British Pregnancy Advisory Service

BPAS - Middlesbrough

Inspection report

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This report describes our judgement of the quality of care at this service. It is based on a combination of what we found when we inspected, information from our ongoing monitoring of data about services and information given to us from the provider, patients, the public and other organisations.

Ratings

Overall rating for this location	Inadequate
Are services safe?	Inadequate
Are services effective?	Requires Improvement
Are services responsive to people's needs?	Inspected but not rated
Are services well-led?	Inadequate

Summary of findings

Overall summary

This was a focused, unannounced inspection in response to specific areas of concern. We rated the service inadequate overall because:

- The service did not always operate effective safeguarding processes and systems to protect people from abuse.
- Staff did not always document risk assessments. They were not carried out comprehensively and did not remove or minimise every key risk.
- The service did not operate effective systems and processes to store medicines at safe temperatures, label medicines appropriately or check stock levels.
- The service did not always manage patient safety incidents well. Staff did not always recognise incidents or report them appropriately. Local managers investigated incidents and shared lessons learned with the whole team and the wider service. However, BPAS central team did not always investigate incidents appropriately.
- The service did not always provide care and treatment based on national guidance and evidence-based practice. Managers did not consistently check to make sure staff followed guidance.
- Staff did not always document support to patients to make informed decisions about their care and treatment. They did not consistently follow national guidance to gain patients' consent. Although staff recognised and assessed a patient's possible lack of mental capacity to make decisions, this was not always clearly documented.
- The service did not always coordinate care with other services and providers.
- Leaders and managers did not always understand and manage the priorities and issues the service faced.
- Leaders did not operate effective governance processes throughout the service. They did not use systems to manage performance effectively. They did not always identify and escalate relevant risks and issues nor take action to reduce their impact.

However:

- The service provided mandatory training in key skills to all staff and made sure everyone completed it. Staff received training on how to recognise and report abuse.
- Staff kept clear and up to date records of patients care and treatment.
- All those responsible for delivering care worked together as a team to benefit patients. They supported each other to provide good care and communicated effectively with each other.
- The service was inclusive and took account of patient's individual needs and preferences. Staff made reasonable adjustments to help patients access services.
- Leaders were visible and approachable in the service for patients and staff.
- Staff felt respected, supported and valued. They were focused on the needs of patients receiving care.

Following this inspection, under Section 31 of the Health and Social Care Act 2008, we served an urgent notice of decision to impose additional conditions on the location's registration as a service provider in respect of regulated activities. We took this urgent action as we believed a person would or may be exposed to the risk of harm if we had not done so.

The provider responded giving assurance of their intention to review systems and processes to minimise risk. The corporate provider responded with an action plan. However, we were not assured of the timeliness of some of the actions to address immediate risk.

This service has been placed into special measures. Services placed in special measures will be inspected again within six months. If insufficient improvements have been made such that there remains a rating of inadequate overall or for

Summary of findings

any key question or core service, we will take action in line with our enforcement procedures to begin the process of preventing the provider from operating the service. This will lead to cancelling their registration or to varying the terms of their registration within six months if they do not improve. The service will be kept under review and, if needed, could be escalated to urgent enforcement action. Where necessary another inspection will be conducted within a further six months, and if there is not enough improvement we will move to close the service by adopting our proposal to vary the provider's registration to remove this location or cancel the provider's registration.

Summary of findings

Our judgements about each of the main services

Service	Rating	Summary of each main service
Termination of pregnancy	Inadequate 	This was a focused, unannounced inspection in response to specific areas of concern. We rated this service as inadequate. In the reporting period 1 April 2020 to 31 March 2021, the centre carried out 137 surgical terminations of pregnancy (SToP) under local anaesthetic/conscious sedation, and 954 early medical abortions (EMA). One surgeon was directly employed by BPAS and one surgeon, who also worked at an NHS trust, worked on a sessional basis at BPAS under practising privileges. BPAS employed two registered nurses and midwife practitioners, and two administrators. Track record on safety: • No never events and no serious incidents requiring investigation reported from July 2020 to June 2021 • No patients were transferred out to another hospital The centre held a current Department of Health licence to practice under the Abortion Act and displayed copies of the licence at the registered location.

Summary of findings

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Summary of this inspection

Background to BPAS - Middlesbrough

BPAS Middlesbrough is operated by British Pregnancy Advisory Service. The British Pregnancy Advisory Service was established as a registered charity in 1968 to provide a safe, legal abortion service following the 1967 Abortion Act. BPAS Middlesbrough opened in 2012.

The BPAS Middlesbrough clinic undertakes; early medical abortion up to ten weeks (EMA) and surgical termination of pregnancy (SToP) up to 13 weeks and six days, with local anaesthetic and conscious sedation. BPAS Middlesbrough did not provide general anaesthetic (GA). Women requiring later surgical and medical abortions were signposted to BPAS Units at Doncaster, Merseyside or Richmond. The clinic also offers long-acting reversible contraception (LARC) in the form of the intrauterine device and contraceptive injections.

BPAS Middlesbrough clinic was last inspected June 2016. We did not rate the service because we did not have a legal duty at that time to rate this type of service or the regulated activities it provided.

We conducted an unannounced inspection on 4 August 2021 following information highlighted at routine engagement with another BPAS location on 15 June 2021. We requested details about the information of concern on two occasions, once informally, and once under Sector 64 of the Health and Social Care Act 2008, however the documents we received did not assure us that the risk had been mitigated and that another similar incident would not occur.

The inspection raised concerns about the management of the service and the safety of patients.

Following the inspection, we requested further information from the provider regarding risks we had identified at the inspection. The service has since produced an action plan. However, we were not sufficiently assured all risks were mitigated.

The location is registered to provide the following regulated activities:

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

The location has a manager registered with CQC.

How we carried out this inspection

We inspected the location using our focused methodology in response to concerns found during routine engagement with another BPAS location. This related to an event where women were unexpectedly transferred to another BPAS location in the North East and BPAS Middlesbrough to another BPAS location in the North West for surgical termination of pregnancy.

Summary of this inspection

Our inspection was unannounced (staff did not know we were coming) to enable us to observe routine activity. The team that inspected the service comprised a CQC lead inspector, inspection manager and specialist medicines inspector. The inspection team was overseen by Sarah Dronsfield, Head of Hospital Inspection.

As this was a focused inspection, we did not inspect all key lines of enquiry. We looked at parts of the safe, effective, responsive and well-led key questions.

During the inspection visit, the inspection team:

- visited all areas of the clinic including, waiting areas, recovery areas and treatment rooms.
- looked at the quality of medicines and emergency equipment and observed how staff were caring for patients
- spoke with the registered manager
- spoke two nurses
- reviewed seven patient care and treatment records
- looked at a range of policies, procedures and other documents relating to the running of the service

You can find information about how we carry out our inspections on our website: https://www.cqc.org.uk/what-we-do/how-we-do-our-job/what-we-do-inspection.

Following our site visit, we took enforcement action which included the use of our urgent enforcement powers, where we placed conditions on the location's registration in relation to safe care and treatment, consent and safeguarding.

Areas for improvement

Action the service MUST take is necessary to comply with its legal obligations. Action a trust SHOULD take is because it was not doing something required by a regulation, but it would be disproportionate to find a breach of the regulation overall, to prevent it failing to comply with legal requirements in future, or to improve services.

Action the service MUST take to improve:

The service must ensure that

- The service must ensure there is an effective system to identify and assess safeguarding issues including the management of vulnerable children and adults. This must include but not limited to a policy and or process for staff to raise safeguarding alerts with the local authority. (Regulation 13 (1) (2) (3))
- The service must implement an effective system for assessing, managing, and responding to service user risk, including but not limited to using specific tools for assessing risk of deterioration in children. (Regulation 12 (1) (2) (a) (b))
- The service must investigate incidents appropriately to identify themes and trends and learning shared. (Regulation 17 (1) (2) (a))
- The service must ensure all notifiable incidents are reported the regulator. (Registration Regulations Regulation 18 (1) (2) (a) (b) (e) (f))
- The service must ensure the safe and proper management of medicines including: medicines are stored at safe temperatures and action is taken if storage does not meet requirements, Duty of Candour is followed if medicines are found to have been administered if affected by being stored in unsafe temperatures, and a full and complete audit of medicines management. (Regulation 12 (1) (2) (g))

Summary of this inspection

- The service must implement a safe system and process to ensure fully informed consent is gained from service users in line with best practice guidance. (Regulation 11 (1))
- The service must ensure all risks to performance measures are recorded and acted upon. (Regulation 17 (1) (2) (a) (b))
- The service must ensure all HSA4 forms are submitted to Department of Health within 14 days of a procedure, in-line with Required Standard Operating Procedures (RSOP).
- The provider must ensure that a patient that has been involved in a notifiable safety incident, receive both a verbal and written apology. (Regulation 20 (1) (2) (3) (e))
- The service must ensure that clinical and operational audits are detailed and robust. (Regulation 17 (1) (2) (a))

Action the service SHOULD take to improve:

- The service should implement a safe system and process reflecting the observation of children under the age of 18 years using the modified early warning score (MEWS) to ensure early recognition and safe timely escalation of a deteriorating patient.
- The service should ensure that Fraser and Gillick assessments are conducted where necessary and there is clear evidence of their completion.

Our findings

Overview of ratings

Our ratings for this location are:

	Safe	Effective	Caring	Responsive	Well-led	Overall
Termination of pregnancy	Inadequate	Requires Improvement	Not inspected	Inspected but not rated	Inadequate	Inadequate
Overall	Inadequate	Requires Improvement	Not inspected	Inspected but not rated	Inadequate	Inadequate

Inadequate

Termination of pregnancy

Safe	Inadequate
Effective	Requires Improvement
Responsive	Inspected but not rated
Well-led	Inadequate

Are Termination of pregnancy safe?

Inadequate

Mandatory training

The service provided mandatory training in key skills to all staff and made sure everyone completed it.

All staff received mandatory training, which included immediate life support for clinical staff and basic life support for non-clinical staff, infection prevention and control, safeguarding children and adults, information governance and other aspects of health and safety at work. There was a programme of training available staff to access updates when required.

Staff had completed training specific to the termination of pregnancy which included sepsis, haemorrhage and anaphylactic shock as well as the use of local anaesthetic and conscious sedation.

All staff told us they were up to date with their mandatory training and training records confirmed this.

Safeguarding

Safeguarding alerts and concerns were not always raised with the local authority in line with best practice standards. This exposed patients to risk of ongoing harm. However, staff received level three safeguarding training on how to protect patients from abuse and the service had access to a central safeguarding team for advice. Staff were aware of local safeguarding contacts and processes.

Systems were in place to safeguard vulnerable adults and children and young people. Staff we spoke with were all aware of their responsibilities and demonstrated experience of using BPAS safeguarding pathways appropriately. Staff could give examples of what constituted as abuse and how to raise any concerns to the BPAS central safeguarding team. They knew how to protect patients from poor care and discrimination, including those with protected characteristics under the Equality Act 2010. Staff were aware of local safeguarding policies and contact details for local safeguarding teams.

Safeguarding cases were forwarded to the centralised BPAS safeguarding team and advice given in line with BPAS policy. We observed a local log, kept by the location which showed that although there had been safeguarding

concerns, alerts were not instigated, and this was confirmed by the registered manager. There was a process to complete safeguarding risk assessment for anyone under the age of 18 years or any patient deemed as vulnerable. The clinic could escalate safeguard concerns to the internal safeguarding hub to request advice and support. The hub was staffed seven days a week from 9-5pm.

We asked if cases logged and identified as safeguarding concerns had been acted upon by BPAS Middlesbrough staff but we were told staff followed BPAS policy and referred them to the BPAS central safeguarding team only. For two of the concerns we discussed with staff, neither were reported to the local authority. This highlighted a lack of professional curiosity and decision making regarding the management of safeguarding concerns and escalation both internally and externally. We were not assured that the service operated a safe system to notify all authorities regarding safeguarding alerts and concerns in line with best practice standards.

Following the inspection, we requested further assurances with regard to local safeguarding referrals and procedures and we found the live logs did not accurately reflect written comments in patient records.

All staff had undertaken the BPAS training programme for protection of vulnerable adults and children's safeguarding training at level three. Staff had an awareness of child sexual exploitation and there were arrangements to safeguard women with, or who were at risk of, female genital mutilation.

Assessing and responding to risk

Staff did not always complete and update risk assessments for each patient and remove or minimise risks. Although, staff could identify and quickly act upon patients at risk of deterioration.

We were not assured that the service had an effective system in place for assessing, managing and responding to patient risk to ensure all women who attended the service were cared for in a safe and effective manner and in line with national guidance. This exposed patients to the risk of harm.

There was an incident at this service whereby five service users had to travel to another BPAS location in the North West at short notice for a surgical termination of pregnancy (within 24 hours of expected surgical procedure). Some of these service users had taken Mifepristone as preparation 24 hours before their expected surgery. Each service user made their own way to the changed location, and were required to travel significant distances, two service users travelled by car and three services users travelled an average of five hours by train each way. We saw no documented evidence of risk assessments and discussions held with the service users or actions taken to mitigate the risks.

The provider told us there was a national shortage of surgeons able to perform late surgical termination of pregnancy (SToP) procedures. During our inspection a senior manager told us that there was no mitigation or contingency in place in the event of any service disruption. We were told the review of business continuity was being undertaken at corporate level and expected to be completed by October 2021. However, following the inspection, the service provided the current business continuity plan (reviewed 17/03/2021) which included a section in the event of loss of staff.

Patients were at a risk of harm as the service did not have a standard operating procedure regarding safe movement of patients to different BPAS locations in the event of disruption to services. The location had a service level agreement with the local acute trust. However, we saw no evidence that the provider had completed risk assessments for patients having to travel to another location and therefore away from the locality of the acute trust, nor that they had given consideration to other national health trusts or private healthcare providers in closer proximity to reduce the duration of transfer.

Patients undergoing elective surgery had a pre-assessment as part of this process. This was a means to identify patient's suitability and other pre-conditions that may lead to patient's complications during the surgery or recovery period.

The service used a Modified Early Warning Score (MEWS), a system adapted for the needs of termination of pregnancy from the National Early Warning Score (NEWS) developed by the Royal College of Physicians for the detection and response to clinical deterioration in adult patients. Records showed staff used this tool to identify deteriorating patients during the surgical procedure and recovery. The clinical staff had received training and updates on the use of the Modified Early Warning Scoring system tool and staff felt confident in using it. We reviewed a sample of four MEWS records and found these were all completed, and staff were aware of the threshold for initiating medical support as needed.

Staff could identify patients at risk of deterioration and could act quickly if their condition deteriorated. The service had a service level agreement for the emergency transfer of patients with a local NHS trust, this was due for review in the month of our inspection.

Patients were assessed for risk of venous thromboembolism (VTE). Venous thromboembolism is a condition in which a blood clot or thrombus forms in a vein, most commonly in the deep veins of the legs or pelvis.

The service had developed policy and procedures to recognise and respond to sepsis (severe blood infection) in line with national guidance. Sepsis is a rare but serious complication of an infection that can lead to multiple organ failure and death if not treated promptly.

The service used the World Health Organisation (WHO) five steps to safer surgery checklist for service users undergoing a surgical termination of pregnancy procedure. The (WHO) checklist is a nationally recognised system of checks designed to prevent avoidable harm and mistakes during surgical procedures. We observed the use of the five steps of the WHO checklist in the four records we reviewed.

The service did not have facilities on site to manage significant blood loss or blood transfusion. However, there were escalation processes if this occurred including using a haemorrhagic pack to stabilise a service user. The service user would be then be transferred to a local NHS trust.

Records

Staff always had access to up-to-date, accurate and comprehensive information on patients' care and treatment.

The service used an electronic record system. There was a paper record made available for those patients undergoing a surgical termination of pregnancy procedure. During the inspection we reviewed seven sets of patients' records. The records contained detailed information of patients' assessments, records from the surgical procedure if relevant, including observations during procedures and in recovery, nursing notes and discharge checklists and assessments which were appropriate to the patient's clinical pathway.

Patient records were stored and maintained securely and there was restricted access to prevent unauthorised access to confidential patients' records.

Access to the electronic patients' notes was password protected and staff ensured they logged off when the computers were not in use.

Record keeping audits had not been completed since February 2020 in line with the BPAS Covid-19 Pandemic Policy.

Medicines

Staff followed systems and processes when safely prescribing, administering, recording and storing medicines. However, the service did not always store medicines at safe temperatures and medicines issued for patients to take home were not correctly labelled.

Medicines were stored securely in locked cupboards. Controlled drugs were stored securely and managed appropriately. Regular balance checks were performed.

Medicines that required storage at fridge temperatures between 2-8 degrees centigrade were not managed safely. The records of fridge temperature showed the maximum was above 8 degrees centigrade on several days in June, July and August 2021. Action taken indicated that the fridge was reset, but there was no action taken to confirm that the medicines contained in the fridge were safe to use. We discussed following Duty of Candour regulations with the registered manager should any medicines have been administered if it was found on investigation that they had been stored at unsafe temperatures prior to use.

Medicines issued by nursing staff known as TTO (to take out) packs did not always have the address of the service on the label, which is a legal requirement. There were no systems in place to oversee the stock control of TTO packs or to track them at the point of discharge.

Staff reviewed patient's medicines regularly and provided specific advice to patients and carers about their medicines. Staff explained to patients what medicines they were taking and any side effects that could occur. If patients preferred to take their prescribed medicines at home, a 24 hour a day contact number was available for advice.

Staff stored and managed all medicines and prescribing documents in line with the provider's policy. Records showed that checks of emergency medicines and equipment had been performed to ensure that they were fit for use

Staff followed current national practice/guidance to check patients had the correct medicines. Policies and procedures were available and accessible to staff. Patient Group Directions (PGDs) were in use and there was a procedure in place to make sure they were prepared and used in a safe way. PGDs are written instructions which allow specified healthcare professionals to supply or administer certain medicines in the absence of a written prescription.

Incidents

The service did not always manage patient safety incidents well. Staff did not always recognise incidents or report them appropriately. Local managers investigated reported incidents and shared lessons learned with the whole team and the wider service. However, BPAS central team did not always investigate incidents appropriately. When things went wrong, staff apologised but patients were not always given a written apology. However, staff gave patients honest information and suitable support.

The service had developed internal processes to report and record incidents and used an electronic system to do this. All staff we spoke with told us they knew what incidents to report and followed their reporting system. Staff also said any incidents were discussed at safety huddles and at staff briefs. Staff were able to describe changes that have been made as a result of incidents.

However, we found staff had not reported as an incident the need for women to travel to another location for completion of their terminations of pregnancy after having taken their preparatory medicines. Therefore, this was not investigated or acted upon appropriately.

We reviewed the BPAS incidents, near misses and serious incident policy which did not highlight all expectations to safeguard or report to the regulator.

All incidents were notified to, reviewed and investigated by the local Treatment Unit Manager and Lead Nurse or Clinical Nurse Manager and the Regional Clinical Director if surgical treatment was involved. Local managers oversaw any necessary local or immediate action and submitted initial reports and 72-hour reviews, which included initial findings and learning, to the central Clinical Risk team.

The treatment unit manager told us incidents were uploaded onto the electronic reporting system and escalated to the risk and governance team who decided whether incidents were escalated as a Serious Incident Requiring Investigation (SIRI). In the cases involving women who had to travel to another BPAS clinic, we saw the central team had not deemed that any case required formal investigation. Therefore, we were not assured local managers investigated all patient safety incidents and learned lessons from them.

Following our inspection, the provider sent additional information that provided some assurance that they had an established process and system to report, escalate and review incidents. However, the provider told us they recognised improvement was needed in documentation of serious incident reviews and told us improvements would be made to the serious incident investigation process including ensuring meetings of the serious incident declaration group were recorded in minutes. The provider made changes to the incident reporting system to make the completion of documentation of review by the clinical risk team mandatory in certain incidents.

Managers communicated high priority safety messages, both internal and from across BPAS through 'Red Top Alerts', sent by email to all staff and locations. We reviewed the five red top alerts sent to staff over the last six months. However, these did not reflect the incidents the provider reported, for example relating to women having to travel between clinics and two related the recall of equipment which was not reflective of learning from incidents. Therefore, we were not assured the 'Red Top Alerts' shared all learning from incidents effectively with staff. We also saw the actions highlighted in these alerts were not always robust enough to address key learning and it was unclear if any actions would be audited as all audits had been suspended. Following inspection, the provider told us that learning from serious incidents and low-level investigations as turned into summary reports shared via an automatic online process directly to staff.

Staff we spoke with were aware of their responsibilities relating to Duty of Candour under the Health and Social Care Act (Regulated Activities Regulations) 2014. The Duty of Candour is a regulatory duty that relates to openness and transparency and requires providers of health and social care services to notify women (or other relevant persons) of "certain notifiable safety incidents" and provide them with reasonable support. However, we discussed this with the registered manager to ensure Duty of Candour is followed if medicines are found to have been administered if affected by being stored in unsafe temperatures.

Staff were aware of the process for submitting statutory notification of incidents to external organisations and the Care Quality Commission.

Are Termination of pregnancy effective?

Inadequate

Termination of pregnancy

Requires Improvement

Evidence-based care and treatment

The service provided care and treatment based on national guidance and evidence-based practice. Managers did not consistently check to make sure staff followed guidance.

Staff protected the rights of patients subject to the Mental Health Act 1983.

Staff followed up to date BPAS policies to plan and deliver care. However, policies did not always include best practice and national guidance. Managers did not have assurance that all staff followed national guidance consistently as observational audits in the treatment room and audits of patient's notes had been suspended due to the COVID-19 pandemic.

BPAS staff followed patient pathways and documented care and interactions with patients in electronic patient records. We reviewed seven patient records, and all had been completed according to BPAS policy and practice. However, since records did not include prompts or sections for best practice and national guidance, staff did not address these or document them in patient records. For instance, staff did not document a two-stage consent process and we were not assured this took place for all women undergoing termination of pregnancy.

Patient records we viewed showed that staff routinely referred to the psychological and emotional needs of patients.

Staff always had access to up-to-date, accurate and comprehensive information on patients' care and treatment. All staff had access to an electronic records system that they could all update.

Staff explained some local CCGs had stopped funding Sexually transmitted infection (STI) testing so staff signposted patients to local sexual health provision.

Women were encouraged to discuss contraception following ToP. Women undergoing SToP were given the option to have a contraceptive implant, coil or intrauterine device (IUD) fitted by the surgeon or a long-acting contraception injection, and women undergoing medical ToP were offered a contraceptive pill or signposted to local services for other methods of contraception. The lead nurse had been undertaking contraceptive implant training prior to the Covid-19 pandemic and explained they could also offer this once their course was completed.

The service was able to provide scans within 48 hours of telephone consultations and on the same day as face to face consultations. The service opened on Saturdays to ensure women could access a scan appointment within the required 48-hour timeframe. The service was able to meet key performance indicators (KPI's) for first contact to treatment within the 10-day requirement.

Women were given online information and advice prior to, during their treatment and following discharge. Staff could offer a My BPAS booklet containing the same information should a woman prefer paper-based information.

We observed staff followed the provider's Covid-19 social distancing, infection prevention and control (IPC) and personal protective equipment (PPE) policies.

Inadequate

Termination of pregnancy

Patient outcomes

Staff did not always monitor the effectiveness of care and treatment.

The service had paused all audits apart from clinical supervision, infection prevention and control, and medicines management as a result of the COVID-19 pandemic.

Consent, Mental Capacity Act and Deprivation of Liberty Safeguards

Staff told us they supported patients to make informed decisions about their care and treatment. However, they did not always follow national guidance to gain patients' informed consent.

Staff completed a BPAS Consent course and explained there were clear guidelines on consent. Nursing staff completed a Treatment and suitability course and explained they were required to witness all treatment options being carried out before being able to take consent from women. Nursing staff therefore made sure patients consented to treatment based on all the information available. Staff told us consent was taken during telephone consultations, but records showed no evidence of this.

Staff could describe and knew how to access policy and get BPAS advice on Mental Capacity Act and Deprivation of Liberty Safeguards. They had recently supported a patient with a mental health problem. Staff had followed guidance and sought input from the patient's mental health support team. Staff had been able to support the patient through the termination process.

We found gaps in documentation of consent. We reviewed seven patient records which all showed staff had not documented a two-stage consent process and a doctor did not document consent taken prior to a termination of pregnancy. In four records for women who underwent Surgical Termination of Pregnancy (SToP) there was no documentation to show second-stage consent had been taken prior to carrying out the procedure. We saw no evidence in any of the records we reviewed that patients were informed of the risks, regarding travelling significant distances following administration of medications.

Staff understood Gillick Competence and Fraser Guidelines and supported children who wished to make decisions about their treatment and staff completed and kept up to date with training in the Mental Capacity Act and Deprivation of Liberty Safeguards. However, there was no process in place for staff to evidence the assessment of mental capacity.

Therefore, staff did not document all the relevant consent and decision-making requirements of legislation and guidance, including the Mental Health Act and Mental Capacity Act 2005.

Are Termination of pregnancy responsive?

Inspected but not rated

Meeting people's individual needs

Inadequate

Termination of pregnancy

The service was inclusive and took account of patients' individual needs and preferences. Staff made reasonable adjustments to help patients access services. They coordinated care with other services within BPAS.

Staff made sure patients living with mental health problems and learning disabilities received the necessary care to meet all their needs. Staff followed processes where they identified women who had a pre-existing disability or mental health condition, and clinical pathways were in place for access to appropriate medical back up services if required. Staff maintained a log which showed where they had arranged additional support and guidance to meet women's needs.

The service could provide information in languages spoken by the patients and local community. Staff made sure staff and patients could get help from interpreters when needed. BPAS complied with Accessible Information standards through provision of information for patients on its website in various formats and languages and they produced leaflets in braille. Staff could organise a telephone interpreter if a woman needed help in understanding the spoken word.

The service offered pre-abortion counselling to all patients and uptake was patient-led. Staff completed risk assessments prior to admission which covered psycho-social factors such as alcohol intake, smoking and drug use. These were complete in all patient notes we reviewed.

During our inspection we observed women of a range of ages, ethnicities, and backgrounds attended the clinic and all were treated by BPAS staff with care and compassion. The BPAS Middlesbrough environment was private and secure and women had conversations and treatment with a nurse or midwife which included an opportunity to meet with staff alone. We observed staff treated all women and girls as individuals and showed care for their needs and feelings throughout their visit to the unit.

All women were offered counselling if they required additional support tailored to their age, comprehension and social circumstances. This was offered by staff during telephone consultations or by nurses at BPAS unit during face to face consultations. Staff told us they had seen no clients in the last year where there was evidence of coercion.

The BPAS website and leaflet contained information for women who wished to make an informed choice about disposal of pregnancy remains or burial of the fetus or pregnancy remains at any gestation and for abortion carried out for any reason. Disposal of fetal remains was also discussed during consultation.

Women receiving treatment for early medical abortion were given the opportunity (if assessed as appropriate) to be supplied with the first and second medication (mifepristone and misoprostol) to take away and administer at home.

Are Termination of pregnancy well-led?

Inadequate

Leadership

Local leaders had the skills and abilities to run the service. They were visible and approachable in the service for patients and staff. They supported staff to develop their skills and take on more senior roles. However, regional and national managers did not understand and manage the priorities and issues the service faced.

Termination of pregnancy

The service was managed by a registered manager with assistance from an Operational Quality Manager (OQM). The service displayed the certificate of approval to undertake termination of pregnancies as issued by the Department of Health.

We conducted an unannounced inspection on 4 August 2021 following information highlighted at routine engagement with another BPAS location on 15 June 2021. This had raised concerns about management of the service and the safety of patients. Senior management confirmed there was no mitigation or contingency currently in place in the event of any service disruption. We were told the review of the business continuity plan was being developed at corporate level and expected to be fully completed by October 2021.

Operational decisions affecting the service were made by the registered manager who was supported by the senior leadership team. A full list of STOP patients had to travel to another BPAS location in the North West because a surgeon could not be provided to attend BPAS – Middlesbrough. Therefore, a decision was made to transfer the care of a group of women who had already taken preparation medication prior to STOP to another BPAS unit at very short notice. This put women at risk. This event and resulting incidents should have been submitted as a statutory notification to the Care Quality Commission in line with registration requirements for providers.

Local and senior managers were visible, available and approachable. Regional managers met with staff regularly and staff were able to contact clinical leads for advice and guidance as required.

Learning from incidents, safeguarding and daily practice was shared locally within the team. Staff described the formal processes for sharing learning and elements of good practice with the wider organisation through registered managers.

Staff in management and lead roles had been appointed according to their skills and experience. The registered manager and lead nurse had regular meetings and supervision with senior staff. Senior staff competencies and training were recorded and monitored in line with BPAS requirements.

Meetings were not structured or documented. Staff explained the team was small, and many discussions took place informally. We saw records of a team brief with handwritten notes which referred to staff attending and a complaint, but nothing was documented in recognition of this. Staff felt these were effective and appropriate for the size of the unit.

Surgical huddles took place between clinicians on the day of surgical TOP lists. However, decisions made at this stage were not documented in patient notes.

Vision and Strategy

The service had a vision for what it wanted to achieve and a strategy to turn it into action, developed with all relevant stakeholders. The vision and strategy were focused on sustainability of services and aligned to local CCG requirements plans. Leaders and staff understood and knew how to apply them and monitor progress.

The manager disseminated the team brief at staff meetings. This included BPAS' ambition and purpose. Staff aimed to treat all patients with respect and provide confidential, non-judgmental and safe services through all aspects of their work**.** We observed staff attitudes and behaviour reflected these values.

Inadequate

Termination of pregnancy

BPAS national and local strategic plans included changes in provision in line with legislation and the needs of women. The service had been able to tailor its provision to the needs of the local community since the introduction of "Pills by Post" and a this had meant fewer women needed to attend the service for consultation or treatment. Therefore, staff had sufficient time available to spend with women with more complex needs.

Culture

Staff felt respected, supported and valued. They were focused on the needs of patients receiving care. The service promoted equality and diversity in daily work and provided opportunities for career development. The service had an open culture where patients and staff could raise concerns without fear.

There was strong team-working and a common focus on improving the quality and sustainability of care and patient experiences. Staff felt proud of the service they provided for their local community and vulnerable women. Staff enjoyed their work and we observed patient and staff team interactions were positive, caring and compassionate.

Staff provided examples of striving to meet equality and diversity needs of clients including religious needs, providing effective translation services and providing weekend clinics.

Staff were confident in reporting incidents and concerns internally and BPAS encouraged learning from all incidents.

All staff we spoke with told us they felt supported by their managers. Staff told us they were encouraged to develop and take part in additional training.

Governance

Leaders did not operate effective governance processes, throughout the service and with partner organisations. We were not assured that the service had effective local oversight and safety systems to keep patients safe. However, staff were clear about their roles and accountabilities and had regular opportunities to meet, discuss and learn from the performance of the service.

There was a clear governance system for the organisation. However, governance systems were not always effective at location level. Processes for declaring and investigating serious incidents and reporting safeguarding concerns were centralised. The clinical governance committee reviewed complications, and patient feedback. They reviewed and ratified policies and received annual reports such as the infection prevention and control annual report. The clinical advisory committee was led by the medical director.

This meant local staff and managers were not empowered to operate effective governance systems and manage risks and performance at a local level and in line with specific local situations or requirements. For example, we were not assured that the provider had taken immediate action to address the business continuity incident in June 2021 which related to the transfer of care for five patients from BPAS Middlesbrough to another BPAS location in the North West. The strength of central corporate control of incidents led to the lack of autonomy and decision making at location level. However, local managers did review all incidents reported via the electronic incident reporting system and had access to electronic dashboards detailing information about incidents and complaints.

In line with the BPAS Covid-19 Pandemic Policy, most audits had been put on hold since February 2020. Therefore, managers were not aware if quality issues existed. The service provided copies of the audit dashboard which showed the only audits undertaken were for clinical supervision, medicines management and part of the infection prevention

and control (IPC) audit. The dashboard simply said 'achieved' or 'not achieved' with no explanation of levels of compliance and what constituted 'achieved'. The dashboards for BPAS Middlesbrough showed audits for all areas had been 'achieved' and had not highlighted any concerns. However, we found some missing information on labelling of medicines for patients to take home, which is a legal requirement, and lack of adequate stock control for medicines which had not been identified or actioned as part of the audit process. This meant we were not assured the service had an effective system of audit and governance to address areas of poor performance and ensure safe care and treatment.

Staff did not fully understand the Duty of Candour. Although staff were open and transparent we found written Duty of Candour was not always applied. This was because the BPAS Duty of Candour policy was not compliant with Regulation 20 of the Health and Social Care Act 2008 as it did not require staff to provide written Duty of Candour. This meant the provider was not meeting the requirements of the regulation to provide information and an apology in writing when things had gone wrong.

The assessment process for termination of pregnancy legally requires that two doctors agree with the reason for the termination and sign a form to indicate their agreement (HSA1 Form). We looked at seven patient records and found that all forms included two signatures and the reason for the termination. The BPAS client administration system (CAS2) provided electronic HSA1 forms which, once reviewed and signed remotely, by two BPAS doctors, were printed out and held in paper patient records. No patients were treated without two signatures.

Managers met regularly as a regional team to discuss quality and performance measures including patient satisfaction reports, to look at capacity reports, staff absence and any incidents reported. Staff explained the regional managers reported governance information to the clinical governance committee. The clinical governance committee reviewed complications, and patient feedback. They reviewed and ratified policies and received annual reports such as the infection prevention and control annual report. The clinical advisory committee was led by the medical director.

Staff reported performance information to CCGs who monitored contract requirements.

Management of risk, issues and performance

We were not assured that the service had effective safe systems in place to cope with unexpected events. They did not consistently identify and escalate relevant risks and issues, nor identify actions to reduce their impact. The service had plans to cope with unexpected events. However, these were not always safe and in line with national guidance.

Immediately after the inspection CQC took enforcement action using our urgent powers whereby we imposed conditions, under section 31 of the Health and Social Care Act 2008, on the provider's registration as people may or will be exposed to the risk of harm. These included:

- The registered provider must implement an effective system for assessing, managing and responding to service user risk at BPAS – Middlesbrough, and two other locations.
- The registered provider must implement a safe system and process at BPAS – Middlesbrough, and two other locations to ensure fully informed consent is gained from service users in line with best practice guidance.
- The registered provider must ensure there is an effective system to identify and assess any safeguarding issues including the management of vulnerable children and adults at BPAS – Middlesbrough, and two other location. This must include but not limited to a policy and or process for staff to raise safeguarding alerts with the local authority.

Inadequate

Termination of pregnancy

Following the imposition of conditions, the provider produced an action plan, focusing on the conditions of registration. This did not provide sufficient assurance on actions taken to mitigate immediate risk. Therefore, we issued a further letter of intent under section 31 of the Health and Social Care Act 2008 to gain assurance on how they would ensure incidents were reported and learning would be shared. We also informally requested further assurances on safeguarding systems and processes.

We were assured by the providers responses that they had taken action to address immediate risk. However, the provider will be providing regular reports to CQC on the actions taken to improve the quality and safety of services.

Staff reported incidents and concerns appropriately and according to BPAS policy.

There was a clear escalation policy and an agreement in place to manage unexpected events such as if a woman required emergency care, they would be transferred by ambulance to the local NHS hospital. There had been no emergency transfers of care in the reporting period between July 2020 and June 2021.

Staff reported no financial pressures that could have compromised the quality of care. Staff explained they would carry out joint decision making with regional and national leads should this happen.

However, an incident occurred where the care of five women undergoing surgical abortion was not managed safely. The women were asked to make their own arrangements and travel to another BPAS clinic in the North West within 24 hours of expecting to have their treatment at BPAS Middlesbrough (we saw women travel up to 140 miles by car and four hours by train). The women took preparatory mifepristone at home before travelling to another BPAS location in the North West, putting them at risk of bleeding or aborting their pregnancy during the journey. BPAS Policy stated women should have their treatment at a location as close as possible to their first intervention. This incident meant staff did not follow BPAS policy.

A serious incident had occurred at another unit and BPAS carried out an audit of safe perioperative pathways which included observation of safer surgical checklist compliance during a theatre session. The regional clinical director carried out the audit in April 2021 and provided feedback to the Middlesbrough unit team with actions to be met and re-audit planned for three months' time.

This section is primarily information for the provider

Requirement notices

Action we have told the provider to take

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

Regulated activity	Regulation
Diagnostic and screening procedures Family planning services Surgical procedures Termination of pregnancies Treatment of disease, disorder or injury	Regulation 18 CQC (Registration) Regulations 2009 Notification of other incidents

Regulated activity	Regulation
Diagnostic and screening procedures Family planning services Surgical procedures Termination of pregnancies Treatment of disease, disorder or injury	Regulation 11 HSCA (RA) Regulations 2014 Need for consent

Regulated activity	Regulation
Diagnostic and screening procedures Family planning services Surgical procedures Termination of pregnancies Treatment of disease, disorder or injury	Regulation 20 HSCA (RA) Regulations 2014 Duty of candour

Regulated activity	Regulation
Diagnostic and screening procedures Family planning services Surgical procedures	Regulation 13 HSCA (RA) Regulations 2014 Safeguarding service users from abuse and improper treatment

This section is primarily information for the provider

Requirement notices

Termination of pregnancies

Treatment of disease, disorder or injury

Regulated activity	Regulation
Diagnostic and screening procedures Family planning services Surgical procedures Termination of pregnancies Treatment of disease, disorder or injury	Regulation 12 HSCA (RA) Regulations 2014 Safe care and treatment

Regulated activity	Regulation
Diagnostic and screening procedures Family planning services Surgical procedures Termination of pregnancies Treatment of disease, disorder or injury	Regulation 17 HSCA (RA) Regulations 2014 Good governance

Regulated activity	Regulation
Diagnostic and screening procedures Family planning services Surgical procedures Termination of pregnancies Treatment of disease, disorder or injury	Regulation 20 (Registration) Regulations 2009 Requirements relating to termination of pregnancy

This section is primarily information for the provider

Enforcement actions

Action we have told the provider to take

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

Regulated activity	Regulation
Diagnostic and screening procedures Family planning services Surgical procedures Termination of pregnancies Treatment of disease, disorder or injury	S12 Notice of Decision to impose a condition of registration