BPAS Merseyside

Quality Report

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This report describes our judgement of the quality of care at this location. It is based on a combination of what we found when we inspected and a review of all information available to CQC including information given to us from patients, the public and other organisations

Summary of findings

Letter from the Chief Inspector of Hospitals

BPAS Merseyside is part of the British Pregnancy Advisory Service and provides services for Merseyside and other areas as well as clients from Ireland and Wales. The service provides consultation and early medical abortion (EMA) procedures for patients with gestational ages up to nine weeks (63 days). Surgical abortion treatment under local anaesthetic is provided up to 12 weeks gestation and under general anaesthetic up to 23 weeks and 6 days.

BPAS Merseyside also offers consultations at its three satellite units (BPAS Wigan, BPAS St Helens and BPAS Warrington) and EMA treatments at one of these (BPAS Warrington).

We carried out this inspection as part of our comprehensive inspection programme of termination of pregnancy services. As part of our inspection we reviewed medical and surgical termination of pregnancy services carried out at the BPAS Merseyside clinic.

The announced inspection of BPAS Merseyside took place on 11 May 2016 and we visited all areas within the service including the theatre, recovery areas, consultation rooms and waiting areas. We also carried out an unannounced inspection on 9 June 2016 to see how patients were cared for during a busy surgery day.

We have not provided ratings for this service. We have not rated this service because we do not currently have a legal duty to rate this type of service or the regulated activities which it provides.

Are services safe at this service

- There was no effective system in place to ensure that resuscitation equipment was regularly checked to protect patients from avoidable harm.
- It was not clear due to poor record keeping whether several pieces of equipment used in theatre had been subject to the appropriate maintenance tests. This was raised with the service at the time of our unannounced inspection.
- The service had reported 11 serious incident notifications to the CQC from January 2013 to March 2016 (eight of which were reported between January 2015 and March 2016). All of these incidents resulted in patients being transferred to the local NHS trust for emergency care. Investigation reports completed following each serious incident did not identify and consider all relevant information and contributory factors.
- The local NHS trust had also carried out a review because they had identified that there had been 16 serious incidents related to the service reported between 01 January 2013 and 29 February 2016. As a result the trust had raised concerns with the service and one of the local commissioners regarding the number of patients who had been transferred and the quality of information that was provided on transfer.
- There was no evidence of a clear system embedded to share lessons learned from local incidents and complaints across the service. Senior managers had dealt with a number of incidents that had involved Duty of Candour, however some staff were not familiar with the Duty of Candour (DOC) regulation, and were unaware of the regulation being taught during any training. However, they did recognise the importance of informing patients when things went wrong.
- Infection control procedures were not always followed in theatre
- The service had clear systems in place to identify and report any safeguarding concerns. Staff we asked were aware of the safeguarding policy and who to report their concerns to.
- At the time of our inspection the clinic had three nurse staff vacancies and was heavily reliant on agency staff. All new nursing staff were formally inducted and competency assessed and shown around the clinic so they became familiar with the service.

Summary of findings

- At the time of inspection there were two doctors employed by the service. No agency staff were used to cover doctors between February 2016 and May 2016 and there were no medical staff vacancies. One surgeon and four anaesthetists had practising privileges with BPAS Merseyside.

Are services effective at this service

- Whilst most services offered by the provider were in line with current RCOG guidance, the practice of simultaneous administration was not in line with current RCOG guidance. BPAS currently offered treatment for early medical abortions either by way of the simultaneous administration of the medicines necessary to effect a termination of pregnancy (only for pregnancy under 9 weeks) or initial dose followed at some point within a 72 hour window with a second medication. The provider no longer offers an interval of 6-8 hours between administrations of the medications because the outcomes with this interval were not found to be significantly better than with simultaneous administration.
- The service had agreed standards in place with commissioners. Whilst quarterly monitoring reports to the commissioners gave details of service delivery, they did not include details of agreed targets so it was not clear how well the service was performing. It was also not clear how this information was used to improve service delivery or patient outcomes.
- The clinic followed the BPAS planned programme of audit and monitoring. Audit outcomes and service reviews were reported to the governance committees and Regional Quality, Assessment and Improvement Forums (RQuAIF).
- Appropriate systems were in place to obtain consent from patients and consent was well documented in the patient record.
- BPAS had various competency frameworks in order to support the training and development of staff. Staff were trained to be multi-skilled and this allowed staff to work between floors/different areas of the service. Information provided by the service stated that all medical staff and 89% of registered nurses had undergone an annual appraisal in the last full year (January to December 2015).

Are services caring at this service

- Staff were non-judgemental and responsive to patients' needs. We observed staff using a caring and compassionate approach particularly in the recovery room where patients were transferred after surgery.
- Patient feedback forms indicated the majority of patients felt listened to and their confidentiality was maintained.
- Staff discussed the different termination procedures with women at their consultation so that they could make an informed decision about the available termination of pregnancy methods. Following treatment, the discharge discussion included a conversation about "what to expect" for example blood loss, pain and counselling was discussed with patients.
- Post abortion counselling was offered as a free service to all BPAS patients, and could be accessed any time after their procedure, whether this was the same day or many years later. As stated by the RCOG clinical guideline all patients had the option to discuss their decision to determine the degree of certainty of their decision. A client care co-ordinator was available to speak to any patient who was unsure about her decision, or needed additional support during pre-assessment.
- However, patients were not informed about the statutory requirement of HSA4 forms. Staff did not explain to patients that these details were sent to the Department of Health and that it was a legal requirement.

Are services responsive at this service

Summary of findings

- The service was planned and delivered to meet the needs of patients. For example, following work in partnership with Antenatal Results and Choices (ARC) the decision had been made to provide terminations of pregnancy for foetal anomalies.
- The electronic triage booking system offered clients a choice of when and where they had the termination. This ensured that patients were able to access a clinic that was most suitable to their needs.
- However, a quarterly monitoring report to one of the commissioners showed patients were not always seen within RCOG recommended timeframes. The reasons for delays or extended waiting times were not given in the report but it was possible that these delays due to patient choice.
- BPAS staff completed generic and role-specific training, which included a workshop in Welcoming Diversity to ensure they recognised different cultural needs and beliefs.
- We asked staff at the time of our inspection what procedures were in place for patients that may have an anxiety diagnosis or a learning disability. Staff told us the patient's carer would be able to stay with the patient throughout the clinic areas from admission to discharge to provide support.
- The team had access to translation support services if required.
- All complaints we reviewed were investigated and complainants were responded to in a timely manner.

Are services well led at this service

- There was a corporate governance committee structure in place that captured and discussed identified risks. The framework also enabled the dissemination of learning and service improvements and a pathway for reporting and escalation to the BPAS board.
- However, local governance arrangements did not ensure the identification, mitigation and monitoring of risks. We were not assured that the registered manager had full understanding and grip of the potential risks within the service and the supporting clinical governance arrangements.
- There was no local risk register or other document that identified local risks and the control measures in place.
- BPAS (the provider) had recognised that local governance processes needed strengthening and had recently employed a risk management and client safety lead who was responsible for reviewing systems and was working with registered managers to implement systems such as a local risk register and improved incident reporting systems (including the implementation of an electronic reporting system).
- Practising privileges were reviewed annually by the medical director and registered manager. The clinical department at Head Office flagged when an individual's practising privileges were due. Clinicians had a month to submit the necessary documentation otherwise their practise was suspended until the information was provided.
- The service had participated in the Workplace Wellbeing Charter the aim of which is to give employers an opportunity to demonstrate their commitment to the health and well-being of their workforce.

There were areas of poor practice where the provider needs to make improvements.

Importantly, the provider must:

- Adopt a robust system that clearly identifies items have been checked on the resuscitation trolleys and the defibrillators.
- Ensure staff follow best practice infection control procedures, particularly in relation to the management of laundry, transfer and movement of staff between theatre and clinic areas and the use of syringes to administer intra-venous

Summary of findings

- Ensure all theatre equipment has been subject to the appropriate maintenance checks and that this is clearly recorded.
- Implement robust local governance processes including: systems to ensure serious incidents are subject to thorough investigation that consider all contributory factors and analyse for any common themes or trends; systems to ensure learning from local incidents are shared with all staff, including bank and agency staff; a clearly documented system to identify, monitor and mitigate local risks.
- Ensure the registered manager has clear sight and understanding of the potential risks within the service and full involvement in the supporting clinical governance arrangements.

In addition the provider should:

- Ensure all staff are able to access the resuscitation equipment on the wards quickly when required.
- Consider how to work with commissioners to ensure Chlamydia screening is offered to all patients in line with RSOP 13.
- Ensure safeguarding policies are reviewed to take account of current statutory guidance.
- Consider what action could be taken to improve uptake of contraceptives.
- Take action to understand the reasons for delays in treatment or extended waiting times and where appropriate take action to improve waiting times to meet with RCOG recommended timeframes.

Professor Sir Mike Richards
Chief Inspector of Hospitals

Overall summary

- There was no robust system in place to ensure that resuscitation equipment was regularly checked to keep patients safe. It was not clear whether several pieces of equipment used in theatre had been subject to the appropriate maintenance tests.
- The service had reported 11 serious injury notifications to the CQC from January 2013 to March 2016 (eight of which were reported between January 2015 and March 2016). All of these incidents resulted in patients being transferred to the local NHS trust for emergency care. Investigation reports completed following each serious incident did not identify and consider all relevant information and contributory factors
- Infection control procedures were not always followed in theatre and we were not assured that medication was regularly reviewed and replaced as required.
- Whilst most services offered by the provider were in line with current RCOG guidance, the practice of simultaneous administration was not in line with current RCOG guidance. BPAS currently offered treatment for early medical abortions either by way of the simultaneous administration of the medicines necessary to effect a termination of pregnancy (only for pregnancy under 9 weeks) or initial dose followed at some point within a 72 hour window with a second medication. The provider no longer offers an interval of 6-8 hours between administrations of the medications because the outcomes with this interval were not found to be significantly better than with simultaneous administration.
- The service had agreed standards in place with commissioners. Whilst quarterly monitoring reports to the commissioners gave details of service delivery, they did not include details of agreed targets so it was not clear how well the service was performing. It was also not clear how this information was used to improve service delivery or patient outcomes.

Summary of findings

- Patients were not informed about the statutory requirement of HSA4 forms. Staff did not explain to patients that these details were sent to the Department of Health and that it was a legal requirement.
- A quarterly monitoring report to one of the commissioners showed patients were not always seen within RCOG recommended timeframes. The reasons for delays or extended waiting times were not given in the report but it was possible that these delays were due to patient choice.
- Local governance arrangements did not ensure the identification, mitigation and monitoring of risks or the improvement of quality and patient outcomes. We were not assured that the registered manager had full understanding and grip of the potential risks within the service and the supporting clinical governance arrangements. When asked to supply the full root cause analysis investigation reports following the recent serious incidents, the registered manager was not clear on who had completed the investigation reports, had not been involved in the production of the investigation reports and had not had sight of the full investigation reports. She was unaware that staff did not have sight into the outcomes of the serious incident reviews.
- There was no local risk register or other document that identified local risks and the control measures in place.
- Information from corporate and regional governance meetings should have been shared with staff via staff meetings and nurses meetings. However, we did not see minutes from any staff meetings where this information was shared despite requesting them. Bank and agency staff were not informed of any changes and were not invited to any BPAS staff meetings.

However:

- The service had clear systems in place to identify and report safeguarding concerns. Staff we spoke with were aware of the safeguarding policy and who to report their concerns to.
- The clinic followed the BPAS planned programme of audit and monitoring. Audit outcomes and service reviews were reported to the governance committees and Regional Quality, Assessment and Improvement Forums (RQuAIF).
- Appropriate systems were in place to obtain consent from patients and consent was well documented in the patient record.
- BPAS had various competency frameworks in order to support the training and development of staff. All medical staff and 89% of registered nurses had undergone an annual appraisal in the last full year (January to December 2015).
- We observed staff using a caring and compassionate approach particularly in the recovery room where patients were transferred after surgery. Patient feedback forms indicated the majority of patients felt listened to and felt that their confidentiality was maintained. They also indicated the majority of patients would recommend the service.
- The service was planned and delivered to meet the needs of patients. Following work in partnership with Antenatal Results and Choices (ARC) the decision had been made to provide terminations of pregnancy for foetal anomalies.
- There was a corporate governance committee structure in place to capture and discuss identified risks. The framework also enabled the dissemination of learning and service improvements and a pathway for reporting and escalation to the BPAS board.
- The provider had recognised that local governance processes needed strengthening and had recently employed a risk management and client safety lead who was responsible for reviewing systems and was working with registered managers to implement systems such as a local risk register and improved incident reporting systems.
- Practising privileges were reviewed annually by the medical director and registered manager. The clinical department at Head Office flagged when an individual's practising privileges were due. Clinicians had a month to submit the necessary documentation otherwise their practise was suspended until the information was provided.

Summary of findings

Our judgements about each of the main services

Service	Rating	Summary of each main service
Termination of pregnancy		• There was no robust system in place to ensure that resuscitation equipment was regularly checked to keep patients safe. It was not clear whether several pieces of equipment used in theatre had been subject to the appropriate maintenance tests. • The service had reported 11 serious injury notifications to the CQC from January 2013 to March 2016 (eight of which were reported between January 2015 and March 2016). All of these incidents resulted in patients being transferred to the local NHS trust for emergency care. Investigation reports completed following each serious incident did not identify and consider all relevant information and contributory factors. • The local NHS trust had carried out a review because they had identified that there had been 16 serious incidents related to the service reported between 01 January 2013 and 29 February 2016. As a result the trust had raised concerns with the service and one of the local commissioners regarding the number of patients that had been transferred and the quality of information that was provided on transfer. • There was no evidence of a clear system embedded to share lessons learned from local incidents across the service. • Infection control procedures were not always followed. We found syringes that were being used to administer intra-venous drugs left with no cap or needle on the end; this presented a risk of cross infection. These syringes were also filled with two millilitres of air which if administered by mistake could place the patient at risk. • We observed staff carrying dirty linen not bagged throughout the clinic and we observed theatre staff moving to other areas in the clinic without changing clothing or placing covers on their shoes to reduce the risk of cross infection. The infection risks we found during our inspection did not

Summary of findings

reflect the findings in the infection control audits and we were not assured the audit approach in place was being implemented in a rigorous manner.
- There was no system in place to make sure the identities of patients accessing the service remained confidential at all times. For example we heard staff announce the full names of patients in open reception areas.

However:

- There were processes in place to report and monitor incidents. Incidents were reported using a paper based system that was reviewed by senior managers. Staff understood their roles and responsibilities in relation to reporting of incidents.
- All staff we spoke with understood how to identify and report safeguarding concerns. Staff were able to describe processes to report concerns relating to child sexual exploitation and female genital mutilation.
- All areas we visited were visibly clean. We observed staff following best practice in relation to hand hygiene.
- Records we reviewed were clear, legible and fully completed. Records were stored securely in locked filing cabinets.
- Every woman attending the clinic completed a medical history and staff carried out a comprehensive risk assessment to ensure they were suitable for treatment.
- There were enough staff with the right mix of skills to deliver the agreed services at BPAS Merseyside. Staff worked across different units on different days, which helped them develop their skills and provide a flexible workforce.

Summary of findings

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Summary of this inspection

Background to BPAS Merseyside

BPAS Merseyside is part of the British Pregnancy Advisory Service Group. The service opened in 1970 and provides services for Merseyside and the surrounding areas as well as clients from Ireland and Wales.

The service provides consultation and early medical abortion (EMA) procedures for patients with gestational ages up to 10 weeks. Surgical abortion treatment under local anaesthetic is provided up to 12 weeks gestation and under general anaesthetic up to 23 weeks and days.

Services provided include: prescribing abortifacient medication (medicines used to bring about abortion), administering abortifacient medication for early-medical abortion, surgical abortion under local and conscious sedation, contraception to clients who undertake a termination of pregnancy, miscarriage management, screening and treatment for sexually transmitted diseases and a vasectomy service (one list every week).

The unit is opened five days a week but BPAS offers a seven day telephone advice service, 24 hours a day. The service has four clinical rooms, and one operating theatre. Patients are taken to the top floor after treatment where there are five reclining chairs and a room with two beds.

The service is registered with the Care Quality Commission to carry out the following regulated activities:

- Diagnostic & Screening Procedures
- Family Planning Services
- Treatment of Disease, Disorder and/or Injury
- Termination of Pregnancy
- Surgical Procedures

The registered manager has been in post since 21 May 1999.

BPAS Merseyside also offers consultations at its three satellite units (BPAS Wigan, BPAS St Helens and BPAS Warrington) and EMA treatments at one of these (BPAS Warrington).

We carried out this inspection as part of our comprehensive inspection programme of termination of pregnancy services. As part of our inspection we reviewed medical and surgical termination of pregnancy services provided at the BPAS Merseyside clinic.

Our inspection team

Our inspection was led by: Two Inspection Managers from the Care Quality Commission

The inspection team comprised two CQC inspectors who have received specialist training in termination of pregnancy services and a specialist advisor who provided remote support in reviewing information about the service and attended the unannounced inspection. Start here...

How we carried out this inspection

To get to the heart of patients' experiences of care, we always ask the following five questions of every service and provider:

- Is it safe?
- Is it effective?
- Is it caring?
- Is it responsive to people's needs?
- Is it well-led?

Before visiting, we reviewed a range of information we held about BPAS Merseyside. The announced inspection of BPAS Merseyside took place on 11 May 2016 and we visited all areas within the service

Summary of this inspection

including the theatre, recovery areas, consultation rooms and waiting areas. We also carried out an unannounced inspection on 9 June 2016 to see how patients were cared for during a busy surgery day.

To inform our inspection we reviewed data provided by the service and spoke to a range of staff which included: registered nurses, midwives, consultants, the registered manager, administration staff and the associate director of nursing.

We spoke with three patients and their relatives. We observed care and treatment and looked at 14 records for both medical and surgical patients. We also reviewed other relevant records held by the service such as complaints, incidents and relevant policies.

We would like to thank all staff and patients for sharing their views and experiences of the quality of care and treatment provided at BPAS Merseyside.

We have not provided ratings for this service. We have not rated this service because we do not currently have a legal duty to rate this type of service or the regulated activities which it provides.

Information about BPAS Merseyside

The service carried out 4867 abortions from 1 January 2015 to March 2016 these included:

701 early medical abortions

4565 surgical abortions including treatments carried out under local and general anaesthetic and manual vacuum aspiration (MVA).

Of the 4565 surgical abortions carried out between January to December 2015, 96 were carried out after 20 weeks gestation.

Between January and December 2015 the service treated 77 children between the ages of 13 and 15 years old. In the same period, the service did not treat any children under the age of 13 years old.

Termination of pregnancy

Safe	
Effective	
Caring	
Responsive	
Well-led	

Information about the service

BPAS Merseyside is part of the British Pregnancy Advisory Service Group. The service opened in 1970 and provides services for Merseyside and other areas as well as clients from Ireland and Wales. The service currently provides consultation, and early medical abortion (EMA) treatments up to 10 weeks gestation. Surgical abortion treatment under local anaesthetic is provided up to 12 weeks gestation, and under general anaesthetic up to 23 weeks and six days.

BPAS Merseyside also offers consultations at its three satellite units in Wigan, St Helens, and Warrington and early medical abortion at the Warrington unit.

BPAS Merseyside has four clinical rooms in total, and one operating theatre. There are facilities to manage four patients in theatre recovery and eight patients on the post-surgical wards.

Services provided include: prescribing abortifacient medication, administering abortifacient medication for early-medical abortion, surgical abortion under local and conscious sedation, contraception to clients who undertake a termination of pregnancy, miscarriage management, screening and treatment for sexually transmitted diseases and a vasectomy service (one list a week).

BPAS has a central dedicated telephone helpline 24 hours a day throughout the year to provide patients with a contact for support and advice during periods when the clinic is closed.

Summary of findings

- There was no effective system in place to ensure that resuscitation equipment was regularly checked to keep patients free from avoidable harm. It was not clear due to poor record keeping whether several pieces of equipment used in theatre had been subject to the appropriate maintenance tests.
- The service had reported 11 serious injury notifications to the CQC from January 2013 to March 2016 (eight of which were reported between January 2015 and March 2016). All of these incidents resulted in patients being transferred to the local NHS trust for emergency care.
- Investigation reports completed following each serious incident did not identify and consider all relevant information and contributory factors.
- The local NHS trust had carried out a thematic review because they had identified that there had been 16 serious incidents related to the service reported between 01 January 2013 and 29 February 2016. As a result the trust had raised concerns with the service, and discussed with them their outcomes regarding the number of patients that had been transferred and the quality of information that was provided on transfer. There was no evidence of a clear system embedded to share lessons learned from local incidents across the service.
- Infection control procedures were not always followed. We found syringes that were being used to administer intra-venous drugs left with no cap or needle on the end; this presented a risk of cross infection. These syringes were also filled with two

Termination of pregnancy

millilitres of air which if administered by mistake could place the patient at risk. This was raised with the service at the time of our unannounced inspection when they were found.

- We observed staff carrying dirty linen not bagged throughout the clinic and we observed theatre staff moving to other areas in the clinic without changing clothing or placing covers on their shoes to reduce the risk of cross infection. The infection risks we found during our inspection did not reflect the findings in the infection control audits and we were not assured the audit approach in place was being implemented in a rigorous manner.
- At the time of our inspection best practice guidelines in relation to first line choice of antibiotics to manage sepsis were not available at the clinic as they were not on the service formulary. However, an alternative antibiotic was available for administration.
- There was no system in place to make sure the identities of patients accessing the service remained confidential at all times. For example we heard staff announce the full names of patients in open reception areas.

However:

- The service had clear systems in place to identify and report safeguarding concerns. Staff we spoke with were aware of the safeguarding policy and who to report their concerns to.
- The clinic followed the BPAS planned programme of audit and monitoring. Audit outcomes and service reviews were reported to the governance committees and Regional Quality, Assessment and Improvement Forums (RQuAIF).
- Appropriate systems were in place to obtain consent from patients and consent was well documented in the patient record.
- BPAS had various competency frameworks in order to support the training and development of staff. All medical staff and 89% of registered nurses, and midwives, had undergone an annual appraisal in the last full year (January to December 2015).

- We observed staff using a caring and compassionate approach particularly in the recovery room where patients were transferred after surgery. Patient feedback forms indicated the majority of patients felt listened to and felt that their confidentiality was maintained. They also indicated the majority of patients would recommend the service.
- The service was planned and delivered to meet the needs of patients. Partnership working with Antenatal Results and Choices (ARC) the decision had been made to provide terminations of pregnancy for foetal anomalies.
- There was a corporate governance committee structure in place to capture and discuss identified risks. The framework also enabled the dissemination of learning and service improvements and a pathway for reporting and escalation to the BPAS board.
- The provider had recognised that local governance processes needed strengthening and had recently employed a risk management and client safety lead who was responsible for reviewing systems and was working with registered managers to implement systems such as a local risk register and improved incident reporting systems.
- Practising privileges were reviewed annually by the medical director and registered manager. The clinical department at Head Office flagged when an individual's practising privileges were due. Clinicians had a month to submit the necessary documentation otherwise their practise was suspended until the information was provided.

Termination of pregnancy

Are termination of pregnancy services safe?

Incidents

- Staff understood the importance of reporting incidents and used critical incident forms to record an occurrence that caused, or may cause harm to the patient, or themselves. This was a paper based system which was kept in the administration office. Incidents were then escalated to the corporate risk and safety team who would record them on a central electronic register.
- There were no never events reported at BPAS Merseyside between January 2015 and December 2015. Never Events are serious incidents that are wholly preventable as guidance or safety recommendations that provide strong systemic protective barriers are available at a national level and should have been implemented by all healthcare providers.
- The service had reported 11 serious injury notifications to the CQC from January 2013 to March 2016 (eight of which were reported between January 2015 and March 2016). All of these incidents resulted in patients being transferred to the local NHS trust for emergency care.
- An internal investigation was undertaken using a root cause analysis (RCA) approach for all incidents that took place. A route case analysis is an investigation of adverse incidents, which can identify system failures and areas for service improvement. However, the RCA investigation reports we reviewed did not identify and consider all relevant information and contributory factors.
- The local NHS trust had carried out a review because they had identified that there had been 16 serious incidents related to the service reported between 01 January 2013 and 29 February 2016. As a result the trust had raised concerns with the service and one of the local commissioners regarding the number of patients that had been transferred and the quality of information that was provided on transfer.
- An internal corporate safety bulletin known as the 'red top alert' was issued to inform staff of any safety issues, including learning from incidents across BPAS.
- However, there was no evidence of a clear system in place to share lessons learnt from local incidents with staff. The registered manager told us lessons learned were discussed during quarterly team brief meetings and staff team meetings that were held as required. We asked for the minutes for team meetings to confirm this but were not provided with any.
- Senior managers had dealt with a number of incidents that had involved Duty of Candour, however some staff were not familiar with the Duty of Candour (DOC) regulation and were unaware of the regulation being taught during any training. They did recognise the importance of informing patients when things went wrong. The duty of candour is a regulatory duty that relates to openness and transparency and requires providers of health and social care services to notify patients (or other relevant persons) of 'certain notifiable safety incidents' and provide reasonable support to that person).

Cleanliness, infection control and hygiene

- The clinic had not reported any methicillin-resistant-staphylococcus aureus (MRSA) cases for the period April 2015 and April 2016.
- The waiting room and the wards were visibly clean, and consulting rooms were well organised. The anaesthetic room, theatre, and theatre recovery room were visibly clean. The theatre had a separate sluice area, and an area for sterile equipment. We observed staff cleaning trolleys in the recovery room when patients were discharged from the area.
- Hand gel and sanitisers were readily available throughout all areas of the clinic although we found signage at sinks to show patients, supporters, and staff the correct way to wash their hands. It was evident during our observations that staff in most areas adhered to current hand hygiene guidelines. However, we observed procedures in theatre where the surgeon did not wash or clean their hands prior to wearing gloves and gauntlets to perform a surgical procedure.
- We observed three members of staff washing their hands (or using hand gel) after performing a variety of clinical procedures which included; examining patients, measuring blood pressures, and following procedures in theatre. All staff adhered to the 'bare below the elbow in clinical areas' guidelines.

- However, at the time of unannounced inspection we observed a large casual bag on the floor in the theatre, and a member of theatre staff with below shoulder length hair that was not tied up or covered during theatre procedures. We also observed theatre staff leaving the theatre environment and attending the ward on the top floor without changing theatre shoes or covering them over to reduce the risk of infection.
- At the time of our unannounced inspection we observed a member of staff coming out of the theatre carrying a bundle of bedding and being told to take it to the top floor to put in a laundry bag. The bundle had not been placed into a bag in theatre. This was not in line with best practice guidance on handling linen and presented a risk of cross infection.
- At the time of our unannounced inspection we observed a total of 19, five millilitre syringes in a kidney dish container in the anaesthetic room. All 19 syringes had two labels in situ with the drugs Midazolam and Rapifen identified and all were drawn up to the two millilitre measure. We asked the anaesthetist what these were for and we were told they were empty; the anaesthetist then proceeded to dispel the air from one of them. The anaesthetist told us that she liked to get things ready for theatre. None of the syringes had a cap or needle on the end so this presented a risk of infection when used to administer medication via a cannula as they were no longer sterile. We were also concerned that this process was placing patients at risk of receiving two millilitre of air via the intra-venous cannula.
- We reviewed cleaning schedules in the recovery room and found that these were completed daily, weekly, and monthly for March 2016, and April 2016.
- On the announced inspection, we noticed that areas of the clinic did not have any cleaning schedules. For example there was no record of when the toilets were cleaned or when surfaces were cleaned. However on the unannounced inspection, this had been addressed and a schedule of cleaning had been implemented.
- The clinic had an outhouse that housed the washing machines for laundry. At the time of our inspection we observed linen being correctly separated into bags and cleaned at high temperatures.
- The clinic mapped their infection and control plan in line with the Health and Social Care Act 2010. An annual report of infection prevention and control practices containing ten standards was regularly reviewed to check if the clinic was compliant. The report identified that the clinic met all the standards set out during the period April 2015 to December 2015. Where actions were identified, there was an ongoing plan in place to manage and review completion and responsibility.
- An audit performed in April 2016 identified the theatre had a score of 91% compliance. The service had lost marks due to a staff member wearing a wrist watch and not being bare below the elbows, no clean shoes available for visitors, tears in stirrups and paint peeling off the walls and damaged doorframes. An action plan was identified and at the time of our inspection actions had been completed.

Environment and equipment

- The service was located in a large Victorian house with three floors. The entrance to the clinic was monitored with controlled access; although wards and surgical areas were not controlled access areas. This meant there was the potential that patients, visitors, and members of the public were able to move freely through the clinic areas. However, during the inspection, we observed staff challenging individuals moving through the clinic, and staff directing or escorting visitors to different areas.
- A nurse's station was located on the top floor of the clinic; nurses and midwives cared for patients on this floor after their termination and they were then discharged from the discharge lounge. There were two recovery rooms on this floor that contained reclining chairs for recovering patients; however, we identified that patients using the recliners only had access to one call bell which was located at the other end of the room. We raised this with the nurse in charge and were told that patients were never left unattended. We spoke to three patients in the discharge lounge at the time of our inspection who all confirmed that a nurse remained in the room.
- There was a resuscitation trolley with a defibrillator in the theatre, and a resuscitation box and a defibrillator on the top floor where the recovery rooms were located. The operating department practitioner (ODP) informed us they were responsible for checking the resuscitation trolleys daily prior to surgery.

Termination of pregnancy

- We found no record available to demonstrate the resuscitation equipment or the defibrillator in the theatre had been checked. We checked a selection of airways, suction tubing, and an ampoule of adrenaline and sodium chloride on the theatre resuscitation trolley and all were found to be in date.
- At the time of our announced inspection, the ODP informed us there was a check list on the trolley on the ward. We checked the ward resuscitation box and found a small red book that had dates and signatures in but there was no record of what had actually been checked. There was no record for the defibrillator to identify that checks had been completed. We were told that when bank or other agency staff were in theatre, the resuscitation box on the ward did not always get checked because the bank or agency staff were not aware there was other resuscitation equipment to check.
- We also noted that the resuscitation box on the ward was locked with a combination lock. At the time of our unannounced inspection there were three agency staff on the ward; two had previously worked there and one was new. Of the two who had previously worked there one did not know the number to access the resuscitation box. The new agency staff was waiting for her induction to the ward from a trained member of nursing staff who arrived on the ward at the time of our visit. At the time of the unannounced inspection we observed staff trying to unlock the box but were unable to. We noted it took five minutes for another member of staff to be called from theatre to unlock the keypad.
- At the time of our unannounced visit we observed a member of staff checking the resuscitation box on the ward. The staff member opened the box, took out the book, signed the book and locked the box. The staff member did not check the defibrillator during this procedure. Later we asked the staff member why the defibrillator was not checked and were told that they went back 20 minutes later and checked it; however, there was no daily check record available for the machine. As a result we were not assured there were robust systems in place to ensure that emergency equipment was appropriately checked.
- There was no resuscitation trolley in the recovery room but there were trolleys in the recovery room that had pieces of equipment on them. At the unannounced inspection we reviewed some of this equipment and found items that had passed the expiry date. These included: a pair of powder free latex gloves that had expired in November 2013, four suctioning sets that had expired in July 2015, and two inter-surgical complete respiratory systems that had expired in May 2015. We were therefore not assured that equipment was regularly checked to keep patients safe. We raised this concern on the day of our inspection with the registered manager.
- We reviewed the checklist for the anaesthetic machine in theatre which was based on the Association of Anaesthetists of Great Britain and Ireland (AAGBI) Guidelines. We found that the daily, weekly, and monthly schedules were all signed and completed. The machine was serviced by a contractor on a three monthly basis and any faults were reported to the contractor.
- An electrical maintenance report dated 26 January 2016 listed all the equipment that had been tested throughout the clinic. Of the 245 items tested, only two failed and were removed from use.
- We observed a suction machine and an anaesthesia machine both in the recovery room with an in date maintenance sticker in place and a suction machine in the lift also had an in date maintenance sticker.
- However, the electrical maintenance test stickers on the naesthetic machine, the scan machine, the airway suction machine and the vacuum machine for doing the TOPs in theatre were all passed the date for inspection. It was therefore not clear whether these pieces of equipment had been subject to the appropriate maintenance checks.
- A Health and Safety Executive (HSE) inspection was performed in May 2015 and out of a potential 77 risks, 73 were rated as insignificant, one was rated as low risk and was in relation to the storage of certificates for thermostatic control mixer valves, and three were rated as medium risk. The medium risks were in relation to the locking mechanism on the fire doors, training in relation to handling medical gases, and the air handling unit. All medium risks had actions in place to mitigate the risk.
- A fire risk assessment was carried out annually and in May 2015 the report confirmed the building had

satisfactory fire exits and all areas met fire safety regulations. At the time of our inspection however, we observed fire doors propped open on the ground floor which could potentially place patients at risk should a fire develop.

- There were hand washing facilities in the theatre staff changing room but we found the room was small and disorganised, and theatre wear was left next to staff members normal clothes increasing the risk of cross infection.

Medicines

- Medicine fridge temperatures in the theatre recovery room were consistently checked, recorded and were within the safe temperature ranges. Both fridges were locked on our announced visit; we checked a box containing ampoules of Fragmin which were in date and a box of Oxytocin ampoules which were in date.
- On our unannounced visit we found one fridge was unlocked, a nurse told us they had just asked the staff member with the keys to unlock it; however, the nurse was providing care to a recovering patient and was not preparing medication from the fridge. The fridges were checked when the clinic was operational.
- There was a locked controlled drugs cupboard in the theatre and in the laboratory room. Keys to these cupboards were held by designated staff and staff on duty were aware of who held the keys to the cupboards. Any medication used during theatre procedures or consultation was recorded in the patient record and stock book.
- We reviewed the controlled drugs book and found drugs were signed and checked by two practitioners. At the time of our inspection we checked a box of ampoules containing pethidine and a box containing morphine and found all the ampoules to be in date. In the controlled drugs cupboard we observed five syringes containing Rapifen drawn up and ready for use. The Association of Anaesthetists of Great Britain and Ireland Guidelines (AAGBI) states that five syringes can be drawn up at one time in advance of surgery.
- Any ampoule where the whole content of the drug was not required for a patient was disposed of. We observed controlled drug destruction kits available for the safe disposal of controlled drugs.
- At the time of our inspection we noted a syringe on the anaesthetic machine that had medication drawn up and was resting on the box of the remaining ampoules. The ODP informed us this was drawn up as an emergency drug should it be required during theatre. This syringe was in theatre all day while surgery took place. We were not assured that this was safe practice due to the length of time it was left unused and the syringe not being labelled.
- There was clear documentation of information about allergies; this was documented in patient records. We observed seven sets of surgical records and all had allergy status recorded. The service used a red wrist band if a patient had an allergy. At the time of our inspection we identified a patient who had an allergy to Penicillin documented in the patient record and we observed the patient to have a red wrist band in place.
- In the recovery room there was a register of all patients receiving an anti-D immunoglobulin injection (given to neutralise any rhesus positive antigens that may have entered the patient's blood during pregnancy).
- We observed antibiotics were prescribed for prophylaxis against infection and all seven prescription charts we reviewed were signed, dated and legible.
- At the time of our inspection a patient was identified with a potential sepsis diagnosis and was prescribed intra-venous antibiotic therapy. The first line drug of choice was not available as this was not on the service formulary however, an alternative antibiotic was available on site and was administered to the patient.

Records

- We reviewed seven surgical and seven early medical abortion patient records. The paper based records we reviewed were legible, complete and up to date.
- Records showed that prior to surgery patients underwent a pre-operative assessment to identify any areas of concern.
- All seven surgical patients had a documented venous thromboembolism (VTE) risk assessment.
- All patient notes were securely stored in a locked cupboard. Patient notes were kept on the premises for up to four months and then securely sent to the head office site via a BPAS courier to be stored accordingly.

- Arrangements were in place to notify the CQC and the Department of Health in the event of the death of a patient. This would be picked up via the serious incident reporting process.

Safeguarding

- The service had clear systems in place to identify and report safeguarding concerns. Staff we asked were aware of the safeguarding policy and who to report their concerns to. However, the 'Safeguarding and management of clients aged under 18 policy and procedure' had last been reviewed in 2014 and so did not take account of current statutory guidance such as "Working Together to Safeguard Children" (2015)
- The registered manager was responsible for the sharing of necessary information with external safeguarding and child protection agencies in a timely manner. They were also responsible for the development and regular review of their local adult and child protection procedures.
- Safeguarding risk assessment forms were completed for patients under 18 years old and vulnerable adults. We saw evidence in a patient record that a safeguarding risk assessment had been performed for a patient that was 17 years old. This was in line with the provider's policy to carry out a safeguarding assessment on all patients under 18 years old.
- All BPAS staff attended the BPAS 'Safeguarding Vulnerable Groups' training every two years, and an introduction to safeguarding was included on the BPAS induction training, which all staff attended.
- Between March 2015 and March 2016 records showed 93% of staff had received level 3 (advanced) safeguarding training (adults and children).
- All staff between March 2015 and March 2016 received training in level two adults and children safeguarding.
- Staff were aware of the issues around female genital mutilation (FGM). A risk assessment for FGM was completed and if indicated, concerns were reported to the police and social services.
- BPAS recognised that pregnancy may result from, or indicate abuse. In the event that abuse was disclosed or suspected, BPAS was committed to interagency working. For example, staff told us that any patient under the age of 18 years old that presented with female genital mutilation was escalated to the manager and the police were informed.
- Any patients under the age of 14 years who attended the service were discussed with the safeguarding leads and were reported to social services. Any patients under the age of 16 years old had to be accompanied by an adult.
- No children aged under 13 years old were treated from January 2015 to December 2015.
- There were 77 children aged between 13 and 15 years old treated between January 2015 and December 2015.
- There was no system in place to make sure the identities of patients accessing the service remained confidential at all times. The Department of Health Required Standard Operating Procedure (RSOP) 6, states that all patients seeking an abortion have the right to remain anonymous and providers should take consideration of "Confidentiality; NHS Code of Practice" (2003). For example we heard staff announce the full names of patients at open reception areas.

Mandatory training

- A training matrix gave senior managers a list of what BPAS described as regulatory and non-regulatory training requirements (For example, regulatory training included infection control, fire safety and safeguarding whereas non regulatory training included PGD training, consent training and ultrasound scanning). The matrix specified the frequency of training, who was required to complete the training and available information. For example anaesthetists were required to complete advanced life support training, every four years and the resuscitation guidelines and policy were available if they required additional information.
- Mandatory staff training covered a range of topics including fire safety, health and safety, basic life support, safeguarding, manual handling, infection control and information governance. Staff told us they were up to date with their mandatory training. All staff had training in either Basic Life Support or Intermediate Life Support.
- Data showed the majority of staff had completed their mandatory training in November and December 2015 or January 2016.

- There were two new staff starters at the time of the inspection; both had completed a 12-week competency based induction programme, which included all the mandatory training topics.

Assessing and responding to patient risk

- Before treatment, all clients were assessed for their general fitness to proceed with the treatment. This assessment included obtaining a full and comprehensive medical and obstetric history, measurement of vital signs, including blood pressure, pulse and temperature. An ultrasound scan was performed to confirm the gestation period, viability, multiple gestations, and either the location of implantation in early pregnancy or location of placental implantation above 14 weeks gestation.
- Relevant blood tests were taken such as haemoglobin levels and Rhesus status. This was so that nurses and midwives could determine any complications. For example it was important that all woman were tested for the rhesus negative blood group, so they could be administrated the anti- D injection.
- During the initial consultation, all women were asked about their medical history and risk assessed for STI's, those who were of high risk were signed posted to other STI testing services.
- BPAS had a specialist placement team that sourced appointments for the woman within the NHS. This service was offered to patients who were not suitable for treatment at BPAS on medical grounds.
- The BPAS Suitability for Treatment Guideline clearly identified which medical conditions would exclude clients from accessing treatment, and those medical conditions which, although not an automatic exclusion, required careful risk assessment by a doctor.
- We observed pre-operative assessments being completed by the anaesthetist in the anaesthetic room at the time of our inspection. We observed the surgeon introducing themselves to the patient, explaining the procedure and asking if the patient had any questions.
- The 5 steps to safer surgery checklist is a system to reduce errors and adverse events for patients having surgery. BPAS had developed its own Surgical Safety Checklist, modelled on the five steps to safer surgery to be fit for purpose within the BPAS care environment. Specific instructions for staff on how to use the BPAS Surgical Safety Checklist within surgical units was included within the Perioperative Care Policy and Procedure.
- We observed the theatre staff using the checklist prior to commencing surgery. When the patients arrived in the anaesthetic room they had the checklist on the trolley with them. This was then taken into theatre and was read out in the theatre for all theatre staff and the patient to hear. There was also a whiteboard in the theatre where the information was displayed whilst the patient was in theatre. We checked seven sets of surgical records and found the surgical safety checklist had been completed for all the surgical termination of pregnancies.
- Following general anaesthetic we observed that patients were monitored in the recovery room for at least 30 minutes prior to being taken to one of the wards.
- After surgical treatment, the client's vital signs including oxygen saturation and level of consciousness (if general anaesthetic), vaginal blood loss, and pain level were monitored. We observed one patient's journey from theatre to the recovery room, and the patient had three sets of observations recorded within a 30 minute period.
- The service had very recently adopted a modified early warning system (MEWS) used during recovery or post operation. MEWS is a tool for recovery staff to use, utilising a points system to indicate when a patient's condition deteriorates and requires escalation for senior clinical advice. We asked staff about MEWS and were shown the new document in use.
- The service reported that all 4661 patients that underwent a surgical abortion from March 2015 to March 2016 were risk assessed for a venous thromboembolism (VTE). We reviewed seven surgical patient records and found all had a documented VTE assessment completed.
- The clinic had formal transfer agreements in place with a local NHS hospital, should a client require transfer post-operatively in an emergency. Flow-charts were displayed on the walls of the recovery room and consultation rooms with the escalation process defined in case of emergency.
- Seven patients requiring urgent medical attention due to complications caused by the surgical termination procedure had been transferred from the service to another health care provider in the last 12 months.

Termination of pregnancy

- In March 2016, CQC were contacted by the local NHS trust who raised concerns regarding the frequency and scope of patients coming into them from BPAS Merseyside. They told us they had also raised concerns with the commissioner and directly with BPAS Merseyside following their own thematic review of the serious incidents. The review identified concerns in relation to the transfer documentation and the limited information it contained. As a result BPAS Merseyside met with the trust to discuss the processes for transfer, in order to improve communication.
- At the time of our unannounced inspection a patient presented with possible signs and symptoms of sepsis. The patient had a raised temperature, raised pulse rate and low blood pressure on admission.at approximately 1030 hours. The patient waited for approximately one hour from admission to receive rectal paracetamol to reduce their temperature. The clinic had no blood culture bottles available and the surgeon wanted to take blood cultures prior to administering antibiotics. A call was placed to a local hospital to request the bottles. BPAS clinics do not routinely stock blood culture bottles due to difficulty in getting analysis performed at a laboratory and the limited occasions when they would be required. If blood cultures are required it is usual that the client would be transferred to appropriate NHS hospital however, this was not the case on this occasion.
- The patient was commenced on intra-venous fluids to prevent hydration and to treat hypotension. The blood culture bottles arrived at 1130 hours and were sent back at 1215 hours when the patient was then given antibiotic medication. The patient entered the recovery room at 1235 hours after having surgery. The Surviving Sepsis Campaign (SSC) (2015) state that all the above should be completed within three hours of presentation for adults: however guidance is different for children and the patient was 16 years old. The paediatric sepsis six guidelines (2015) advocate that antibiotics should not be delayed because of a delay in obtaining blood cultures and antibiotic therapy should be commenced within the hour. However, the service followed Gillick Competence and Fraser Guidelines to ensure the patient had capacity to consent to the treatment and would therefore follow the adult pathway in relation to sepsis management and received treatment in the three hour timeframe. .
- Following surgical treatment, patients were assessed to ensure they were medically fit for discharge by a registered nurse or midwife. The patients were given a letter that contained information about the procedure they had received at the clinic and information about any medication they were given. This was so that the information could be shared with other care providers particularly if they had any problems post-discharge. They were also given a 24 hour contact telephone number to call for advice and support if required.
- At the time of our inspection we found that five of the chairs on the post-operative ward did not have call bells. Senior managers were informed and we were told that a nurse was always present in the room when it was occupied with patients. Whilst on the unannounced we saw nurses in the room awaiting patients' arrival.

Nursing staffing

- The clinic employed 18 registered nurses and at the time of our inspection had three nurse staff vacancies.
- There was a heavy reliance on agency staff, the clinic reported 977.25 hours were filled by agency staff between February 2015 and April 2016. These hours covered vacancies, long term sickness and annual leave.
- All new nursing staff were formally inducted and shown around the clinic so they became familiar with the service. The service had an orientation checklist for new staff which included orientation to the environment and awareness of service policies including: infection control and cardio-pulmonary resuscitation. At the time of our unannounced inspection the wards had three agency staff working with the nursing sister. Two of the agency staff had worked at the clinic previously and one had not but had been given an orientation and was made aware of emergency procedures.
- The nurses' professional registration was confirmed with the Nursing and Midwifery Council regulatory body. The clinical nurse manager was responsible for monitoring nurse's NMC registration and revalidation.

Medical and surgical staffing

- The service told us they only utilised experienced doctors in the provision of termination of pregnancy (TOP) treatments. Consultants were registered on the General Medical Council (GMC) Specialist Register for TOPs.

Termination of pregnancy

- At the time of inspection there were two doctors employed by the service. No agency staff were used to cover doctors between February 2016 and May 2016 and there were no medical staff vacancies.
- One surgeon and four anaesthetists who were mainly employed by other organisations (usually in the NHS) in substantive posts had practising privileges with BPAS Merseyside. Practising privileges were reviewed annually by the medical director and registered manager.
- Nominated doctors provided medical support to the staff working and were also responsible for signing the HSA1 abortion forms. These forms was signed by two doctors using electronic signature system, doctors reviewed the patients notes electronically to ensure they were signing HSA1 forms in good faith.
- When patients were undergoing a general anaesthetic, the theatre was staffed with a surgeon, an anaesthetist, an operating department practitioner (ODP), a scrub nurse, a theatre orderly and a healthcare assistant. At the time of our inspection the staffing level in theatre met the recommended staffing standard identified by the Association for Perioperative Practice (AFPP).
- The anaesthetist and the ODP were present in theatre for the duration of time that a patient was receiving a general anaesthetic.
- There was a very brief handover from the theatre staff to the nurse in the recovery room when the patient was transferred from theatre.
- A 24 hour telephone line was available if a patient deteriorated outside service opening hours. In the event a patient deteriorated, nurses assessed the patient over the phone and gave advice or advised patients to go to A&E.

Major incident awareness and training

- Staff were unaware what constituted a major incident, they had never participated in a skills and drills activity and were uninformed of their roles and responsibilities during a major incident.
- We found no contingency planning in place or protocol that instructed the roles and responsibilities of designated staff members.
- An emergency backup generator was stored in the garage in case of electricity failure; all staff we spoke to were aware that the service had a backup generator.

Are termination of pregnancy services effective?

- The service provided care and treatment that took account of best practice policies and evidence based guidelines including standards set by the Royal College of Obstetricians and Gynaecology (RCOG) guidance and the Required Standard Operating Procedures (RSOP) guidance from the Department of Health.
- Staff felt supported in their roles and welcomed the opportunities BPAS offered them to develop. Annual appraisals were completed and used to discuss progression.
- There was evidence of multidisciplinary working between nursing staff and BPAS doctors based in the clinic or at other locations. The clinic had links with the local NHS hospital and local safeguarding team. The NHS trust received patients and were forthcoming in raising concerns with senior managers of the clinic when best practice was not followed.
- The service had agreed standards in place with commissioners.
- The clinic followed the BPAS planned programme of audit and monitoring. Audit outcomes and service reviews were reported to the governance committees and Regional Quality, Assessment and Improvement Forums (RQuAIF).
- Appropriate systems were in place to obtain consent from patients and consent was well documented in the patient record. Staff were familiar with the importance of obtaining consent from patients, including those under 18 and children under 16 years of age.

However:

- Whilst most services offered by the provider were in line with current RCOG guidance, the practice of simultaneous administration was not in line with current RCOG guidance. BPAS currently offered treatment for early medical abortions either by way of the simultaneous administration of the medicines necessary to effect a termination of pregnancy (only for pregnancy under 9 weeks) or initial dose followed at some point within a 72 hour window with a second medication. The provider no longer offers an interval of

6-8 hours between administrations of the medications because the outcomes with this interval were not found to be significantly better than with simultaneous administration. BPAS introduced simultaneous administration of abortifacient medications in March 2015.. A structured approach had been taken when planning and implementing this pathway and it was kept under regular review. Minutes from June 2015 and November 2015 both showed there had continued to be an increase in the number of complications since the introduction of simultaneous EMAs but that these were within the rates quoted in the BPAS guide.

- All patients under the age of 24 were offered a Chlamydia test. However only patients over the age of 25 years old from certain areas across the North West were offered tests because it was funded by their local authority. This was not in line with RSOP 13 which states that "all women should be offered testing for chlamydia, offered a risk assessment and tested as appropriate" (Department of Health, page 26).

Evidence-based care and treatment

- Staff took account of best practice guidelines and standards such as National Institute for Health and Care Excellence (NICE), Royal College guidelines, and Department of Health Required Standard Operating Procedures (RSOPs). For example, patients were offered a choice of procedure within appropriate timeframes.
- The exception to this was the simultaneous administration of abortifacient medication (medicines used to bring about abortion) for early medical abortions (EMAs). BPAS introduced simultaneous administration of mifepristone and misoprostol in March 2015. Whilst most services offered by the provider were in line with current RCOG guidance, the practice of simultaneous administration was not in line with current RCOG guidance. BPAS currently offered treatment for early medical abortions either by way of the simultaneous administration of the medicines necessary to effect a termination of pregnancy (only for pregnancy under 9 weeks) or initial dose followed at some point within a 72 hour window with a second medication. The provider no longer offers an interval of 6-8 hours between administrations of the medications because the outcomes with this interval were not found to be significantly better than with simultaneous administration.
- Simultaneous early medical abortions were piloted in three BPAS clinics prior to implementation across the country. We reviewed a document titled "Service evaluation – Simultaneous administration of mifepristone and misoprostol for early medical abortion" (undated). The document reported the findings were that the simultaneous early medical abortions were less effective than those where medicines were administered in line with RCOG guidance but were still successful in 90% of women. As a result the outcome of the pilot was that women should be offered the choice of simultaneous administration but the risks and side effects should be made clear. A structured approach had been taken when planning and implementing this pathway and it was kept under regular review.
- The clinic worked with different commissioning groups to provide a sexual health screening programme to patients visiting the clinic. During the initial consultation, all women were asked about their medical history and risk assessed for sexually transmitted infections (STIs), those who were at high risk were signposted to other STI testing services.
- All patients under the age of 24 were offered a Chlamydia test. However only patients over the age of 25 years old from certain areas across the North West were offered tests because it was funded by their local authority. This was not in line with RSOP 13 which states that "all women should be offered testing for chlamydia, offered a risk assessment and tested as appropriate" (Department of Health, page 26).
- When clinical guidelines, policies and procedures were created or revised, staff were trained in their application; all policies were easily accessible for reference via the BPAS Intranet. We reviewed an array of guidance such as management of haemorrhage (2016) and cervical priming after 14 weeks (2015), these were in date and current.
- We saw evidence at the time of our inspection that feticide was performed prior to a medical abortion that was after 21 weeks and six days gestation in line with RCOG Guidelines.
- Those who opted for surgical abortion were also offered the contraceptive injection, contraceptive implant or the coil fitted at the same time as the procedure. All patients were offered condoms and other forms of contraception. Contraception was discussed during the consultation.

- Patients were given prophylactic antibiotics to reduce the risk of infection post-surgery; we saw evidence of this in the patient records that we reviewed.
- Patients were scanned in theatre to make sure that all products of pregnancy were removed from the uterus.
- We observed evidence that the Association of Anaesthetists of Great Britain and Ireland (AAGBI) (2011) day case and short stay surgery guidelines were followed, which included a clear escalation process to a nearby NHS provider should a medical emergency occur, and sufficient staffing during time in the recovery room.
- Compliance with the BPAS Surgical Safety Checklist was audited regularly within the surgical unit. In February 2015, all relevant registered managers were required to audit effective use of the BPAS Surgical Safety Checklist within their own units and report their findings centrally. BPAS Merseyside scored 100% in this audit. At the time of our inspection we observed the checklist being actively utilised in theatre.
- BPAS monitored national and international developments in care and service delivery and reported to the BPAS Clinical Governance Committee on developments. BPAS had a Clinical Advisory Group which brought together clinicians to review and advise on clinical guidelines.
- BPAS had been involved in providing advice and guidance to the Human Tissue Authority (HTA) on production of its recent document, 'Guidance on the Disposal of Pregnancy Remains Following Pregnancy Loss or Termination', and was part of the team that was updating the Royal College of Nursing's guidance document, 'Sensitive Disposal of all Foetal Remains'.

Nutrition and hydration

- Information about fasting prior to surgery was given to the patient in the 'My BPAS Guide' which was an information booklet given to the patient during their consultation.
- Patients were given biscuits and water after surgery to aid recovery.
- Patients were regularly asked if they wanted refreshments during their stay. A water machine was located in the waiting rooms and a hot drinks machine for patients was available in the discharge room on the top floor.

Pain relief

- Patients were offered appropriate pain relief during and after surgical or medical abortion.
- We observed patients being regularly asked if they were in any discomfort or pain and of the seven surgical records we reviewed, all had a pain assessment documented. When identified as experiencing pain, patients were given pain control in a timely manner.
- Medication was prescribed prior to a patient entering theatre and additional medication could be prescribed. Pain medication offered after surgery was in line with RCOG best practice guidelines and included non-steroidal anti-inflammatory medication which is identified as a drug of choice.

Patient outcomes

- The service followed the BPAS planned programme of audit and monitoring that included areas recommended by RCOG such as consent for treatment, discussions related to different options of abortion, contraception discussion, confirmation of gestation, and medical assessments audits. Audit outcomes and service reviews were reported to the governance committees and Regional Quality, Assessment and Improvement Forums (RQuAIF).
- Audit outcomes fed into monthly dashboards along with safeguarding, serious incidents, lab sampling/labelling errors, sickness absence, complaints and staffing levels. The dashboards for April to December 2015 showed BPAS Merseyside achieved all standards in every month except July and August. In July, the service failed to meet targets on minimum staffing levels and reported one lab sampling/labelling error. In August, the service again reported one lab sampling/labelling error.
- The service had agreed standards in place with commissioners. This was in line with RSOP 16 which states providers must have clear standards against performance and they must work towards RCOG guidelines.
- The service monitored waiting times to ensure service delivery was in line with best practice. Waiting times for consultation from initial contact to treatment were within the Royal College of Obstetricians and Gynaecologists' recommended timeframes.
- Information about any previous abortions was noted as part of the pre-assessment process, this was so the nurse could determine if the woman had any previous complications. The clinic collected data from women

about their previous terminations, in the quarterly monitoring report to Wirral CCG for January to March 2016, 42.3% of patients who were seen at the clinic had undergone a previous abortion.

- Patients were screened for sexually transmitted disease. In the quarterly monitoring report to Wirral CCG (1 January to 31 March 2016) the service reported 111 patients were eligible for the chlamydia screening during the period however only 60.3% were screened. The report indicated the reason that eligible patients had not been tested was either because the patient had refused (87.7%) or had recently been tested (12.2%).
- The report also showed that of 111 eligible patients, the service had screened 30 patients for HIV under the point of care scheme. The vast majority of those eligible who had not been tested had refused the test (98.1%)
- The number of patients who left the service with suitable contraception including the uptake of long acting reversible contraceptives (LARC) was also recorded. Between January and March 2016, 128 patients were given advice on contraception, 40 patients left with LARC (36%) and 12 patients took oral contraception. We asked staff what action was being taken to improve the uptake of different contraceptive methods but they didn't know.
- The rate of complications was also documented. Information on complications such as perforation of the uterus, uncontrolled haemorrhage and any other scenario that required a transfer to the NHS on an emergency basis was collated and reviewed. From January 2015 to May 2016 the service reported six complications.
- Whilst the quarterly monitoring reports gave details of service delivery, they did not include details of agreed targets so it was not clear how well the service was performing. It was also not clear how this information was used to improve service delivery or patient outcomes.
- Patients undergoing medical abortion were asked to complete a pregnancy test two weeks after treatment to ensure that the treatment had been successful. Patients could contact the BPAS aftercare telephone service and were invited back to the clinic if there were any concerns.
- Simultaneous EMAs were introduced nationally by the provider following a pilot study in March 2015. Clinical Governance Committee meeting minutes for March 2015 include presentation of the findings of the study and recommendations for practice. The minutes state: "Comparatively, simultaneous administration was associated with more frequent need for vacuum aspiration (7% vs. 3.3%), a higher continuing pregnancy rate (2.1% vs. 1.2%), and more frequent need for a 2nd dose of misoprostol (6.4% vs. 2.4%). When the analysis was restricted to women who used misoprostol 24 hours or more after mifepristone, the incidence of surgical evacuation and continuing pregnancy dropped to 2.8% and 0.56%, respectively, in that group."
- The minutes also state: "Although same time EMA was less effective than EMA with a 6-72 hour interval or 24 hour or greater interval between medications, many women appear to value a shorter interval, even at greater risk. An additional benefit of simultaneous administration is that fewer resources are needed at BPAS and for the woman if a routine 2nd visit is not needed. We already know from internal audits that same day EMA has a higher complication rate than a standard (24 hour or more) interval". Following discussion the committee agreed to continue to offer same time EMA (incorporating data on outcomes in written and verbal information provided to women), discontinue same day EMA and continue to monitor same time EMA outcomes and impact on resources.
- The service monitored the outcomes of this new method which were reported to the clinical governance committee. Minutes from June 2015 and November 2015 both showed there had continued to be an increase in the number of complications since the introduction of simultaneous EMAs but that these were within the rates quoted in the BPAS guide. We observed that complications and risks of having simultaneous EMA's were discussed with women at consultation.

Competent staff

- BPAS had various competency frameworks in order to support the training and development of staff. This was to ensure that agreed standards were monitored, met, and maintained.
- The registered manager explained that staff were trained to be multi-skilled and this allowed staff to work between floors/different areas of the service.
- Staff were supported to undertake continuous professional development activities, in order to update

their skills and knowledge. For example, all clinical staff were expected to attend the BPAS Clinical Forum, where expert speakers presented on topics relevant to BPAS work.
- Information provided by the service stated all medical staff had undergone an annual appraisal in the last full year (January to December 2015).
- 89% of registered nurses and 83% of administrative staff had received an annual appraisal in the last full appraisal year (January to December 2015).
- BPAS staff who provided post abortion counselling completed the BPAS Client Support Skills and Counselling & Self Awareness courses, and were fully competent with the Client Care Co-ordinator competencies framework. This training was designed to provide staff with skills specific to supporting patients with making decisions about their pregnancy. Following this, they then attended the BPAS Post Abortion Counselling training.
- Staff had access to specific training to increase their skills and meet the needs of patients. For example, nurses had completed a scanning course with a competency assessment, in conjunction with Bournemouth University, which helped them determine the gestational age for patients undergoing termination of pregnancy. Nurses would scan women at consultation to confirm the pregnancy and gestation.
- Other health professionals such as ODP's were not fully accredited but had part way finished the course, such staff were asked to assist the surgeon during surgical procedures. Their role was to move the scan probe during the procedure for the surgeon to review the uterus.
- Audits were used to identify the competencies of scanning staff and to improve practice.
- Initial contact with BPAS services was made through the national contact treatment centre run by BPAS staff that had completed a competency based training specific to the role.

Multidisciplinary working

- We observed good team working between all the nurses, health care assistants, anaesthetists and consultants.
- We reviewed the service level agreement which was in place with a local NHS provider should an unplanned emergency transfer be required. All staff we spoke to were aware of the procedure and felt confident in following it, should an emergency occur. The registered manager explained they met with the local trust once a year to review the service level agreement and discuss any issues. If any concerns were identified in between formal review sessions, meetings were arranged as required to ensure clear communication and discussion of any issues.
- The service had links with the local safeguarding team and with the police should they need to refer a safeguarding concern.
- The service employed counsellors who were available to counsel patients, pre and post termination. In one record we reviewed, the counsellor documented uncertainties expressed by the patient; this led to the patient leaving the clinic to re-think their decision.

Seven-day services

- The service offered treatment six days a week. Advice and support was available seven days a week throughout the year via a 24 hour helpline. This service was also offered to patients who lived aboard.

Access to information

- Staff had access to care plans, test results and policies. Hard copies of policies were available but could also be accessed using the computer at the reception desk .
- A copy of the discharge letter was given to patients; staff said they did not routinely send discharge letters to the general practitioners because often patients wanted the procedure to remain undisclosed.
- We reviewed seven letters and found they contained the relevant information regarding the termination procedure and outcome. In the cases where general practitioners were informed, discharge letters allowed the practitioner to manage any complications in the event the patient deteriorated.
- Patients were given the 'My BPAS Guide' at their consultation which had information which included: consultation process, preparing for any of the procedures, risks associated with procedures, contraception choices, screening, and how to make a complaint or leave feedback.

Consent, Mental Capacity Act and Deprivation of Liberty Safeguards

- All records we reviewed had a completed signed consent form.

Termination of pregnancy

- We observed nurses, doctors and health care assistants obtaining consent from patients before clinically assessing them. Staff spoke to patients about any care and treatment that was being carried out before they went ahead with the procedure. The service made sure that patients were seeking abortions voluntarily. All consultations were conducted alone. This was so that staff could determine the reasons why and how they had reached their decision to terminate their pregnancy
- A trained pregnancy counsellor offered patients the opportunity to discuss their options and choices in line with department of health RSOP 14: 'counselling' as part of the consent process.
- All patients under 18 years discussed their options with a counsellor prior to being asked for their consent.
- Provisions were in place to assess children using the Fraser Guidelines and Gillick competence to ensure that consideration was taken to the medical, psychological and social needs of children under the age of 17 years old.
- Staff understood and were aware of the mental capacity act and sought advice from head office safeguarding team if they required further support.

Are termination of pregnancy services caring?

- Staff were non-judgemental and responsive to patients' needs. We observed staff using a caring and compassionate approach particularly in the recovery room where patients were transferred after surgery.
- Patient feedback forms indicated the majority of patients felt listened to and felt that their confidentiality was maintained.

However:

- Patients were not informed about the statutory requirement of HSA4 forms. Staff did not explain to patients that these details were sent to the Department of Health and that it was a legal requirement.

Compassionate care

- We observed most patients being cared for with dignity and respect. Staff were non- judgemental in their approach and this was confirmed by two patients in the discharge lounge. Both patients told us, staff were kind and supportive and were not condescending.
- However, at the time of our inspection we observed a sedated patient being transferred from theatre to the recovery room, a handover was given; however, there were other patients in the area and the curtains were not pulled round the patient.
- We observed patients in theatre having their legs placed in stirrups prior to being sedated and due to the number of staff in the theatre; we were not assured that this maintained the patient's dignity.
- Patients on the ward were happy with the care they received, they said the staff were non-judgemental and caring.
- All patients were provided with a feedback form prior to discharge. The completed questionnaires were returned to a secure lockable box in the reception area or could be posted to head office. From January 2016 to April 2016 the service received 1413 responses and 99% of these stated they would recommend the service, 99.9% said they felt listened to and their confidentiality was maintained.

Understanding and involvement of patients and those close to them

- Staff discussed the different termination procedures with patients at their consultation so that they could make an informed decision about the available termination of pregnancy methods. For example the risks and complications of simultaneous EMA's were discussed with patients. Written information in the 'My BPAS Guide' was given to patients at the consultation, the booklet contained information on topics such as sexual transmitted diseases, contraception and contact details of the 24 hour helpline.
- Following treatment staff observed patients until they were fit and ready for discharge. Patients in the discharge lounge said they felt involved in the care delivered to them. Nurses asked them for permission before any treatment or intervention was carried out. For example nurses asked if they could feel their stomach before they did.
- The discharge discussion included a conversation about "what to expect" for example blood loss, pain and counselling was discussed with patients.
- Patients were not informed about the statutory requirement of HSA4 forms, Staff did not explain to patients that these details were sent to the Department of Health and that it was a legal requirement.

- Patients who were responsible for full or partial cost of care or treatment, such as those patients travelling from Ireland, were taken into the registration room where a discussion took place about the cost involved. This was done in a sensitive manner and without the supporter. This was to ensure that the choice to terminate the pregnancy was the patient's decision.

Emotional support

- The waiting room was large and spacious which meant supporters were able to stay and wait with patients. Data provided by the clinic showed during the period January 2016 to April 2016 87.1% of patients wanted to have their escort with them. Of this 87.1%, 74.9% were invited to join the patient after the initial discussion had taken place.
- Post abortion counselling was offered as a free service to all BPAS patients, and could be accessed any time after their procedure, whether this was the same day or many years later.
- As stated by the RCOG clinical guideline, all patients had the opportunity to discuss their decision to determine the degree of certainty of their decision. A Client Care Co-ordinator was available to speak to any patient who was unsure about her decision, or needed additional support during pre-assessment.
- At the time of our inspection we observed patients in the recovery room who became emotional and upset being supported by staff in a caring compassionate manner.

Are termination of pregnancy services responsive?

- The service was planned and delivered to meet the needs of patients.
- The electronic triage booking system offered clients a choice of when and where they had the termination. This ensured patients were able to access a clinic that was most suitable to their needs
- Patients were offered support and information about their termination, additionally there was a 24 hour telephone advice/help line that patients could use for information, support or post-operative concerns. Procedures were in place for patients and supporters to raise their concerns about the service. Patients were able to telephone the service, speak to a member of staff, or write to the service formally. A robust complaints pathway was in place.
- Following work in partnership with Antenatal Results and Choices (ARC)the decision had been made to provide terminations of pregnancy for foetal anomalies.
- The 'My BPAS Guide', described how pregnancy remains would be disposed of and invited the patient to inform staff if they had specific wishes. BPAS facilitated, wherever possible, any request made by a patient concerning management of the pregnancy remains.

However:

- A quarterly monitoring report to one of the commissioners showed patients were not always seen within RCOG recommended timeframes. The reasons for delays or extended waiting times were not given in the report but it was possible that these delays were due to patient choice.

Service planning and delivery to meet the needs of local people

- BPAS Merseyside was contracted by several local Clinical Commissioning Groups (CCGs) to provide a TOP service for the population of Merseyside and the surrounding area. BPAS Merseyside was located on the south side of Liverpool and was well served by public transport. The unit was open for treatment from Wednesday to Saturday and included late afternoon sessions.
- Appointments for BPAS Merseyside were booked via the BPAS Contact Centre, which was available 24 hours a day for telephone booking and service information. Patients were able to choose their preferred treatment option and location, subject to their gestation and medical assessment.
- Consulting rooms were for single consultations and were used to speak to patients privately without their supporter. During the consultation patients were asked about their decision and any specific needs they required such as wanting to speak to a counsellor.
- The service had two female surgeons who performed surgical abortions.
- BPAS offered a web chat service, via their internet page, for patients who wanted to know more about the services provided.

Access and flow

Termination of pregnancy

- BPAS closely monitored the appointment availability at all units. The electronic triage booking system offered patients a choice of dates, times and locations. This ensured that patients were able to access the most suitable appointment for their needs.
- BPAS development managers were responsible for overseeing capacity management and unit managers amended their appointment templates, adding additional appointments when necessary.
- The service received patients from a variety of referral methods; these included GPs, hospitals, family planning service, intranet, self-referrals and recommendations. The service collected data on the different referral methods across areas of Merseyside and used the information to inform commissioners of their regional referral rates. For example, data from January to March 2016 showed, the service received 36% of their referrals from GPs and 54% patients had self-referred.
- BPAS' system recorded what appointments were available to patients, within a 30 mile radius of their home address, at the point of booking. This meant that BPAS could monitor their waiting times and patient choice of clinic. Data provided an evaluation of the number of women seen with 7 days and BPAS head office could also monitor which clinic saw the most activity.
- The quality monitoring report submitted to Wirral CCG for January to March 2016 showed on average, patients waited 8.6 days from initial contact to consultation. 35.9% of patients were seen within the target of 7 days although 98.3% of patients could have attended consultation within 7 days. RCOG guidance states providers should have arrangements in place to minimise delays in women accessing services and a choice of method should be provided at all gestations. It was not clear from the report why only 35.9% of patients were seen within the target timeframe. Similarly, the report shows that for the same period of time, patients waited on average 16.2 days from initial contact to treatment and 19 patients waited over 21 days. Again the reasons for delays or extended waiting times are not given in the report so it is possible that some cases may have been due to patient choice.
- The percentage of patients treated at less than ten weeks gestation was regularly reviewed by commissioners. During the period January 2015 – December 2015, 87% of patients were treated under ten weeks gestation. The clinic also reported terminating 96 pregnancies over 20 weeks during the same period.

Meeting people's individual needs

- BPAS staff completed generic and role-specific training, which included a workshop in Welcoming Diversity to ensure they recognised different cultural needs and beliefs. This training was designed to equip them with the knowledge and skills to support patients in making reproductive choices, whilst acknowledging and respecting their individual needs.
- The booklet 'My BPAS Guide' was given to every BPAS patient and provided written information about their post treatment care. The guide had a section dedicated to recovery, which detailed what would normally be expected following treatment.
- The 'My BPAS Guide', described how the pregnancy remains would be disposed of and invited the patient to inform staff if they had specific wishes. BPAS facilitated, wherever possible, any request made by a patient concerning management of the pregnancy remains. Where a patient wished to dispose of the pregnancy remains privately, they provided them with a specific information sheet that explained how the remains should be managed.
- The clinic had up to date information about local funeral services to assist patients who wished to arrange a cremation or burial. BPAS Merseyside advised patients who were travelling by air of airline specifications and had copies of the relevant paperwork. At the time of our inspection we did not observe any recordings in patient records in relation to disposal of pregnancy remains.
- Where patients did not have specific wishes with regard to disposal, pregnancy remains tissue was collected by an authorised carrier and stored separately from other clinical waste before being sent for incineration. A full audit trail was maintained at the unit.
- Equality and access to treatment was monitored via the quarterly monitoring reports submitted to the CCG.
- Abnormal symptoms following treatment was also explained and listed, with information on what patients should do if they experience these. Patients were given leaflets about what to expect after the procedure, this was so that they could refer to the literature once they had left the clinic. This also included details of the 24 hour advice line.

- A range of printed information was available for patients to take home, this included advice on contraception and sexual health.
- Following work in partnership with Antenatal Results and Choices (ARC) the decision had been made to provide terminations of pregnancy for foetal anomalies. Patients attending for this service waited in a small waiting room that was separate from other patients and appointments were allocated for the end of the day.
- Patients were offered pre and post abortion counselling. We did not see and were not shown any information about referring patients to supporting organisations or a designated care pathway as per Royal College of Gynaecology guidance 28.
- We asked staff at the time of our inspection what procedures were in place for patients that may have an anxiety diagnosis or a learning disability. Staff told us the patient's carer would be able to stay with the patient throughout the clinic areas from admission to discharge.
- The team had access to translation support services if required. An interpreter was allowed to stay with the patient if they did not speak English. Due to the nature of the treatment, staff informed us they would always ask the interpreter if they were happy to proceed with providing support once they were told the patient was having an abortion.

Learning from complaints and concerns

- There were six complaints received from January 2015 to May 2016, these related to retained products and waiting times. In the complaints we reviewed, patients received an apology for the experience they received and an explanation to the concern they raised either from the surgeon or the registered manager
- Patients and supporters were able to raise their concerns through a number of ways. 'Making a complaint or giving us feedback' posters were clearly displayed throughout the clinic for patients to read.
- The clinic also had "BPAS Complaints and Feedback Policy' leaflets that patients could take home with them. Information in the leaflet informed patients of the complaints process and reassured them that each complaint was investigated.
- Patients were able to raise a complaint via the telephone service, speak to a member of staff, or write to the service formally. Patients were encouraged to raises concern whilst at the clinic so that they could have a discussion with a member of staff or the manager.
- The registered manager told us learning from complaints would be discussed during team meetings.

Are termination of pregnancy services well-led?

- Local governance arrangements did not ensure the identification, mitigation and monitoring of risks or the improvement of quality and patient outcomes.
- Root cause analysis investigation reports did not identify and consider all relevant information and contributory factors and there had been no review to identify any common themes or trends.
- There was no local risk register or other document that identified local risks and the control measures in place.
- We were not assured that the registered manager had full understanding and grip of the potential risks within the service and the supporting clinical governance arrangements. When asked to supply the full root cause analysis investigation reports following the recent serious incidents, the registered manager was not clear on who had completed the investigation reports, had not been involved in the production of the investigation reports and had not had sight of the full investigation reports. She was unaware that staff did not have information about the outcomes of the serious incident reviews.
- Information from corporate and regional governance meetings should have been shared with staff via staff meetings and nurses meetings. The registered manager explained that team brief meetings were held four times a year and additional staff meetings and nurse meetings were held as required.

However:

- There was a corporate governance committee structure in place which discussed identified risks. The framework also enabled the dissemination of learning and service improvements and a pathway for reporting and escalation to the BPAS board.
- The provider had recognised that local governance processes needed strengthening and had recently employed a risk management and client safety lead

who was responsible for reviewing systems and was working with registered managers to implement systems such as a local risk register and improved incident reporting systems (including the implementation of an electronic reporting system).
- The service had participated in the Workplace Wellbeing Charter, the aim of which is to give employers an opportunity to demonstrate their commitment to the health and well-being of their workforce.
- Practising privileges were reviewed annually by the medical director and registered manager. The clinical department at Head Office flagged when an individual's practising privileges were due. Clinicians had a month to submit the necessary documentation otherwise their practise was suspended until the information was provided.

Vision and strategy for this this core service

- The service clearly displayed the certificate of approval that was issued by the Department of Health on the ground floor in the waiting area and at the entrance of the clinic.
- The 'About BPAS' guide clearly defined the BPAS vision as 'Supporting pregnancy choices – trusting women to decide' and these were underpinned by a set of values such as "We believe that contraception and legal abortion are an essential part of health care and should be freely available to all women through a publicly funded NHS" and "We exist to provide support and care for women seeking legal abortion". This information was also available on the BPAS website.
- BPAS had a clear strategy for its service nationally. However, there was no clearly defined strategy for the Merseyside service at local level.
- Staff we spoke with were unaware of the specific BPAS vision and values, but they understood that there role was to support women in an open, non-judgemental way.

Governance, risk management and quality measurement for this core service

- There was a corporate governance committee structure in place that discussed identified risks. The framework also enabled the dissemination of learning and service improvements and a pathway for reporting and escalation to the BPAS board.
- The clinical advisory group was a sub-committee chaired by the medical director and attended by a group of clinicians. Minutes for these meetings confirmed they took place every three months and the purpose of the committee was to review policies, practice concerns, complication rates and serious incidents. This then fed into the clinical governance committee meetings.
- Information from corporate and regional governance meetings should have been shared with staff via staff meetings and nurses meetings. The registered manager explained that team brief meetings were held four times a year and additional staff meetings and nurse meetings were held as required.
- There was a corporate risk register that listed general risks relating to health and safety issues across the service. The risks that were listed did have actions and time frames against them.
- However, local governance arrangements did not ensure the identification, mitigation and monitoring of risks or the improvement of quality and patient outcomes. This was because root cause analysis investigation reports did not identify and consider all relevant information and contributory factors; despite eight serious incidents occurring in 15 months all leading to the transfer of patients to an NHS hospital there had been no review to identify any common themes or trends. There was also no local risk register or other document that identified local risks and the control measures in place.
- Following the inspection, the risk management and client safety lead confirmed in an email dated 09 June 2016 that a thematic review of serious incidents spanning the last three years at BPAS Merseyside was taking place; this was being led by Halton CCG.
- The provider had recognised that local governance processes needed strengthening and had recently employed a risk management and client safety lead who was responsible for reviewing systems and was working with registered managers to implement systems such as a local risk register and improved incident reporting systems (including the implementation of an electronic reporting system).
- Practising privileges were reviewed annually by the medical director and registered manager. The clinical department at Head Office flagged when an individual's practising privileges were due. Clinicians had a month to

submit the necessary documentation (including proof of indemnity, appraisal and registration with the General Medical Council) otherwise their practise was suspended until the information was provided.

- A register of patients undergoing a TOP was updated and completed; this was kept onsite. A HSA1 form was completed, signed, and dated by two registered medical practitioners before an abortion took place. The reason for a patient's decision for termination of pregnancy was assessed against the criteria set out in the Abortion Act 1967. The HSA1 was completed by both practitioners certifying their opinion. The certification took place in "good faith" after doctors had sight of the patient's circumstances. All HSA1 forms were stored with the patient's record in line with best practice guidance.
- The clinic completed monthly HSA1 audits to ensure and evidence compliance with accurate completion. The January -December 2015 audits showed 100% compliance with completion requirements.
- The service kept a comprehensive record of each HSA4 reference number and the date it was sent to the Department of Health. The registered medical consultant maintained responsibility for the patient and prescribed all abortion medication. BPAS used an on-line system to submit the HSA4 forms. The online HSA4 forms were completed by the clinic, and submitted to the Department of Health post treatment. BPAS doctors obtained a secure login and password from the Department of Health to use this service. The HSA4 was 'signed' online within 14 days of the completion of the abortion by the doctor who terminated the pregnancy. For medical abortion, the doctor who prescribed the medications was the doctor who submitted the HSA4 form. At the time of our inspection all the records we reviewed had documented that the HSA4 form had been completed.

Leadership / culture of service

- BPAS' ethos was to treat all clients with dignity and respect, and to provide a caring, confidential and non-judgemental service. Staff were supported to promote such values through training and ongoing support.
- An initial assessment was undertaken before the termination procedure to ensure patients were free of any fear of financial exploitation when accessing termination of pregnancy services. This assessment was done alone, during this assessment staff informed patients that the treatment was provided on behalf of the NHS. Those patients who were not English residents were asked to pay a set fee in line with BPAS pricing structure.
- Registered managers received training in key policy areas of their role, which included any current legal or regulatory requirements. These included: modular management training courses, and conference calls to discuss new or amended guideline and policies.
- However, we were not assured that the registered manager had full understanding and grip of the potential risks within the service and the supporting clinical governance arrangements. When asked to supply the full root cause analysis investigation reports following the recent serious incidents, the registered manager was not clear on who had completed the investigation reports, had not been involved in the production of the investigation reports and had not had sight of the full investigation reports. She was unaware that staff did not have sight of the outcomes of the serious incident reviews.

Public and staff engagement

- Feedback from patients was routinely collected so that the clinic could improve their service. BPAS Feedback forms were left for patients to complete pre and post treatment. Feedback forms and comments were reviewed by managers and were used to inform service development.
- BPAS received 8434 responses nationally between January 2016 and March 2016. The data showed that 99% of patients would recommend the service. The data was not disaggregated by clinic and therefore we could not determine how many of these responses were for BPAS Merseyside and what the overall satisfaction score was for the service.
- Staff were able to engage with the wider organisation through an online staff forum.
- Staff could access an employee assistance programme for practical issues outside of work and there was an anonymous counselling service available for staff when upset by work related issues.
- Staff received regular BPAS 'Connect' updates, which provided news, updates and training information, and team briefs, which included information about finance, marketing and clinical changes.
- There was an annual managers' conference attended by the CEO.

Termination of pregnancy

Innovation, improvement and sustainability

- BPAS Merseyside had worked in partnership with Antenatal Results and Choices (ARC) to produce a report about the abortion services available for women in Northern Ireland.
- The service had participated in the Workplace Wellbeing Charter the aim of which is to give employers an opportunity to demonstrate their commitment to the health and well-being of their workforce.

This section is primarily information for the provider

Requirement notices

Action we have told the provider to take

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

Regulated activity	Regulation
Termination of pregnancies	Regulation 12 HSCA (RA) Regulations 2014 Safe care and treatment **Regulation 12 Safe Care and Treatment; (1) (2) (a) (b) (e) (g) (h)** Care and treatment was not always provided in a safe way because the registered person had not done all that is reasonably practicable to mitigate risks to the health and safety of services users receiving care and treatment. This is because: We found a lack of robust systems in place, to ensure that resuscitation equipment was appropriately checked and stored to keep patients safe. It was not clear whether several pieces of equipment used in theatre had been subject to the appropriate maintenance tests. There were trolleys in the recovery room that had pieces of equipment on them. At the unannounced inspection we reviewed equipment stored in the recovery room and found items that had passed the expiry date. We were therefore not assured that equipment was regularly checked to keep patients safe. We observed a syringe with medication insitu, unlabelled and placed on a box of ampoules on the anaesthetic machine during surgery. The OPD informed us this was drawn up as an emergency drug should it be required during theatre. This syringe was in theatre all day whilst surgery took place. We were not assured that this was safe practice due to the length of time left unused and the syringe not being labelled.

This section is primarily information for the provider

Requirement notices

Patients were being placed at risk of infection. We found staff did not always follow best practice infection control procedures, particularly in relation to the management of laundry, transfer and movement of staff between theatre and clinic areas and the use of syringes to administer intra-venous drugs.

We found no evidence to confirm that a robust system was in place and embedded to share lessons learned from incidents and complaints across the service. Staff were unaware of the lessons learnt from the serious case incidents.

Regulation

Regulation 17 Good Governance (1) (2) (a) (b) (f)

We were not assured that the registered manager had full understanding and grip of the potential risks within the service and the supporting clinical governance arrangements. When asked to supply the full root cause anaylsis investigation reports following the recent serious incidents, the registered manager was not clear on who had completed the investigation reports, had not been involved in the production of the investigation reports and had not had sight of the full investigation reports. She was unaware that staff did not have sight into the outcomes of the serious incident reviews.

Local governance arrangements did not ensure the identification, mitigation and monitoring of risks or the improvement of quality and patient outcomes. This was because:

There had been 8 serious incidents between January 2015 and March 2016. Root cause analysis investigation reports did not identify and consider all relevant information and contributory factors; despite these serious incidents all leading to the emergency transfer of patients to an NHS hospital and concerns raised by the local NHS hospital.

This section is primarily information for the provider

Requirement notices

At the time of our inspection there had been no thematic review initiated by BPAS following the incidents to identify any common themes or trends, despite the fact that the inspection team (including specialist advisor) identified that the same surgeon had been involved in at least four of the incidents.

There was no local risk register or other document that identified local risks and the control measures in place.