British Pregnancy Advisory Service

BPAS - Merseyside

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?	Inadequate
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. Our rating of this location went down. We rated it as inadequate because:

- The service did not always operate effective safeguarding processes and systems to protect people from abuse.
- Staff did not always identify nor quickly act upon patients at risk of deterioration following a surgical procedure. Though staff completed risk assessments these were not comprehensive nor removed or minimised every key risk.
- Though staff kept records of patients care and treatment these were not always fully completed, clear or up to date.
- The service did not operate effective systems and processes to safely prescribe, administer, record and store medicines.
- Staff did not always recognise and report incidents and near misses. Managers did not always investigate incidents.
- Managers did not consistently check to make sure staff followed national and local guidance.
- Staff did not always support patients to make informed decisions about their care and treatment. They did not consistently follow national guidance to gain patients' consent. Staff did not recognise, assess or record a patient's possible lack of mental capacity to make decisions.
- 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.
- The service had enough staff with the right qualifications, skills, training and experience to keep patients safe from avoidable harm and to provide the right care and treatment.
- When managers investigated incidents, they shared lessons learnt with the whole team and across BPAS.
- The service provided care and treatment based on national guidance and evidence-based practice.
- 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 patients' 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. The service had an open culture where staff could raise concerns without fear.

Following this inspection, under Section 31 of the Health and Social Care Act 2008, we served an urgent notice of decision to impose 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.

Summary of findings

We served a further urgent letter of intent on 18 August 2021 to require the service to review and investigate incidents where service users had been transferred to the local NHS service.

We received assurance from the provider that immediate risk had been addressed and did not take any further enforcement action.

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 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. Our rating of this location went down. We rated it as inadequate. Between August 2020 and July 2021, the service carried out 3,305 terminations of pregnancy, of which 1,469 were surgical terminations of pregnancy. Between July 2020 and June 2021, the service transferred six patients in an emergency due to complications or the patient becoming unwell. BPAS Merseyside held a current Department of Health licence to practice under the Abortion Act and displayed copies of the licence at each of its registered locations Two surgeons were directly employed by BPAS. Track record on safety • One never event and no serious incidents requiring investigation reported from July 2020 to June 2021 • Six patients were transferred out to another hospital • No incidences of hospital acquired Methicillin-resistant Staphylococcus aureus (MRSA)

Summary of findings

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Summary of this inspection

Background to BPAS - Merseyside

BPAS Merseyside is operated by British Pregnancy Advisor Service (BPAS). BPAS was established as a registered charity in 1968 to provide a safe, legal abortion service following the 1967 Abortion Act. BPAS is a national charity and around 97% of patients are funded by the NHS. BPAS Merseyside opened in 1970.

The BPAS Merseyside clinic provides termination of pregnancy services for women from Merseyside and surrounding areas as well as patients from Ireland and across the United Kingdom. It also offers pregnancy testing, unplanned pregnancy counselling/consultation, miscarriage management, sexually transmitted infection testing and treatment, contraceptive advice, contraception supply and abortion aftercare. The clinic has six screening rooms, three consulting rooms and one treatment room. It operates surgical lists from Wednesday to Saturday.

BPAS Merseyside provides consultation and early medical abortion treatments up to 10 weeks gestation, including home use pills by post. Surgical termination of pregnancy are offered up to 23 weeks and 6 days gestation using local anaesthetic and conscious sedation or general anaesthetic. In addition, the Merseyside clinic offers vasectomies at a monthly clinic, though this was suspended at the time of our inspection.

We conducted an unannounced inspection on 4 August 2021 following information highlighted at routine engagement with the provider 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. This raised concerns about the management of the service and the safety of patients.

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.

The last comprehensive inspection was in May 2019. We rated the service as requires improvement overall and issued requirement notices for Regulation 12 Safe care and treatment and Regulation 17 Good governance. These requirement notices have not yet been fully met.

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 from two BPAS locations in the North East 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, team inspector 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.
- spoke with the registered manager and operational and quality manager
- spoke with eight other members of staff including nurses, midwives, surgeon, operating department practitioner and health care assistants
- reviewed 10 patient care and treatment records
- attended one multidisciplinary team meeting
- looked at a range of policies, procedures and other documents relating to the running of the service
- observed care and treatment in the treatment room

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.

Areas for improvement

Action the service MUST take is necessary to comply with its legal obligations. Action a provider 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 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 risk assessments, mental capacity assessments, theatre records and modified early warning scores. (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 ensuring staff complete anaesthetic and sedation records accurately, ensuring all prescriptions are clear and patient details and allergy status is recorded, ensuring when medicines are not administered at the recommended time intervals as per national guidance that patients are informed, and consent has been obtained, ensuring fridge temperatures are measured and monitored at all times and having a robust system to ensure out of date medicines are removed in a timely manner.(Regulation 12 (1) (2) (g))
- 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))

Summary of this inspection

- The service must ensure all risks to performance are recorded and acted upon. (Regulation 17 (1) (2) (a) (b))
- The provider must ensure that patients that have 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 under 18.
- 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	Inadequate	Not inspected	Inspected but not rated	Inadequate	Inadequate
Overall	Inadequate	Inadequate	Not inspected	Inspected but not rated	Inadequate	Inadequate

Inadequate

Termination of pregnancy

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

Are Termination of pregnancy safe?

Inadequate

Our rating of safe went down. We rated it as inadequate.

Mandatory training

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

Most mandatory training was delivered online and this was expanded during the COVID-19 pandemic to ensure staff could continue to access training. The service provided some face to face training such as manual handling and this had been provided through the pandemic.

The registered manager maintained a computer spreadsheet of mandatory training completed by all staff along with copies of training certificates in the staff file. The service provided information that showed 73% of clinical and 82% of non-clinical staff were up to date with mandatory training requirements.

Managers monitored mandatory training using the spreadsheet to recognise when staff's mandatory training was due for expiry, and alerted staff when they needed to update their training.

The mandatory training was comprehensive and met the needs of patients and staff. The training requirements for staff role were set out by BPAS nationally and this training matrix was displayed in the manager's office. However, managers told us they could arrange additional training to meet local needs and the needs of their staff. For example, they told us of planned training in the use of the evacuation chair in event of a fire.

Staff completed skills and drills simulation training which was a mix of live simulation and round table discussions. Topics included dealing with a haemorrhage during a procedure and over sedation of the patient.

Staff completed training on recognising and responding to patients with mental health needs and learning disabilities. However, the manager had recognised the need for additional training for staff in responding to patients experiencing an acute episode of mental ill health and was liaising with a local provider to get this training for staff.

Safeguarding

Termination of pregnancy

Safeguarding alerts and concerns were not always raised internally or with the local authority in line with best practice standards. This exposed patients to risk of ongoing harm. Staff were not always aware of local safeguarding contacts and processes. However, the service had access to a central safeguarding team for advice.

Staff did not consistently identify adults and children at risk of, or suffering, significant harm. We saw one patient where the safeguarding summary in their record stated they had post-traumatic stress following a history of sexual abuse which had not been reported to authorities. This was reviewed with the central safeguarding team who advised there was no statutory requirement to notify as the patient was now over 18. Following our inspection, BPAS told us they have now developed a policy to enable clinicians to make anonymous reports to local authorities regarding non-recent disclosures of abuse.

The registered manager kept a "Live Log" of all patients where safeguarding concerns were recorded. Cases were forwarded to BPAS safeguarding team and advice received in line with BPAS policy. We observed the log, and this showed in July 2021, three under 18's and 12 adults were referred to BPAS central safeguarding team, in June 2021, one under 18 and 10 adults and in May 2021, one under 18 and 13 adults. We reviewed the detailed safeguarding log submitted by the service for May to July 2021. We saw 35 adult safeguarding concerns were logged, of these 16 were referred to the central BPAS safeguarding team and four to the local authority. The log was not fully completed with gaps in columns, the manager review column not completed and response from central safeguarding team not always completed. Following the inspection, we asked the provider for further information on local safeguarding processes and found the 'Live Log' did not accurately reflect the actions taken as recorded in case notes.

We saw several examples where referrals to local authority safeguarding teams or other agencies may have been appropriate and were not recorded as having been made on the safeguarding log and it was not clear if a referral had been considered. The provider told us the log did not reflect all actions taken to safeguard patients and provided additional information. Following this we requested further information from the provider on three specific cases and the provider reviewed a 10% sample of the remaining 262 cases across three locations. They found one case at BPAS Merseyside where an adult did not have a safeguarding risk assessment completed despite a trigger for one being identified during their care.

Through discussions during and following our inspection, and our review of documentation including patient records and safeguarding logs we were not always assured staff demonstrated professional curiosity regarding safeguarding concerns.

We saw one patient's notes where consideration of Fraser competency was not correctly recorded. However, following our inspection BPAS provided evidence that this patient was an adult and therefore Fraser competency was not relevant.

The provider told us from April 2021 to June 2021 there had been 36 near misses nationally where safeguarding assessments had not been completed in a timely manner. Each of these patients did receive a safeguarding assessment before their episode of care was completed. They had identified a theme relating to failure to safeguard adults with mental health concerns; however, we were not given evidence of specific actions to address this theme. The provider told us that the safeguarding team were currently designing improvements to the electronic patient record system to support staff members to identify when a safeguarding risk assessment was required. This was not in place at the time of our inspection and was planned for August 2021.

However, staff received level three safeguarding adults and children training on how to recognise and report abuse. We saw 79% of clinical and 91% of non-clinical staff had completed this training.

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 central safeguarding team to request advice and support. The central team provided cover seven days a week from 9-5pm.

The organisation had policies and procedures for staff to follow if female genital mutilation or sexual exploitation were discovered, and staff were clear what actions they needed to take in this situation.

Patients could be accompanied by a partner, relative or friend for the subsequent consultation if they chose, and staff were knowledgeable regarding the signs of coercion.

Assessing and responding to patient risk

Though, staff completed and updated risk assessments for each patient these were not comprehensive nor removed or minimised risks. Staff did not always identify and quickly act upon patients at risk of deterioration following surgery.

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 attend the service are cared for in a safe and effective manner and in line with national guidance. This was exposing patients to the risk of harm.

Staff used modified early warning scores (MEWS), a tool to assess adult patients in recovery following surgery. However, they did not always complete this fully and correctly to identify deteriorating patients. They did not always escalate patients appropriately. Though the clinic treated patients under the age of 18, staff did not use specific early warning scores for children such as paediatric early warning system (PEWS).

The provider told us due to the ages of the adolescents receiving treatment at BPAS clinics they had baseline observations which were comparable to adults and the MEWS chart used had the ability to be adjusted for clients that have baseline observations which fell outside of normal parameters. The provider told us they had not identified differences in the adolescent population in any form and felt that the MEWS tool was suitable for use for all ages.

We reviewed the abortion related complications identification and management BPAS policy (review date November 2023) which did not reflect the assessment of children under 18 years of age when using the MEWS assessment. We were therefore not assured that all clinical staff would understand the key risks of patient identification and deterioration specifically children under the age of 18 years. However, the BPAS treatment policy did outline differences in cervical preparation requirements for women aged 18 and under.

We reviewed MEWS charts in 10 patient records and in nine out of 10 records these were incorrectly completed. In five records we found observations had not been fully completed, in two records the totals were incorrect and in two records there was no evidence of escalation of MEWS of 5 or above as per BPAS guidance. In one patient record we saw MEWS recorded as unresponsive, but the simultaneous nursing note stated, ‘patient is awake’. In addition, one of the patients who had their care transferred from a BPAS location in the North East had a final MEWS score of three with no evidence of escalation or continuance of observations until a MEWS had improved

In six patient records we reviewed the doctor had not completed the pre-operative assessment and in two records the surgical safety checklist was not completed.

We were told the audit of case notes which included safer surgery checklist compliance and MEWS was suspended in 2020 due to the COVID-19 pandemic.

Staff completed risk assessments for each patient using a standardised BPAS template. However, risks assessments were not individualised, nor did they address all key risks. For example, in the four patient records for the service users who had their care transferred from a BPAS location in Yorkshire and the North East on 9 and 10 of June 2021 there was no evidence of the need to transfer, the care provided during that time and the delays they experienced with their treatment in their records or discharge plan.

Patients were at 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 service used exclusion/inclusion criteria that was set nationally by BPAS in the 'Treatment Suitability' policy. This clearly outlined the types of suitable treatment against known underlying conditions such as anaemia, hypertension and asthma. However, the service provided an alert sent to staff in March 2021 which showed BPAS had seen a rise in suitability related incidents. This related to clients being booked and attending treatment appointments when their suitability had not been confirmed, or they had factors which made them unsuitable for treatment at BPAS. This included incidents where clients had been provided cervical preparation before their suitability had been confirmed which increased the risk of complications.

However, staff knew about and dealt with some specific risks. For example, VTE assessments were completed in all but one patient record we reviewed. VTE stands for venous thromboembolism and is a condition where a blood clot forms in a vein.

We observed the daily 'huddle' which took place prior to the surgical treatment list and this included all necessary key information to keep patients safe.

Midwife and nurse staffing

The service had enough staff with the right qualifications, skills, training and experience to keep patients safe from avoidable harm and to provide the right care and treatment. Managers regularly reviewed and adjusted staffing levels and skill mix, and gave bank, agency and locum staff a full induction.

The service had enough nursing and support staff on each shift to keep patients safe. However, at the time of our inspection the service had two vacancies for a health care assistant and a clinical nurse manager. Following our inspection, the service provided information showing a further two vacancies for an operating department manager and a perioperative practitioner.

Managers told us staffing was a cause for concern due to sickness absence and staff isolating due to COVID-19. This had been escalated through regional management structures and was on the risk register. The service was recruiting to the vacancies and using staff from other units as well as bank and agency staff to ensure minimum staffing levels were reached.

Managers told us a staffing review was underway to identify the optimum staffing levels needed. During our inspection, staffing was planned using the BPAS staffing requirements matrix which identified the number and type of staff required for different types of clinics and treatment lists.

Managers accurately calculated and reviewed the number and grade of midwives, nurses, nursing assistants and healthcare assistants needed for each shift. The registered manager planned staffing in advance using an online rota and recorded actual staffing on the same system. This allowed the registered manager to flex staffing and identify any gaps which might require agency or bank cover.

The registered manager maintained a log of disclosure and barring service (DBS) checks for all staff which highlighted when these were due for renewal, which was every three years.

Managers made sure all bank and agency staff had a full induction and understood the service. The registered manager checked agency staff's CVs and completed agency checklists which detailed mandatory training completed and immunisation history. At the time of our inspection, the service did not have any long-term agency staff but was using bank and agency staff to ensure it met minimum staffing requirements. We spoke to an agency member of staff who told us they had received an induction on their first shift. The registered manager told us agency staff could access BPAS mandatory training if required. The induction for staff was set centrally by BPAS, however the registered manager told us they were looking at what changes might be needed to local induction.

Medical staffing

The service had enough medical staff with the right qualifications, skills, training and experience to keep patients safe from avoidable harm and to provide the right care and treatment.

The medical staff matched the planned number for surgical termination of pregnancy treatment days in line with the requirements outlined by the BPAS staffing matrix. The service employed two doctors. The registered manager told us there had been no issues with surgical staffing and they were able to get the number of surgeons needed to meet the number of surgical lists planned.

On days where surgery was taking place under general anaesthetic there was always a surgeon, an anaesthetist and an operating department practitioner who acted as anaesthetic assistant in the treatment room.

The registered manager told us a central register was maintained which outlined which surgeons were competent to carry out each type of procedure and this was monitored centrally by BPAS.

Records

Staff kept detailed records of patients' care and treatment. However, not all records were clear, legible and up to date.

Electronic patient records for consultations and early medical abortion were implemented in November 2020. All other patient records were paper. Records included initial and on-going consultation information, documentation of patient care during the operative phase and anaesthetic records for surgical termination of pregnancy (STOP).

Storage of paper records was adherent to GDPR (General Data Protection Regulation) and maintained patient confidentiality. Computers had been positioned to minimise the likelihood of people seeing patient records and privacy screens were in place to reduce to risk. Paper records were stored securely in in a small external building. This building was gated, and the gate and door secured by three locks. It was fireproofed and had a burglar alarm.

Patient records were comprehensive, and all staff could access them easily. We observed staff reading through a patient's notes together prior to the patient being brought into the treatment room.

In all records we reviewed there were discharge letters for patient's GPs.

However, not all patient records were fully completed, clear nor legible. In four out of ten records we reviewed the operation notes were not legible. We found discharge plans were not complete in one record and incomplete or incorrect observations in nine out of ten records. We also found unclear recording of consent in three patient records and pre-operative assessment not completed by a doctor in six patient records.

When patients were transferred from one BPAS site to another, records were inconsistent with regard to documentation of risk assessment, MEWS, and duty of candour. When patients were transferred to a new team, there was no handover documentation and transfer documents were not completed in every instance increasing the risk of staff having delayed access to patient information.

Managers told us audits of patient records has been suspended in 2020 due to the COVID-19 pandemic. Senior managers told us there were going to review the audit programme at corporate level.

Medicines

The service did not use systems and processes to safely prescribe, administer, record and store medicines.

Staff did not consistently follow systems and processes when safely prescribing, administering, recording and storing medicines.

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

Medicines were prescribed onto the surgical records or on a 'as required or variable prescription chart'. The as required variable prescription chart did not have a space for the patient's details and allergy status to be recorded. Staff wrote the patient's name or initials and their patient number on the top of the chart. Allergies were not documented. We found some prescription charts had no details of the patient and could not be certain the chart belonged to the patient. We found handwritten medicines were not clearly written, which may increase the risk of medication errors. For example, one prescription had been prescribed as POP, which was an abbreviation for a medicine.

Medicines used for medical abortion were not always given at the time intervals recommended in national guidance [*NICE NG140 Abortion care]*. Although the provider did not follow NICE guidance on the time intervals for medicines used for medical abortion, the clinical advisory group had considered available evidence and best practice when formulating treatment plans.

The way some medicines were prescribed for medical abortion was 'off label' or unlicensed. There was no evidence in the notes we reviewed that this had been discussed with women to take account of their preferences and allow them to make informed decisions about their treatment.

Medicines issued by nursing staff known as TTO (to take out) packs did not always have the name of the pharmacy supplier address of the clinic 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 did not always store and manage 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. Medicines fridge temperature records were completed only on the days the service was open and the service did not have a way of measuring the temperature of the fridge when it was closed. We found that anaesthetic and sedation records were poorly completed. For example, there were no signatures or times of administration, so it was not possible to tell from the records which medicines had been administered, when, or by whom. There was a section in the surgical notes for doctors to document their pre-operative review. The review from a doctor before the procedure was not always signed so we could not be sure this had been completed.

Incidents

The service did not always managed patient safety incidents well. Staff did not consistently recognise and report incidents and near misses. When things went wrong, staff apologised but patients were not always given a written apology or support. Managers did not consistently investigate patient safety incidents. However, when managers did investigate incidents, they shared lessons learned with the whole team and the wider service.

Staff knew what incidents to report internally and how to report them using an online incident reporting system, however we were not assured staff reported all incidents and near misses. We reviewed the BPAS incidents, near misses and serious incident policy which showed reporting incidents to external bodies including the CQC was the responsibility of the area manager, not the registered manager. It did not outline what types of incidents should be reported to CQC, though following our inspection the service told us this was highlighted on the electronic reporting system.

Staff were required to confirm their understanding of the incidents, serious incidents and near miss policy during induction and received additional e learning on the incident reporting system. However, the service did not provide compliance rates with this training at the time of inspection. During the factual accuracy period, the provider told us 86% of Nurse and Midwife Practitioner's had completed this e-learning module.

The service told us there had been no serious incidents reported from January to June 2021. However, we saw the service transferred three patients in this period due to complications. These were not reported as serious incidents or near misses. The service also reported that throughout 2020 staff reporting of near misses had decreased significantly

We also found an incident which had not been recognised or reported regarding consent. We raised this with the registered manager who immediately reported it using the online system.

Managers investigated some incidents. However, incidents were reported and reviewed centrally to decide if a serious incident should be declared and investigated. In the six cases involving emergency transfer, 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 learnt lessons from them. However, following the inspection the provider told us local managers submit initial reports and 72-hour reviews of 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 all incidents the provider reported, for example relating to transfers between clinics. Two alerts 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 learning from serious incidents and low-level investigations was turned into summary reports shared via an automatic online process directly to staff.

Staff did not fully understand the duty of candour. Though 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 in line with Regulation 20 of the Health and Social Care Act 2008 as it did not require staff to provide written duty of candour. The service told us six patients had their care transferred to an NHS provider in an emergency between September 2020 and August 2021. In five of these cases only verbal duty of candour was enacted, and no written duty of candour was undertaken, in one case no duty of candour was undertaken. At our last, inspection we told the service it should ensure it carried out full duty of candour in all appropriate cases.

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.

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.

The service had one never event in the treatment room, in August 2020 during vasectomy surgery, this had been reported as a serious incident and investigated. Never events are serious patient safety incidents that should not happen if healthcare providers follow national guidance on how to prevent them. 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. Though verbal duty of candour was fulfilled written duty of candour was not applied in this case.

The registered manager had taken immediate action to mitigate risks identified through the incident investigation. At the time of our inspection, vasectomy services were suspended at the location until the registered manager was assured all actions and learning had been implemented including staff training.

All staff investigating incidents were trained in root cause analysis.

Inadequate

Termination of pregnancy

Are Termination of pregnancy effective?

Inadequate

Our rating of effective went down. We rated it as inadequate.

Evidence-based care and treatment

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

Staff followed up-to-date policies to plan and deliver high quality care according to best practice and national guidance. In the recovery area outside the treatment room staff could access an emergency algorithm folder. This included relevant up to date guidelines such as the 2012 Association of Anaesthetists safety guidelines, the maternal sepsis toolkit from Sepsis UK and 2021 Resuscitation Council post resuscitation care guidelines.

We observed the daily 'huddle' that took place prior to the surgical list starting. In this staff referred to the psychological and emotional needs of patients.

However, managers did not consistently check to make sure staff followed guidance as all observational audits in the treatment room and audits of patient's notes had been suspended due to the COVID-19 pandemic.

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.

There were six transfers from BPAS Merseyside to NHS care. During inspection, we saw no evidence of a review of these cases to identify any themes and trends or learning. However, following the letter sent by the Care Quality Commission post-inspection under Section 31 of the Health and Social Care Act 2008, the provider told us incidents, including transfers, are reviewed and discussed locally and nationally.

Multidisciplinary working

Doctors, nurses and other healthcare professionals worked together as a team to benefit patients. They supported each other to provide good care.

Staff held regular and effective multidisciplinary meetings to discuss patients and improve their care. The daily safety huddle was attended by all members of the multidisciplinary team and the registered manager.

We observed staff of all disciplines working well together in the treatment room.

Staff worked across health care disciplines and with other providers when required to care for patients. The service had a transfer agreement with a local NHS trust which was reviewed annually which outlined roles and expectations when patients had their care transferred in an emergency.

Consent, Mental Capacity Act and Deprivation of Liberty Safeguards

Staff did not consistently support patients to make informed decisions about their care and treatment. They did not follow national guidance to gain patients' consent. They did not always show awareness of how to support patients who lacked capacity to make their own decisions or were experiencing mental ill health.

Staff did not always gain consent from patients for their care and treatment in line with legislation and guidance. Though staff recorded consent in the patients' records this was not always clear nor in line with the treatment carried out.

We also saw occasions where patients did not receive the procedure they consented for and the change was not documented or the reasons for doing so.

One patient signed consent for vacuum aspiration under general anaesthetic, the procedure carried out was dilatation and evacuation as recorded in surgery notes, theatre register, discharge letter and HSA4 form.

In one patient's records we found the consent for the use of mifepristone medicine was unclear, it was been ticked but the form also stated mifepristone not to be used.

In another patient record we saw the patient had reported to the provider she was unhappy with her teleconsultation and felt she was not given enough information on her options for treatment between general anaesthetic and conscious sedation or location of procedure to make an informed choice.

We saw no record which clearly demonstrated the two-step process of consent in line with best practice guidance. We saw no evidence in all of the records we reviewed that patients were informed of the risks of travelling significant distances following administering of medications.

Managers did not audit consent forms or carry out observational audits of consent as all case note audits had been suspended in 2020 due to the COVID 19 pandemic.

Staff did not understand how and when to assess whether a patient had the capacity to make decisions about their care. We saw no evidence of mental capacity assessment for patients identified with cognitive impairment.

We saw an example where patient records identified a learning disability, however there was no documented evidence of a mental capacity or best interest assessment being carried out. This meant there was no evidence the patient had the capacity to provide informed consent.

Managers told us there was only one member of staff who could carry out a capacity assessment and they did not attend the clinic every day it was open and were not there during our inspection. Following our inspection, the provider told us staff training on consent included training on assessment of patient capacity. Therefore, we were unclear of the arrangements for assessment of patients' capacity under the Mental Capacity Act 2005.

Inadequate

Termination of pregnancy

The service told us staff received training on the Mental Capacity Act 2005 or Mental Health Act as part of consent and safeguarding training. We reviewed the training presentation for consent and saw that only the Mental Capacity Act was mentioned and there was no further detail given. This meant we were not assured staff received comprehensive and effective training on the Mental Capacity Act 2005 or Mental Health Act

However, staff received training on and understood Gillick Competence and Fraser Guidelines. They supported children who wished to make decisions about their treatment and altered the BPAS central safeguarding team to all under 18 years who presented for treatment. The service told us between July 2020 and June 2021 they treated 100 16 and 17-year olds, 30 13 to 16-year olds and no under 13-year olds.

Are Termination of pregnancy responsive?

Inspected but not rated

Meeting people's individual needs

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 and providers.

Managers made sure staff, and patients, loved ones and carers could get help from interpreters or signers when needed. They could access British Sign language interpreters as well as translators and used visors rather than face masks to support patients who used lip reading.

We saw staff respond openly and with compassion to an extremely distressed patient in the treatment room. Staff preserved patients' privacy and dignity throughout treatment.

Pre-abortion counselling is offered to all patents and uptake is 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.

The service had a transfer agreement with a local NHS trust in case a patient required transfer due to an emergency or complication. This agreement was reviewed annually and supported by a written procedure for all staff to follow which included arrangements for handover of care and transfer of patient notes. We saw when care was transferred in an emergency, managers followed this up with the NHS provider to coordinate any further care or treatment.

Are Termination of pregnancy well-led?

Inadequate

Our rating of well-led went down. We rated it as inadequate.

Leadership

Inadequate

Termination of pregnancy

Leaders did not understand and manage the priorities and issues the service faced. However, they were visible and approachable in the service for patients and staff.

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 carried out an unannounced inspection on 4 August 2021 following information highlighted at routine engagement with another BPAS location on 15 June 2021. This raised concerns about management of the service and the safety of patients. Senior management confirmed the business continuity plan did not include disruption to the service due to the unexpected absence of a key clinician. We were told the review of the business continuity plan was being developed at corporate level and expected to be completed by October 2021.

During and following the inspection we found examples of events and incidents which should have been submitted as statutory notifications the Care Quality Commission in line registration requirements for providers. This included serious incidents, safeguarding and police involvement.

Culture

Staff felt respected, supported and valued. They were focused on the needs of patients receiving care. The service had an open culture where 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. Managers told us they aimed to continually improve and provide 'exemplary' care to patients. We observed staff worked together to share responsibility and care for patients. This included managers who were happy to join in with the wider team to meet the needs of the patients.

We observed positive working relationships throughout our inspection and staff at all levels worked together and supported each other. We attended the treatment room during our inspection and observed effective teamworking. We saw all staff showed respect for each member of the multidisciplinary team and the contribution they made.

Staff we spoke with told us they felt supported by their managers. They spoke positively about the culture and were passionate about the service and the need to provide safe and compassionate care to patients.

Managers had recognised culture in the treatment room as a possible contributory factor in a never event in 2020, as a healthcare assistant had not felt able to challenge a doctor. Therefore, they planned additional communication training in August 2021 led by the clinical director to improve communication and promote a culture of positive challenge.

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 at all levels 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 any 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 five patients from BPAS in the North East to BPAS Merseyside. 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.

The service provided copies of the audit dashboard for August 2020 to July 2021. These had three areas, medicines management, clinical supervision and infection prevention. The dashboard simply said 'achieved' or 'not achieved' with no explanation of levels of compliance and what constituted 'achieved'. In all months, all audits showed as 'achieved'. There was no information provided for February 2021.

Despite medicines management audits showing as 'achieved' we found areas of poor practice during our inspection. This meant we were not assured the service had an effective system of audit to address areas of poor performance and ensure safe care and treatment.

The service provided copies of five quarterly cleaning audits carried out between August 2020 and August 2021. These showed high levels of compliance, all above 95%. However, in all five audits unclean sinks were highlighted but there was no evidence of action taken to address this. Therefore, we were not assured managers and staff learnt from local audits and made changes to practice following audits.

The BPAS policy for duty of candour was not in line with Regulation 20 of the Health and Social Care Act 2008 as it did not require staff to provide written duty of candour.

The BPAS client administration system with its electronic patient records for consultations and early medical abortion was implemented in November 2020. However, BPAS Merseyside was not a pilot location and therefore many elements of the patient record system including surgical records remained in paper format. There were plans to develop a full electronic patient record in the future.

Management of risk, issues and performance

Leaders and teams did not always use systems to manage performance effectively. They did not consistently identify and escalate relevant risks and issues nor identify actions to reduce their impact. However, the service had plans to cope with unexpected events.

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 Merseyside, and two other locations.
- The registered provider must implement a safe system and process at BPAS Merseyside, 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 Merseyside, 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.

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.

We reviewed the risk register post inspection and saw the recent transfer of patients from a BPAS locations in the North East to Merseyside on the 9 June 2021 had not been identified as a key risk. The Care Quality Commission had escalated concerns regarding the safe transfer of patients following this incident and had requested assurance that the provider would review systems and process to address this.

In September 2020, BPAS nationally suspended all audits bar medicines management, infection prevention and clinical supervision due to the COVID-19 pandemic. On inspection we found areas of poor practice that may have been highlighted by a full and effective audit schedule. There were no observational audits of practice in the treatment room or audits of adherence to World Health Organisation standards on Steps to Safer Surgery.

Local managers met with regional managers on a quarterly basis to look at capacity reports, staff absence and any incidents reported. There was a set agenda for these meetings which included incidents and patient satisfaction reports. We requested minutes of local team meetings and received the schedule of meetings and agendas but no minutes. This meant we could not be assured all items on the agenda were regularly discussed, and information disseminated to staff.

At this inspection we found areas of poor practice that the location had been told it must or should address at last inspection. These related to medicines management, duty of candour and local governance. This meant the service was not acting effectively to correct continued breaches of regulatory requirements of the Health and Social Care Act.

However, the service had a comprehensive business continuity plan which was last reviewed March 2021. The risk register had been reviewed by the treatment unit manager and actions identified with timescales to manage risk.

We reviewed the annual unit assurance submission for BPAS Merseyside submitted in September 2020. This also included equipment checks, including emergency equipment, staff training, DBS and registration, stock checks, unit management and COVID-19 specific checks. The submission showed this was fully complete in all areas and no action needed.

Managing information

Inadequate

Termination of pregnancy

Data or notifications were not submitted to external organisations as required. The information systems were integrated and secure.

The registered manager and OQM told us it was the responsibility of the registered manager to submit such statutory notifications to the Commission. However, we were not assured notifications were consistently submitted in line with statutory requirements. For example, the provider had reported an incident to the police, and we did not receive a statutory notification regarding this.

During our inspection we saw documentary evidence that two doctors had reviewed the reason for termination prior to signing HSA1 forms. We also saw that the reason for the termination of pregnancy was provided on all HSA1 forms. This was in line with the Department of Health Required Standing Operating Procedures (RSOP). The service used an online secure portal to submit the forms. The provider did not have a current audit process to ensure that the completion of legal paperwork (HSA1 and HSA4) met the requirements of the Abortion Act 1967, however the electronic patient record system automatically generated reports on the completion and submission of the forms.

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
Family planning services Diagnostic and screening procedures 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 20 HSCA (RA) Regulations 2014 Duty of candour

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

This section is primarily information for the provider

Requirement notices

Termination of pregnancies

Treatment of disease, disorder or injury

Regulated activity	Regulation
Family planning services Diagnostic and screening procedures Surgical procedures Termination of pregnancies Treatment of disease, disorder or injury	Regulation 13 HSCA (RA) Regulations 2014 Safeguarding service users from abuse and improper 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

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