposed of pregnancy remains sensitively and in accordance with recommendations by the Royal College of Obstetricians and Gynaecologists and the Human Tissue Authority. Patients were given information about the disposal of pregnancy remain in the 'My BPAS Guide' and staff told us they would facilitate wherever possible any request made by a patient concerning the management of her pregnancy remains.
- BPAS provided an 'Aftercare Line', which was a 24 hour a day, 7 days a week freephone service, which could provide support or advice to any patient after any kind of treatment. Staff told us this line was staffed by registered nurses or midwives, who could give patients immediate advice or signposted to other services, which would then be followed up on the next working day by the treatment unit if necessary.

Access and flow

- Patients could book appointments for BPAS Leicester City or BPAS Solihull through the BPAS contact centre which was a 24-hour, seven day a week telephone booking and information service. Patients could self-refer or be referred by their GP.

Termination of pregnancy

- The booking system provided information about appointments available to patients within 30 milesof their home address. Patients were offered treatment options and locations, subject to their gestation date and any medical conditions. Not all treatment options were offered by BPAS Leicester City or BPAS Solihull, if patients required a different treatment option they would be referred to the next closest available location. Patients did not have to use the same treatment centre for both the consultation appointment and procedure.
- Staff could provide the initial consultation to discuss patients' options either as a face to face meeting or by telephone. There was also an option of consultation and medical treatment on the same day. BPAS submitted quarterly activity reports to the commissioners of the service which gave details of the average number of days from contact to consultation, from 'decision to proceed' to treatment and for the first point of contact to treatment. For example, for the period January to March 2018 the average wait for patients in the three Leicestershire commissioning areas was 10 days, with the average wait for treatment being two days. Service leads told us some patients may delay treatment to access the option of consultation and treatment on the same day and other may choose to be treated at a different unit. Some patients might need additional time to decide about treatment or whether to proceed with the termination.
- Data provided by BPAS showed 117 patients waited longer than 10 days from decision to proceed to termination of pregnancy between 1 August 2017 and 30 April 2018. For the period January to March 2018,the average wait for clients from the three Leicestershire clinical commissioning groupswas 10 days, with the average wait to treatmentbeing 2days. Some patients might choose to be treated at a different unit or need extra time in which to decide about whether to proceed to abortion.
- We spoke with five patients during the inspection who described the booking process as easy to arrange and told us the call centre staff were pleasant and friendly. However, the patients described the initial part of the process from first contact to consultation as slow, describing waiting times of between three and six weeks. Patients agreed they had been offered a choice of appointment location but waiting times meant they had to travel to get the appointment within the timescales they wanted. One patient described this as a positive aspect, as it meant there was a wider range of surgical clinics to choose from to fit with her personal life. However, another patient was unable to access her local clinic due to the waiting times. This meant she was unable to have treatment under conscious sedation, but received a local anaesthetic, because she would be travelling alone by public transport. Due to the lack of conscious sedation she told us she found the treatment traumatic and painful. We saw staff supported her well throughout this process.
- The percentage of patients treated at less than 10 weeks gestation is an NHS target; in the three-month period up to June 2018, 79-82% of patients across the three clinical commissioning groups had been treated below 10 weeks gestation.
- BPAS produced quarterly activity reports which provided detailed information about the average number of days from contact to consultation, from 'decision to proceed' to treatment and from first point of contact to treatment. This information was shared with commissioners of the service.
- Waiting times were monitored through the BPAS booking system. Service leads we spoke with were aware the waiting times for BPAS Leicester were higher than they would like. Nationally waiting times was on the risk register. Leads explained this was due in part to having several new team members at the location who were not yet fully up to usual working speed. The BPAS capacity manager was working with the treatment unit manager to make the best use of resources, for example offering more initial consultations by telephone. At the time of inspection data was not available to reflect the impact of the actions taken.
- Staff told us they would telephone patients who did not attend for their appointments to discuss their decision and check if they wished to proceed.

Learning from complaints and concerns

- Data provided by BPAS prior to the inspection showed there had been one complaint during 2017/18. The complaint related to waiting times and attitude of staff.

During our inspection we saw staff were aware of the complaint and the learning about early communication with patients about possible waiting times had been widely shared.

- We reviewed BPAS's Annual Clinical Governance Report 2017 (published March 2018) and saw complaint data was collated for the organisation, to identify themes and trends and to ensure learning was shared across the organisation. This was cascaded to staff through emails and team meetings.
- Information about how to provide feedback was clearly displayed on a poster in the waiting area of the treatment unit. In addition, there was a clear process for patients to follow detailed in the 'My BPAS Guide', of which every patient received a copy. Staff told us they used feedback from the patients to make improvements to the service, for example there were changes planned to treatment unit to provide a better waiting area.
- Patients we spoke with knew how to make a complaint or raise concerns. The feedback forms and easy access to the website gave them the confidence to speak up.

Are termination of pregnancy services well-led?

Leadership

- We saw local leaders had the skills, knowledge, experience and integrity they need and were supported to develop on an ongoing basis.
- In April 2018, BPAS had made some changes to the structure and governance of the organisation and replaced the three geographical regions with two (north and south) and maintained the seven geographical areas. These changes had been introduced to develop a more robust layer of middle managers in the form of area managers. BPAS Leicester was now part of the midlands area of the northern operational region. The Midlands area had an area manager who reported to the Associate Director of Operations (ADO), who in turn reported to the BPAS Director of Operations. Clinical leadership was provided by the Director of Nursing and the Medical Director. At the time of our inspection there was a vacancy for ADO (north) which was being covered by the Regional Director of Operations (RDO) south.
- The registered manager (RM) oversaw operations at BPAS Leicester City and the satellite at BPAS Solihull and had been in post since the location was registered with the CQC in July 2017. The RM also used to be the treatment unit manager. Regional changes had led to the RM being given additional regional responsibilities and a new treatment unit manager had very recently started in post and would be beginning the application process to become the RM.
- The treatment unit manager oversaw the day to day running of the unit, whilst the lead nurse provided clinical leadership for the nursing and midwifery staff.
- The organisation provided a variety of management and leadership training. Managers told us they could access the Diploma of Management Studies and several cohorts were being supported through an in-house leadership development programme (LDP).There were plans in place for the new treatment unit manager to complete a first line management course and, after six months in the role, would be considered for the LDP.
- All staff we spoke with agreed managers and leaders were visible, supportive and approachable. The area manager regularly visited the treatment unit to support the new treatment unit manager. Staff told us other senior managers doctors and clinical leads were easily accessible by phone or by email during opening hours.
- Staff maintained a register of people undergoing a termination of pregnancy which would be retained for at least three years. Staff reported electronic statistics of the number and ages of patients undergoing termination of pregnancy to the Department of Health and within BPAS.
- The certificate of approval, issued by the Department of Health, was prominently on display within the treatment unit, which is good practice.
- The organisation ensured that an electronic record of the total number of terminations of pregnancy was maintained. This record was kept for more than three years which is line with Regulation 20 (6) of the CQC registration Regulations 2009.

Vision and strategy

- BPAS had clear vision and values, which was to treat all clients with dignity and respect and to provide a confidential, non-judgemental and safe service. The organisation's aims were;
  - To provide inclusive, reproductive health care services that are responsive to the needs of everyone who wishes to use them.
  - Promote the development of services that are accessible, effective, safe and confidential.
  - Safeguard individual freedom and moral autonomy in making reproductive choices.
  - Use their experience of abortion provision to contribute to the collective knowledge of those who provide reproductive healthcare.
- Staff were supported to promote the values through training and support. BPAS policies and procedures reflect the patient's right to influence and make decisions about their own care, in accordance with BPAS quality standards of confidentiality, dignity, privacy and individual choice.
- Staff we spoke with had a good understanding of the ethos and aims of the organisation and we observed staff behaviour was consistent with the values.

Culture

- Without exception, all staff we spoke with were proud of the organisation and the service they provided for patients. Staff told us they felt supported, respected and valued by the organisation and by other members of their team.
- Some staff we spoke with had worked for the organisation for many years and particularly valued the regular training and additional study day and conference opportunities. Staff told us they were proud that the organisation was 50 years old and they provided services that met the needs of a modern inclusive population.
- Service leads told us staff were recruited in accordance with the BPAS 'Recruitment and Selection' policy and procedure, which explores whether potential candidates were pro-choice.The organisation did not employ or subcontract individuals with a conscientious objection to abortion or those who do not embrace the organisational ethos.
- Staff understood the principles of Duty of Candour (DoC). DoC is a regulatory duty that relates to openness and transparency and requires providers of health and social care services to notify patient (or other relevant persons) of certain 'notifiable safety incidents' and provide reasonable support to that person. Staff confirmed they had not been any occasions when the DoC needed to be applied within the 12 months prior to our inspection.
- The service ensured patients were free of financial exploitation when accessing TOPs. Leaflets and internet services clearly described accessing NHS funded abortions, and the cost of privately funded treatments.

Governance

- There were systems, processes and systems of accountability to support the delivery of the strategy and good quality, sustainable services.
- There had been recent changes to the structure of the governance meeting model to reflect the new regional and middle management changes. At the time of our inspection the organisation was replacing the regional quality and improvement forums (RQuAIFs) and regional managers meetings with operational activity committee (OAC), clinical quality and risk committee (QRC) and area manager/treatment unit manager (TUM) meetings. The area manager/TUM meetings were planned to be every two months and would assess performance and quality against targets and reviewing the dashboard at a local level, and ensure actions plans were in place to correct any deficiencies. The area manager/TUM meetings would feed into the four monthly QRC meetings, which would identify areas of risk or need and identify where quality standards were not being met or persistent poor audit outcome. The OAC would meet every four months and would focus on more organisational issues such as national resources, service capacity and delivery and innovations and developments to the services provided by BPAS.
- At the time of our inspection the last of the RQuAIFs had just been held, and future governance meetings would be based on the new structure. Therefore, we were unable to assess the impact or effectiveness of these new governance arrangements.
- BPAS had a central authorisation system (CAS) where staff uploaded completed documentation following an

initial assessment by a nurse or midwife. Two BPAS doctors working remotely were allocated on a rota to review the documentation on CAS and sign the HSA1 forms, which was a legal requirement. This meant there were always two doctors available within the organisation to sign the forms in a timely way. This was particularly important for patients who attended for both the initial consultation and the medical treatment on the same day.

- There were systems in place to ensure all legal requirements relating to a TOP were documented in patients' records. Each record we reviewed had a completed HSA1 form completed electronically by two of the doctors working remotely, in line with the Abortion Act 1967.We saw nursing staff checked that the HSA1 had been signed by two registered medical practitioners prior to commencing any termination of pregnancy procedures. Staff carried out monthly audits of the HSA4 submissions to ensure compliance. We reviewed the most recent audit report from April 2017 to March 2018 and saw both BPAS Leicester City and BPAS Solihull were compliant with the HSA4 submissions, apart from December 2017 where no data was submitted for BPAS Solihull.

Managing risks, issues and performance

- There was a systematic programme of clinical and internal audit to monitor quality and operational processes.
- We reviewed the BPAS clinical audit plan for 2018 and saw there were a range of organisation wide clinical audits and performance monitoring measures planned under the headings of audit, performance management and clinical risk. The plan outlined expected timescales for completion and individuals with the responsibility for ensuring their completion.
- The organisation had a clinical dashboard for each treatment unit to provide a near real-time measure of quality and safety. There were 10 standards which covered medicines management, safe staffing, clinical supervision, infection prevention, record keeping, patient group directives (PGDs), treatment audits, competent staff, HSA4 submission and appraisals. The data produced by the dashboard was used to inform the regular reports to the clinical commissioning groups (CCGs). All treatment units were required to submit a return at the end of every month. This data was then collated into a RAG rated (red, amber, green) dashboard so managers and staff could clearly see whether standards were being achieved or whether data was not submitted.
- We reviewed the dashboards for both BPAS Leicester City and BPAS Solihull for April 2017 to March 2018. BPAS Leicester City was almost entirely compliant against all standards for the year, apart from two months non-compliance with the clinical supervision standard. Apart from one missed submission for December 2017 for BPAS Solihull, the satellite unit was compliant with almost all standards throughout the year.
- There was a corporate risk register for the organisation, which was the responsibility of the BPAS risk manager. Following the organisational restructure, the risk register was also changing to reflect area risks rather than the previous regional structure. There was a shared local risk register with BPAS Coventry which was overseen by the registered manager with involvement of the area manager and treatment unit manager. There was an alignment between the risks on the risk register and those the managers were aware of both nationally and locally. We saw local risks were categorised, regularly reviewed and control measures and mitigation was in place where possible.
- There was an 'Agreed Transfer of Care Procedure' between BPAS Leicester City and the local acute trust, which was the nearest emergency department. This agreement was dated March 2018 and outlined actions that should be taken in the event of a patient requiring further management which could not be provided at BPAS.

Managing information

- The Department of Health requires every provider undertaking termination of pregnancy to submit details of the pregnancy and demographic data within 24 hours using a HSA4 form, following each termination of pregnancy procedure. We saw there was a process in place to complete the forms on-line and staff at the treatment unit monitored their completion through audit.
- The organisation had moved to an electronic incident reporting system which was fully implemented by the end of 2017. From our review of clinical governance

meeting minutes, we saw there had been an increase in the number of incidents reported across the organisation as a whole, which gave service leads a better understanding of clinical and organisational risks.

Engagement

- The three local clinical commissioning groups (CCGs) of Leicester City, East Leicestershire and Rutland and West Leicestershire had a contract with BPAS until March 2019. The CQC contacted the CCGs as part of the inspection process to ask for them to comment on the services provided.
- The CCGs evaluate the service provided to Leicester, Leicestershire and Rutland (LLR) patients and look at data for the five most used treatment units, which included BPAS Leicester City. The CCG told us they found BPAS to be responsive and keen to engage with the CCGs.
- Patients were encouraged to complete feedback forms to share their views of their experience in the BPAS satisfaction survey 'Your Opinion Counts'. We saw a poster displayed in the waiting area which gave information about the survey. We saw staff giving the feedback forms to complete before leaving the centre. We saw survey results were shared with staff and commissioners.
- Staff told us they felt involved in planning and improving services at a local level and their views and opinions were sought at staff meetings and information discussions.

Learning, continuous improvement and innovation

- BPAS have increased the number of patients having surgical procedures under conscious sedation because of recommendations by the Royal College of Obstetricians and Gynaecologists, the World Health Organisation and the Department of Health, which has significant advantages over other forms of anaesthesia.
- BPAS have been in consultation with the Department of Health in relation to a review of the 'Required Standard Operating Procedures'.
- In response to staff feedback, the organisation has made significant changes to the middle management structure to provide greater support at a local level, and changes to the governance meetings to better reflect this new structure.