British Pregnancy Advisory Service

BPAS - Doncaster

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 this service inadequate overall 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 did they remove or minimise all key risks
- 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
- 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 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 had processes in place to make sure everyone completed it
- 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
- 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. 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 they had taken action to address the risks and we 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. In the reporting period 1 April 2020 to 31 March 2021, the centre carried out 904 surgical terminations of pregnancy (SToP) under local anaesthetic/conscious sedation and under general anaesthetic, 1,897 early medical abortions and 136 late medical terminations of pregnancy. The service also carried out 184 non scalpel vasectomies. The centre 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 • No never events and no serious incidents requiring investigation reported from July 2020 to June 2021 • 12 patients were transferred out to another hospital from December 2020 to May 2021 • No incidences of hospital acquired Methicillin-resistant Staphylococcus aureus (MRSA) • Six complaints were received within the reporting period from August 2020 to August 2021

Summary of findings

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Summary of this inspection

Background to BPAS - Doncaster

BPAS Doncaster 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 Doncaster opened in 1982.

The BPAS Doncaster clinic undertakes; early medical and late medical termination of pregnancy (MTOP), Surgical Termination of pregnancy (SToP), under general anaesthetic, conscious sedation and local anaesthetic up to gestation of 23+6, feticide treatment, screening for sexually transmitted diseases, contraception advice, counselling and non-scalpel vasectomy procedures. It offers a full range of contraception including long acting reversible contraception (LARC) to clients attending for surgical and late medical treatment. A pilot around restoration of the LARC offer to clients post early medical abortion (EMA) treatment is in progress. This offer was suspended due to COVID-19.

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 provide assurance 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 October 2019. At that time we rated the service as good overall with requires improvement in responsive.

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 West for surgical termination of pregnancy.

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.

Summary of this inspection

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 the operational quality anager
- spoke with 14 other members of staff including nurses, midwives, surgeon, operating department practitioner and health care assistants
- reviewed 13 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 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: staff must administer medicines at the recommended time intervals as per national guidance, complete prescription charts on the day of treatment, complete anaesthetic and sedation records accurately, stop the use of pre-labelled syringes, audit of medicines management (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))
- 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))

Summary of this inspection

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

Our rating of safe 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 throughout the pandemic.

The registered manager maintained a computer spreadsheet of mandatory training completed by all staff along with copies of training certificates in staff files. The service provided information that showed 83% clinical and 92% non-clinical staff were up to date with training compliance. The target range for mandatory training was 100%. The registered manager told us it had been difficult arranging training courses with external providers during the pandemic. The service had requested training dates for face to face basic life support training. Immediate life support training had been booked for the 24th September 2021. There were several new staff who were currently in the process of completing the training programme. New starters were expected to complete induction training within a three-month timeframe.

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 by email. Staff verified this on inspection.

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.

Safeguarding

Inadequate

Termination of pregnancy

Safeguarding alerts and concerns were not always raised with the local authority in line with best practice standards. This exposes patients to risk of ongoing harm. However, staff received training at level three safeguarding 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.

The Registered Manager (RM) told us they kept a "Live Log" of all patients where safeguarding concerns were recorded. Not all incidents that identified safeguarding concerns were forwarded to BPAS safeguarding team for advice in line with BPAS policy. The safeguarding log did not always show when incidents were notified to social services and GP, not all concerns were reported to the local authority. We found from our discussions with staff and through our review of patient records including the safeguarding log, there was limited evidence that staff demonstrated professional curiosity to understand safeguarding concerns or fully documented these discussions and subsequent decision making. However, following the inspection the service provided information that showed some local authorities had confirmed in cases where concerns had been discussed with allocated social workers and new referrals were not required.

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.

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 surrounding seven specific cases and the provider reviewed a 10% sample of the remaining 262 cases across three locations. The provider reviewed three cases treated at BPAS Doncaster and reported that policies and safeguarding procedures had been followed and no further action was required. One of the cases reviewed involved a young person who had made an allegation of sexual assault resulting in pregnancy. The police attended the service in relation to the allegation on the day of inspection and the provider told us staff had escalated the concern to the internal safeguarding team for further advise, however they advised no further action was needed and no referral to the local safeguarding authority had been made in line with best practice. However, following the inspection the service provided evidence that a referral had been made to the local authority.

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 these were planned for August 2021.

There was a process to complete safeguarding risk assessment for anyone under the age of 18 years or any patient deemed as vulnerable. The organisation had policies and procedures for staff to follow if cases of female genital mutilation or sexual exploitation were discovered, and staff were clear what actions they needed to take in this situation. The service could escalate safeguard concerns to the internal safeguarding team to request advice and support. The team provided cover seven days a week from 9-5pm.

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.

The registered manager and the clinical lead for service were the named safeguarding leads. We saw 89% of clinical staff and 100% of non- clinical staff had completed this safeguarding training.

Inadequate

Termination of pregnancy

Cleanliness, infection control and hygiene

The service had processes in place to control infection risk. Staff used equipment and control measures to protect patients; however, staff did not always adhere to the corporate infection control policy regarding uniform guidance.

Clinic areas were clean and had suitable furnishings which were well-maintained. We inspected consultation rooms, a waiting room, utility rooms and storerooms and found them all to be visibly clean. Staff cleaned equipment after patient contact and labelled equipment to show when it was last cleaned. We saw green 'I am clean' stickers being used to identify equipment that had been cleaned and ready for use.

We were satisfied that the service was ensuring all equipment meets infection and prevention control requirements. This was a Must do action from the previous inspection in October 2019,

Staff worked effectively to prevent, identify, and treat surgical site infections. We saw that there were enough hand washing sinks and alcohol gel hand rub in all areas that we visited and observed that staff washed their hands and followed the world health organization's five moments for hand hygiene guidance.

All clinical areas we visited had arrangements in place for the handling, storage and disposal of domestic and clinical waste and sharps, however bathrooms for public use did not always have domestic disposal bins.

As part of the providers response to the COVID-19 pandemic the service had environmental risk assessments of each clinical area to ensure the appropriate social distancing guidance for staff and patients was in place to prevent potential transmission of the COVID-19 virus. All areas of the building had COVID-19 environmental risk assessments for maximum occupancy and where required excess seating was removed. All visitors to the facility were requested to use alcohol hand gel at point of entry. Lateral flow testing of staff was undertaken twice weekly in line with the Department of Health and Social care recommendations.

BPAS monitored infection control practice using the essential steps audit. Essential steps were developed by the Department of Health to support existing infection control recommendations, with the aim of addressing infection control throughout the patient journey. The service achieved essential steps audit results of 100% compliance throughout the reporting period of January 2021 to July 2021. The essential steps audit tool was instigated monthly and reviewed hand hygiene, personal protective equipment, aseptic technique, and sharps in varying practices. The Essential steps audit stated any required actions were shared at team meetings; however, we saw no evidence of this in the team meeting minutes we reviewed.

On the day of inspection, we observed two staff members arrive for work by car who entered the premises wearing scrubs increasing infection risks. The RM confirmed BPAS policy states that all staff were required to change into uniform on arrival to the premises. The service had staff changing areas where staff had access to clean theatre scrubs and individual staff lockers for valuables to be stored.

Cleaning records were not always up to date to demonstrate that all areas were cleaned regularly. We escalated this to the registered manager on the day of inspection.

Assessing and responding to risk

Inadequate

Termination of pregnancy

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 patients 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 completed risk assessments for each patient using a standardised BPAS template. However, risks assessments were not individualised nor addressed all key risks. For example, in the four patient records for the service users who had their care transferred from BPAS – Doncaster 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.

We saw no risk assessments of potential complications for patients taking medicines for cervical preparation and travelling long distances for their procedure. These medicines are used to prime, soften and open the cervix in preparation for surgery. The records review also evidenced no recording of MEWS (modified early warning scores) at point of, or reasoning for, transfer or to identify patient deterioration.

During the inspection we saw staff were not monitoring patients in the waiting room prior to surgery, two patients approached members of the inspection team to seek assistance for pain management. We discussed this with the clinical lead who stated that there was always a midwife available for waiting room oversight and patients were encouraged to approach them if they had any concerns.

Staff did not routinely undertake) observations or pain assessment at the first stage of the treatment process however, the service had a policy for pain management in line with best practice from Royal College of Obstetricians and Gynaecologists (RCOG).

BPAS - Doncaster are the only location performing late medical abortions, this often resulted in women receiving consultation and abortifacient medication at their nearest BPAS site and travelling large distances to complete the procedure at BPAS-Doncaster (the provider describes this as a ‘split-site’ procedure). This meant there was a risk of complication during patient travel.

The provider told us there is a national shortage of surgeons able to perform late surgical termination of pregnancy (STOP) procedures. During our inspection a senior management 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 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 service disruption. The location did have 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 travel.

Staff used modified early warning scores (MEWS), a tool to assess patients in recovery following surgery. However, they did not always complete this fully and correctly to identify deteriorating patients. The service did not have a specific paediatric early warning score (PEWS) for use with appropriate children undergoing surgical terminations of pregnancy. This meant that any patients under the age of 16 were being assessed as adults.

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 fall 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.

We reviewed MEWS charts in 13 patient records and saw three observation charts where patient MEWS scores had increased however, no action was recorded in response to this. Patients were at risk of not receiving clinical/medical intervention in a timely manner if elevated MEWS scores were not escalated appropriately. 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.

The registered manager was not escalating risk in line with provider policy. There had been 12

patients transferred to the local NHS acute trust due to complications arising during surgical intervention. We requested details of incidents that had been classified as a serious incident within the last 12 months, however, we were informed that none had been escalated as a serious incident within this time frame. We requested additional detail of the external transfers post inspection which highlighted eight of the 12 incidents were notifiable safety incidents. However, the provider had not investigated these as serious incidents or reported to the regulator in line with the regulations.

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.

We saw data which evidenced 10 patients treated during COVID-19 for surgical termination of pregnancy (STOP) had not had pre-assessment scans impacting on incorrect gestation.

Staff carried out safety checks and kept records of these in a maintenance schedule; however, this did not reflect actions identified on the refurbishment plan. The schedule stated that a fire alarm BPAS unit test was carried out weekly. The refurbishment plan identified a fire door that required attention as it was not functioning correctly; however, this was not documented in the maintenance schedule.

Midwife and nurse staffing

Inadequate

Termination of pregnancy

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 to keep patients safe. At the time of our inspection the service had several vacancies. Interviews had been conducted for a part time nurse/midwife practitioner position. The service had shortlisted for one part time healthcare assistant, administrative assistant and two midwife practitioners (overnight).

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. On the day of inspection, the service had requested the assistance of a continuity nurse practitioner due to rota gaps who works across the North West region for BPAS.

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. 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.

Managers accurately calculated and reviewed the number and grade of midwives, nurses, nursing assistants and healthcare assistants needed for each shift in accordance with national guidance. Managers made sure all bank and agency staff had a full induction and understood the service.

The registered manager maintained an electronic 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 curriculum vitae's and completed agency checklists which detailed mandatory training completed and immunisation history.

At the time of our inspection, the service was using bank and agency staff to ensure it met minimum staffing requirements. We spoke to two agency members 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. Managers regularly reviewed and adjusted staffing levels and skill mix and gave locum staff a full induction.

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 registered manager told us surgical staffing was monitored closely 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. We spoke to the medical team on inspection who clarified that medical staffing was managed and monitored by the registered manager.

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.

When patients were transferred from one BPAS site to another, records were inconsistent with regard 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.

We observed incomplete or incorrect observations in five out of 13 records reviewed. Not all patient records were fully complete, in one patient's notes the surgical safety checklist (sign out) had not been completed to evidence the counting of swabs and removal of cannula, and not all documents were signed and dated. We found discharge plans were completed on a standardised template which highlighted incorrect recording of consent and treatment type. We also found unclear recording of consent in three patient records.

Audits of records had been suspended during the COVID-19 pandemic. Senior managers told us there were going to review the audit programme at corporate level.

However, records were a mixture of paper and electronic. 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 (Tops). We reviewed 13 sets of patient records and we saw that HSA1 forms (legal forms which must be signed by two doctors who agree that a patient is suitable to undergo a termination of pregnancy as per The Abortion Act, 1967) were present for every patient; with two signatures from doctors.

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.

Staff could access patient records easily. We observed staff reading through a patient's notes prior to the patient being brought into the anaesthetic room.

Medicines

The service did not always have systems and processes in place to safely administer and record medicine use.

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

Termination of pregnancy

We found that standardised printed prescription charts were completed in advance of women attending the clinic, in some cases up to a week beforehand. These charts included multiple medicines from the same class. Prescriptions were not tailored to the individual needs of women; for example, we saw a woman had been prescribed a medicine when blood test results had indicated this was not required. Although the medicine had not been administered, this blanket prescribing increased the risk of adverse effects from giving more than one medicine from the same class or giving medicines which were not required.

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.

Syringes were stored pre-labelled in cupboards outside of their sterile packaging. This increases the risk of infections or contamination. In addition, labelling syringes before they are filled increases the risk of the wrong medicine being drawn up and given.

Medicines issued by nursing staff known as TTO (to take out) packs did not always have the name of the service on the label, which is a legal requirement. The provider told us that an additional label was affixed to medicines when they were dispensed to the patient. There were no systems in place to oversee the stock control of TTO packs or to track them at the point of discharge.

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. In addition, batch numbers of medicines given were not recorded which meant it would not be possible to determine who had received which medicines in the event of a product recall.

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

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. Medicines fridge temperature records were completed daily in accordance with national guidance to ensure the safe storage of medicines.

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 in line with best practice. 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. However, managers investigated some incidents and shared lessons learned with the whole team and the wider service.

Staff knew what incidents to report internally and how to report them using the online incident reporting system. Staff were required to confirm their understanding of incidents, serious incidents and near miss policy during induction and received additional eLearning on the incident reporting system. However, the service did not provide compliance rates about this training at the time of writing this report. During the factual accuracy period, the provider told us 100% of Nurse and Midwife Practitioner's had completed this e-learning module.

Following inspection, we requested reported incidents that had required transfer to the local acute trust. Information provided evidenced that there had been 12 transfers due to complications arising within this timeframe. The location had only reported three of these as a serious incident in line with provider policy. The remaining incidents had been reviewed and did not progress to a serious incident investigation. None of the incidents were reported as notifiable safety incidents in line with CQC registration standards to identify trends, learning or required actions to prevent an occurrence.

We reviewed the BPAS incidents, near misses and serious incident policy which highlighted there was no expectation to safeguard or report to the regulator.

Senior leaders told us that all incidents are uploaded onto the electronic reporting system and escalated to the risk and governance team who decide whether incidents are escalated as a Serious Incident Requiring Investigation (SIRI). In the 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.

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 internally 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 transfers between clinics and two related the recall of equipment which was not reflective of learning from incidents. Therefore, we were not assured the

Inadequate

Termination of pregnancy

'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 were 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 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, 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. In the case of the patient's whose care was transferred from BPAS-Doncaster on the 9 June 2021, we could not find evidence of written duty of candour in all five patient records. The registered manager told us that verbal duty of candour was instigated; however, they would not routinely undertake written duty of candour in line with provider policy.

We reviewed data post inspection which evidenced the provider had transferred 12 patients to the local acute trust from December 2020 to May 2021. All 12 patients had received verbal duty of candour; however, none had received written duty of candour in line with best practice guidance.

Are Termination of pregnancy effective?

Requires Improvement

Our rating of effective down. We rated it as requires improvement.

Evidenced 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.

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.

Staff told us that clinical supervision was provided, we reviewed clinical supervision data which evidenced 15 staff out of 19 had completed these. Two new staff members completing induction training were expected to have completed the training by 31 August 2021.

However, staff followed up-to-date policies to plan and deliver quality care according to best practice and national guidance. We saw staff refer to the maternal sepsis toolkit from the Sepsis UK. Staff confirmed that they referred to the 2021 Resuscitation Council post resuscitation care guidelines.

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

Competent staff

The service made sure staff were competent for their roles. Managers appraised staff's work performance and held supervision meetings with them to provide support and development. Staff were experienced, qualified, and had the right skills and knowledge to meet the needs of patients.

Managers gave all new staff a full induction tailored to their role before they started work. Managers supported staff to develop through yearly, constructive appraisals of their work. Appraisal rates compliance figures showed 84% compliance for clinical staff and 100% compliance for non-clinical staff.

Managers identified any training needs their staff had and gave them the time and opportunity to develop their skills and knowledge. Staff had the opportunity to discuss training needs with their line manager and were supported to develop their skills and knowledge.

We saw evidence to support skills and drills training with planned training dates assigned. This evidenced training compliance for sepsis (late medical) training of 87.5%. Sepsis training (early medical abortion) 75% compliance. Anaphylaxis training 67% compliance and a reported over sedation incident evidencing a compliance rate of 40% compliance. The clinical lead told us they had scheduled further dates for staff completion regarding the over sedation training and we saw evidence to support this.

The clinical lead told us that BPAS had instigated a teaching and clinical assessment training course to manage audit practice at location level. BPAS Doncaster had a named advanced nurse practitioner who was to attend this course and be the named audit lead for the site on completion.

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 12 transfers from BPAS Doncaster to NHS care. During our inspection we saw no evidence of a review of these cases to identify any themes and trends or learning. Following our inspection, we wrote to the provider under section 31 of the Health and Social Care Act 2008 and the provider told us incidents, including transfers, were 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.

We observed staff of all disciplines working well together in the theatre environment and clinical areas.

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.

Inadequate

Termination of pregnancy

Consent, Mental Capacity Act and DoLs

Staff did not consistently support patients to make informed decisions about their care and treatment. They did not follow national guidance to gain patient's 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.

We saw no record which clearly demonstrated the two-step process of consent in line with best practice guidance. There was no evidence of mental capacity assessment for patients identified with cognitive impairment. 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.

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. We saw there was no process in place for staff to evidence the assessment of mental capacity, Fraser or Gillick competence in line with best practice guidance.

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

Managers did not audit consent forms or complete observational audits of consent as record audits of patient notes had been suspended in 2020 due to the COVID 19 pandemic.

The provider told us staff received training on the Mental Capacity Act 2005 and Mental Health Act as part of consent and safeguarding training. We reviewed the training presentation for consent and saw that the Mental Capacity Act was included but not the Mental Health Act but 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.

Are Termination of pregnancy responsive?

Inspected but not rated

Meeting people's individual needs

The service was inclusive and took account of patient's 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 services.

Pre-abortion counselling was offered to all patents 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.

Inadequate

Termination of pregnancy

However, the service has a transfer agreement with a local NHS trust in the event a patient required transfer due to an emergency or complication. This agreement was reviewed and agreed 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 that the document had been reviewed and agreed April 2021 and signed by both the acute trust and the provider in June 2021. The non-emergency patient transfer flow chart within the agreement was last reviewed November 2018. However, following inspection the provider told us that the review date on the non-emergency transfer flow chart not being updated was due to an oversight and had been addressed. We saw evidence to support when care was transferred in an emergency, managers followed this up with the NHS provider to coordinate any further care or treatment.

Access and flow

People could access the service when they needed it and received care promptly. Waiting times from referral to treatment and arrangements to admit, treat and discharge patients were in line with national standards.

From July 2020 to June 2021, 70% of patients received point of consultation within one week from point of contact and 71% of patients were booked for consultation to treatment within seven calendar days (five working days). The provider told us that to provide a degree of procedural choice for women (in line with National Institute of Clinical Excellence (NICE) and RCOG guidance on abortion care. BPAS has maintained a second trimester medical abortion service at Doncaster and is currently the only provider to offer this option.

The service ensured waiting times for patients were reduced and in-line with Royal College of Obstetricians and Gynaecologists (RCOG) standards and Required Standard Operating Procedures (RSOP 11). This was a Must do action at the previous inspection in October 2019.

Waiting times were monitored weekly by a central team. The service was able to adjust lists and add additional appointments to meet demand. The service also expedited patients who were nearing the legal limit or who were under the age of 18. Date showed 39 patients from November 2020 to May 2021 had exceeded the Department of Health RSOP 11: Access to Timely Abortion which states that patients should be offered an appointment within five working days of referral or two weeks from referral to treatment. We reviewed this data which showed that 18 patients out of the 39 had failed to attend scheduled appointments for differing reasons.

The service monitored reasons for any delays from first consultation to treatment to ensure delays do not impact upon patient outcomes. This was a Must do action at the previous inspection in October 2019.

Patients were able to choose their own dates and times of appointment to suit their lifestyle and staff aimed to see patients as quickly as possible. Clinical staff at the telephone booking service carried out an initial consultation and offered patients a choice of dates, times and locations. This ensured patients were able to attend the most suitable appointment for their needs, subject to their gestation and clinical assessment.

Are Termination of pregnancy well-led?

Inadequate

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

Leadership

Inadequate

Termination of pregnancy

Leaders did not demonstrate clear oversight of the service and failed to consistently manage the priorities and issues the service faced. However, they were visible and approachable in the service for patients and staff.

The location was managed by a registered manager with assistance from an operation's quality manager. 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.

On inspection we discussed concerns regarding non-compliance of the service to notify the regulator (Care Quality Commission) regarding serious incidents, events that stop service and police involvement in line with provider registration. The registered manager was unaware of the need to escalate and report notifiable incidents.

There had been 12 patients requiring transfer to the local NHS acute trust due to complications arising during treatment. We requested incidents that had been classified as a serious incident within the last 12 months and were informed by the registered manager that none had been escalated within this time frame. We requested additional detail of the external transfer's post inspection which highlighted eight of the 12 incidents were notifiable safety incidents. The provider had deemed three of the incidents met the serious incident criteria in line with their policy. None of the incidents identified were reported as notifiable safety incidents in line with CQC registration standards to identify trends, learning or required actions to prevent occurrence.

The registered manager told us that safety incidents were logged on the electronic incident reporting system and reviewed by the central clinical Risk team. Potentially serious incidents were escalated to the serious incident declaration group comprising of the medical director, director of nursing and quality, associate director of risk and governance and the clinical risk manager. The registered manager told us that they maintain autonomy and oversight of incidents at local level. When an incident is escalated as a serious incident (SIRI) an investigation report and action plan was shared with the staff in the location where the incident occurred, and a summary of the incident was shared with staff nationally.

On the day of our inspection, the registered manager informed us of a safeguarding concern with police involvement, we did not see evidence that this had been escalated to the local authority. Following inspection, the service provided documentation to show a safeguarding referral had been made to local authority. We discussed concern regarding non-compliance of the service to notify the local authority with regard safeguarding adult and children notifications. The registered manager agreed to review this with immediate effect.

Post inspection we requested site of the safeguarding log for the location; the notification had not been recorded on the log so we were not assured that this had been escalated to safeguard the patient in line with best practice guidance.

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, their families 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. 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.

The service provided opportunities for career development if staff wished to specialise or take on a lead role. The leadership development strategy with succession planning at a local level was evident and we saw staff were supported during development.

We observed good staff relationships, medical staff were members of the team and staff at all levels worked together and supported each other. We observed multidisciplinary teamworking and collaboration throughout the inspection. 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.

All staff we spoke with, including administrative staff consistently 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 both locally and centrally. We were not assured that the provider at location level had effective oversight and safety systems to keep patients safe. However, staff at all levels were clear about their roles and accountabilities.

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 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 out of five patients from BPAS Doncaster 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 reviewed 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 from July 2020 to April 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’. Three out of the nine months audited identified that the audit had not been achieved. There was limited information to evidence non-compliance for all three highlighted as not achieved and there was no action plan to demonstrate action taken.

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 and governance to address areas of poor performance and ensure safe care and treatment.

Inadequate

Termination of pregnancy

We reviewed data to evidence compliance and findings following instigation of the essential steps audit from January 2021 to July 2021. The audits in February 2021 highlighted concerns with regard to waste collection by the registered carrier. The audit in May 2021 highlighted concern regarding staff non-compliance surrounding infection control. There was no indication on either audit template to evidence what action was required, the named person responsible or where this would be reported and disseminated.

Data requested post inspection evidenced the provider had transferred 12 patients to the local acute trust from December 2020 to May 2021 Two patients did not receive any form of duty of candour. Ten of the 12 patients had received verbal duty of candour; however, none had received written duty of candour in line with best practice guidance. We were not assured that the service had an effective system and policy in place to ensure the adherence of duty of candour in line with best practice guidance.

We reviewed staff meeting minutes undertaken in March 2021 and June 2021, there was no set agenda template in use to evidence named leads or actions taken forward to the next meeting. The minutes did not reflect the discussions held at the meeting for example the minutes in June stated that incidents had been discussed. However, there was no detail regarding which incidents, to reflect actions taken and learning to prevent recurrence. The meeting stated that fire drills were to be discussed, however, there was no evidence to identify the date of the drill, action or learning. The minutes also stated that the units risk register had been discussed; however, there was no evidence to support actions, named lead or outcome. The meeting minutes in March 2021 stated a number of staff were non-compliant with regard reading recent serious incidents. There was no detail to support which staff members or how many were non-compliant. We were not assured that staff meetings reflected the business as a whole surrounding the key risks, training compliance, audit findings and learning.

The local managers meetings, held 5 July 2021, demonstrated similar findings to that in team meeting minutes. We found there was no clear recommendations, named lead and date of completion for actions to be taken.

The refurbishment plan demonstrated key areas of the environment that required attention, however there were no time frame in which these were to be completed. The plan did not prioritise the areas which posed significant risk, for example, exposed flooring in clinical areas (recovery area) and fire doors that were not fit for purpose. There was no evidence of ownership of the refurbishment plan or oversight of when actions would be completed.

However, 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 13 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, as the CAS2 system would not allow a patient to be booked for treatment until two medical practitioners had completed the HSA1 form. We requested oversight of compliance; however, staff told us that the audits had been suspended because of COVID 19. The provider corporately was currently reviewing the audit dashboard with a view to including recommencing audit within this area.

The BPAS client administration system had been implemented in pilot locations including BPAS Doncaster; however, this was relatively new and not all functionalities developed yet for example the surgical element of the system remains in paper format. There are plans to develop a full electronic surgical record in the future.

There was a clear governance system for the organisation and senior staff explained to us how information was shared up to board level and trustees through the clinical governance committee, and down to staff at location level. 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.

Management of risks, issues, and performance

We were not assured that the service had effective safe systems in place for assessing, managing and responding to patient risk to ensure all patients who attend the service are cared for in a safe and effective manner 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 – Doncaster, and two other locations.
- The registered provider must implement a safe system and process at BPAS – Doncaster, 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 – Doncaster, 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 locations risk register post inspection which highlighted the recent transfer of patients from Doncaster to another BPAS location in the North West 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.

The risk register had been reviewed post inspection by the registered manager on the 6 August 2021; however, this did not address all of the immediate concerns identified on inspection but had included service interruption due to unavailability of key staff members.

On inspection we discussed concerns regarding non-compliance of the service to notify the regulator (Care Quality Commission) regarding serious incidents in line with provider registration. The registered manager was unaware of the need to escalate and report serious incidents. This concern was not evident on the risk register.

We also discussed concern on inspection regarding non-compliance of the service to notify the local authority with regard to safeguarding adult and children notifications. This concern was not evident on the risk register.

The risk register included a statement which evidenced that management of risk is a challenge across all units, and a reporting mechanism is needed to collate performance. This could include stock levels, vacancies for key positions, capacity performance, complaints etc. This risk had no risk score, owner, or action to address.

Four of the nine risks recorded on the risk register did not have ongoing actions to address the risk identified. Two of the risks had been completed and recorded as green (complete); however, these remained on the risk register.

We were not assured that key risks on the risk register were up to date or evidenced key risks for the service. This was a must do action at the previous inspection in October 2019 however, during this inspection we saw that the provider had still not ensured all risks to performance measures were recorded and acted upon.

We were not assured, corporately or locally, that leaders had clear oversight of the risks we identified during inspection. The governance documentation we reviewed, including risk register, audits, and team meetings, did not reflect knowledge of, or actions taken, to risks identified.

However, the provider had a comprehensive business continuity plan which was last reviewed March 2021.

Managing information

Data or notifications were not submitted to external organisations as required. The service did not collect data and analyse it, however staff could find the data they needed, in easily accessible formats, to understand performance, make decisions and improvements. The information systems were integrated and secure.

The registered manager was not aware of the need to submit statutory notifications to the regulator with regard serious incidents or police incidents and children and adult safeguarding notifications to the local authority. The provider had reported one incident to the police for investigation, we did not receive information to support the reasoning behind this referral.

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, however 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.

This was reported as a must do action at the previous inspection in October 2019 however, during this inspection we saw that the provider had still not implemented a process to assure themselves that HSA4 forms were submitted.

However, staff had access to policies and procedure in electronic and paper form.

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 20 HSCA (RA) Regulations 2014 Duty of candour

Regulated activity	Regulation
Diagnostic and screening procedures Family planning services 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 12 CQC (Registration) Regulations 2009 Statement of purpose

Regulated activity	Regulation
Diagnostic and screening procedures Family planning services Surgical procedures	Regulation 11 HSCA (RA) Regulations 2014 Need for consent

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 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 18 CQC (Registration) Regulations 2009 Notification of other incidents

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