

Humanitas Healthcare Services Ltd

Blakenall Village Centre

Inspection report

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Overall summary

We carried out an announced comprehensive inspection on 3 May 2018 to ask the service the following key questions; Are services safe, effective, caring, responsive and well-led?

Are services safe?

We found that this service was not providing safe care in accordance with the relevant regulations.

Are services effective?

We found that this service was providing effective care in accordance with the relevant regulations

Are services caring?

We found that this service was providing caring services in accordance with the relevant regulations.

Are services responsive?

We found that this service was providing responsive care in accordance with the relevant regulations.

Are services well-led

We found that this service was not providing well-led care in accordance with the relevant regulations.

We carried out this inspection under Section 60 of the Health and Social Care Act 2008 as part of our regulatory

functions. This inspection was planned to check whether the service was meeting the legal requirements and regulations associated with the Health and Social Care Act 2008.

Humanitas Healthcare Services Ltd operates from Blakenall Village Centre, Walsall. The services they provide for both NHS and private patients include:

- Vasectomy
- Carpel tunnel decompression
- Trigger finger release
- Soft tissue and joint injections
- Excision of clinically benign lumps
- Nail surgery

Dr A Benjamin is the registered manager for Humanitas Healthcare Services Ltd. A registered manager is a person who is registered with the Care Quality Commission to manage the service. Like registered providers, they are 'registered persons.' Registered persons have legal responsibility for meeting the requirements in the Health and Social Care Act 2008 and associated Regulations about how the service is run.

We spoke with two patients following the inspection. The feedback demonstrated positive outcomes for patients. Patients spoke highly of the care and treatment they had received from the clinic. They described staff as friendly and caring. They also commented that staff put them at

Summary of findings

their ease during the procedure. Staff we spoke with told us they were well supported in their work and were proud to be part of a team which provided a good quality service.

Our key findings were:

- Patients received detailed and clear information about their proposed treatment which enabled them to make an informed decision.
- Patients were offered convenient, timely and flexible appointments.
- Staff helped patients be involved in decisions about their care. Patients were provided with written pre and post treatment literature. The provider did not have a written recruitment and selection policy and procedure. They had not obtained the appropriate staff checks in accordance with the regulatory requirements for staff who worked occasionally.
- There was an effective system to manage infection prevention and control (IPC).
- There were limited systems to assess, monitor and manage risks to patient safety. Risk assessments in relation to safety issues for the building and the range of emergency medicines available to staff had not been completed.
- There was a system and procedure for recording and acting on significant events and incidents.
- There were limited processes for managing risks, issues and performance. Health and safety risk assessments had not been completed to identify hazards and mitigate potential risks at the site.
- There was little evidence to support that clinical audit had a positive impact on quality of care and outcomes for patients.
- Information about the range of procedures offered by the provider was not up to date and accurate.

We identified regulations that were not being met and the provider must:

- Establish effective systems and processes to ensure good governance in accordance with the fundamental standards of care.
- Ensure recruitment procedures are established and operated effectively to ensure only fit and proper persons are employed.

You can see full details of the regulations not being met at the end of this report.

There were areas where the provider could make improvements and should:

- Implement an effective process to ensure the identification of significant events.
- Review the process for annual appraisals and development plans.
- Review the process used to check the expiry dates of single use items.
- Review and update the consent form to include the recent updates in guidance.
- Update the information about the range of procedures offered by the provider so that accurately reflects what is offered.

Summary of findings

The five questions we ask about services and what we found

We always ask the following five questions of services.

Are services safe?

We found that this service was not providing safe care in accordance with the relevant regulations.

We have told the provider to take action (see full details of this action in the Requirement Notices section at the end of this report).

The impact of our concerns is minor for patients using the service, in terms of the quality and safety of clinical care. The likelihood of this occurring in the future is low once it has been put right. We have told the provider to take action (see full details of this action in the Requirement Notices at the end of this report).

- Systems were in place to check the identity of all patients prior to offering them an appointment.
- The provider did not have a formalised system for undertaking recruitment checks on staff who worked on an adhoc basis.
- There was an effective system to manage infection prevention and control (IPC).
- There were limited systems to assess, monitor and manage risks to patient safety. Risk assessments in relation to safety issues for the building and the range of emergency medicines available to staff had not been completed.
- There was a system and procedure for recording and acting on significant events and incidents. However, the service needed to review the effectiveness of the process to improve upon the identification of significant events.

Are services effective?

We found that this service was providing effective care in accordance with the relevant regulations.

- Patients referred to the service were assessed as suitable for the procedure by the referring clinician. However the service provided further counselling for patients if they felt they needed this. The medical director assessed private patients during their consultation appointment.
- The service had a limited programme of quality improvement activity and review of the effectiveness and appropriateness of the care provided.
- Staff had the skills, knowledge and experience to carry out their roles.
- The consent process for patients was detailed and effective although the form needed updating to include details of the new guidance.

Are services caring?

We found that this service was providing caring services in accordance with the relevant regulations.

- Staff treated patients with kindness, respect and compassion.
- Staff helped patients be involved in decisions about their care. Patients were provided written pre and post treatment literature.
- The practice respected and promoted patients' privacy and dignity.

Are services responsive to people's needs?

We found that this service was providing responsive care in accordance with the relevant regulations.

- The service provided a vasectomy, carpal tunnel decompression service, trigger finger release, soft tissue and joint injection, excision of clinically benign lumps and nail surgery for NHS and private patients. Procedures were carried out from a local health centre in Walsall.

Summary of findings

- Patients were offered convenient, timely and flexible appointments.
- The practice took complaints, concerns and comments seriously and responded to them appropriately.

Are services well-led?

We found that this service was not providing well-led care in accordance with the relevant regulations. We have told the provider to take action (see full details of this action in the Requirement Notices section at the end of this report).

- The service had a clear vision and set of values, which were communicated to staff. A culture of openness and honesty was promoted throughout the service.
- Patient and staff views was encouraged and shared to review, shape and improve the service provided.
- Due to a small staff team and close working relationships, arrangements for supervision and appraisals were informal and information was not documented. Regular meetings took place and these were documented.
- There were limited processes for managing risks, issues and performance. Health and safety risk assessments had not been completed to identify hazards and mitigate potential risks at the site.
- There was little evidence to support that clinical audit had a positive impact on quality of care and outcomes for patients.
- Not all information about the service was up to date and accurate.

Blakenall Village Centre

Detailed findings

Background to this inspection

Humanitas Healthcare Services (HHS) Ltd is an organisation registered with the Care Quality Commission (CQC). Procedures are carried out at Blakenall Village Centre, 79 Thames Road, Blakenall, Walsall, WS3 1LZ. Humanitas Healthcare Services Ltd provides a vasectomy, carpal tunnel decompression service, trigger finger release, soft tissue and joint injection, excision of clinically benign lumps and nail surgery for NHS and private patients.

The service is commissioned by NHS Walsall Clinical Commissioning Group through an Any Qualified Provider contract for Walsall CCG's Minor Surgery Service.

The staff team is led by an experienced Medical Director Dr Albert Benjamin, supported by an experienced nurse with additional training in minor surgery. Clinics are held between 10am and 4pm on Tuesdays and Saturdays.

We inspected Blakenall Health Centre on 3 May 2018 as part of our inspection programme. Our inspection team was led by a Care Quality Commission (CQC) Lead Inspector. The team included a GP specialist adviser.

Before visiting we reviewed a range of information we hold about the service and asked the service to send us a range of information. This included information about the number of complaints received in the last 12 months and the details of their staff members, their qualifications and training. HHS provided information on the day of the inspection that included audits and policies. We spoke with both members of staff from the service during the inspection.

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

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

These questions therefore formed the framework for the areas we looked at during the inspection.

Are services safe?

Our findings

We found that this service was not providing safe care in accordance with the relevant regulations.

Safety systems and processes

The service had clear systems to keep patients safe and safeguarded from abuse. Staff had received training in safeguarding and equality and diversity. Staff understood their responsibilities, had access to a safeguarding policy, and a designated safeguarding lead member of staff. Contact details for the children's and adult safeguarding teams was on in display in the treatment room.

All NHS referrals were received through the NHS e-referral system. The NHS e-Referral Service (e-RS) combines electronic booking with a choice of place, date and time for first hospital or clinic appointments. Patients can choose their initial hospital or clinic appointment, book it in the GP surgery at the point of referral, or later at home on the phone or online. The provider did not currently have access to the NHS electronic data base in order to check the identity and details of patients. Consequently these were checked when staff contacted patients to arrange appointments. The provider also received private referrals and patient details were checked during the consultation.

The medical director and nursing director had been in post since registration with the Care Quality Commission. Information held on file included proof of identity, employment history, immunisation status, professional registration checks and a Disclosure and Barring Service (DBS) check. (DBS checks identify whether a person has a criminal record or is on an official list of people barred from working in roles where they may have contact with children or adults who may be vulnerable). The provider did not have a formalised system for undertaking recruitment checks on staff who worked on an adhoc basis. The provider told us that occasionally additional staff, a male theatre technician and a consultant community gynaecology colleague supported the service. The provider had not undertaken any recruitment checks on these staff. Following the inspection, the provider provided evidence of proof of identity, DBS check, qualifications, training and immunisation status for the theatre nurse.

Two members of staff were always present when procedures were being carried out. Designated staff who acted as chaperones were trained for the role and had received a DBS check.

There was a system to manage infection prevention and control (IPC). The nursing director was the designated infection prevention and control lead. An infection control policy was in place. The local IPC team had carried out an audit in February 2018. External cleaners were contracted to maintain the cleanliness within the building and cleaning schedules were in place.

The provider ensured that their equipment were safe and maintained according to manufacturers' instructions. There were systems for safely managing healthcare waste.

HHS held clinics in a building that was managed by NHS Estates. The landlord had carried out a number of risk assessments including fire and legionella risk assessments. However, the provider had not completed any risk assessments in relation to safety issues for the areas of building that they used.

Risks to patients

The provider had arrangements in place to respond to emergencies. Staff had completed training in emergency resuscitation and life support to ensure they were able to respond appropriately to any changing risks to patients' health and wellbeing during their treatment.

Emergency medicines and equipment were easily accessible to staff during clinic times and stored in a secure area. The clinic had emergency resuscitation equipment available including an automatic external defibrillator (AED) and oxygen. The clinic also had medicines for use in the event of an emergency. We saw that the service did not stock the full range of medicines that would be expected for this type of service. This included an antiemetic (for nausea and vomiting), atropine (to treat a slow heart beat), rectal diazepam (for epileptic fits), glucagon (for low blood sugars) and GTN spray (for chest pain). A risk assessment had not been completed to outline the rationale for not stocking all of the suggested emergency medicines.

The service had professional indemnity arrangements in place for the medical director who conducted the minor surgery. The provider had group professional indemnity in place with covered the role of the nursing director. All clinical staff were up to date with their professional

Are services safe?

registration and revalidation. However there was no information available regarding indemnity arrangements or professional registration and revalidation for the clinical staff employed on an ad hoc basis.

The service did not have an effective system for checking expiry dates of single use items. We found a number of steristrips and needles which were past their use by expiry date. There were also a number of bandages where it was not clear what the use by expiry date was.

Information to deliver safe care and treatment

Staff had the information they needed to deliver safe care and treatment to patients.

- The service received completed referral forms via the NHS e-referral service for each NHS patient from other health care professionals.
- Private patients were offered a consultation, during which their needs and suitability for the surgery were assessed.
- Individual care records were written and managed in a way that kept patients safe. The service maintained a mixture of electronic and paper records for patients. All paper records were stored securely. The laptop used on site during clinics was encrypted. The provider told us they planned to scan paper records on to the electronic system in the near future.
- The nursing director told us they recorded the batch number and expiry date for all medicines administered to patients.
- The service shared information with the patient's GP by receiving referral letters detailing the patient's condition and personal circumstances and always communicating with them after a procedure had been carried out.

Lessons learned and improvements made

The service learned and made improvements when things went wrong.

- There was a system and procedure for recording and acting on significant events and incidents. We saw staff had access to a policy and standard form to record and report adverse incidents and events. The provider told us that there had been no significant events recorded in the previous 12 months.
- Significant events were a standing agenda item at staff meetings. We saw that any incidents were discussed as required. We found the service needed to review the effectiveness of this process to improve upon the identification of significant events.
- We reviewed the patient satisfaction surveys and noted that incidents could be identified through feedback. For example we noted that a patient had commented about the cleanliness of a pillow and perceived lack of infection control procedures. The nursing director told us of the action that had been taken following this feedback. However, this had not been recorded as an incident.
- The provider was aware of and complied with the requirements of the Duty of Candour. The provider encouraged a culture of openness and honesty. The service gave affected people reasonable support, truthful information and a verbal and written apology.
- The provider had a system for receiving and dealing with safety alerts.

Are services effective?

(for example, treatment is effective)

Our findings

We found that this service was providing effective services in accordance with the relevant regulations.

Effective needs assessment, care and treatment

The service had systems to keep clinicians up to date with current evidence-based practice. We saw that clinicians assessed needs and delivered care and treatment in line with current legislation, standards and guidance supported by clear clinical pathways and protocols.

NHS patients referred to the service had already been assessed as suitable for the procedure by the referring clinician. However, patients were offered further counselling if they felt they needed this. The medical director assessed private patients during their consultation appointment.

The provider had developed an electronic template to record all required information in relation to any procedures that had been carried out in the patient record. For example batch numbers and expiry dates for any medicines used. All sections had to be completed before the template could be saved and closed.

Monitoring care and treatment

The provider had some procedures in place for reviewing the effectiveness and appropriateness of the care provided. Patients were asked as part of the satisfaction survey whether they developed an infection which needed antibiotic treatment. The results were collated on a monthly basis. The results seen for April 2017 demonstrated that no patients had developed an infection. The provider shared their results on an annual basis with Association of Surgeons in Primary Care (ASPC). There was no evidence to support that the provider used the national data provided by the ASPC as a baseline for comparisons.

The service did not proactively monitor whether patients returned a sample for testing post vasectomy or audit post vasectomy sterility rates.

Effective staffing

Staff had the skills, knowledge and experience to carry out their roles.

- The medical director and nursing director had undertaken additional training to enable them to carry out their role.
- The service understood the learning needs of staff and provided protected time and training to meet them. Staff were encouraged and given opportunities to develop.
- The nursing director told us that they received an annual appraisal although the process was informal. There were no recorded appraisals and learning and development plans.

Coordinating patient care and information sharing

The service routinely shared information for NHS patients with their GP. The provider notified the patient's GP as to whether the patient had attended and received treatment and/or if they had not. Information about private patients was either shared with their GP if permission given or requested that the patient share information with their GP. Patient information was stored electronically or in paper form. The patient information that was stored electronically was on the same system as the GPs, although the two systems were not yet currently linked.

Consent to care and treatment

Staff sought patients consent to care and treatment in line with legislation and guidance. Staff understood the relevant consent and decision-making requirements of legislation and guidance, including the Mental Capacity Act (MCA) 2005. The service was aware of recent changes around consent, although the consent forms had not been amended to reflect these changes.

Separate consent forms were used, one for vasectomies and one for primary care surgery. We saw that the forms obtained parental consent to treatment as appropriate. We saw examples of completed consent forms.

Are services caring?

Our findings

We found that this service was providing caring services in accordance with the relevant regulations.

Kindness, respect and compassion

Staff treated patients with kindness, respect and compassion.

- The practice gave patients timely support and information.
- Comments seen on the provider satisfaction survey were positive about the service provided.

All patients were asked to complete a satisfaction survey on the day of their operation and after one week. The nursing director reviewed the surveys and collated the results. The nursing director told us they discussed any negative comments or issues with the medical director and acted upon these as required. Patient satisfaction returns was a standing agenda item at staff meetings.

The results were also shared with the Association of Surgeons in Primary Care (ASPC), who produced annual report. This enable the provider to bench mark themselves against other providers delivering the same service.

Involvement in decisions about care and treatment

Staff helped patients be involved in decisions about their care.

- Patients were provided with written patient information literature both pre and post treatment.
- Interpretation services were available for patients who did not have English as a first language.

Staff told us that patients were encouraged to ask questions about any treatment and were listened to. Patients were offered either a one-stop appointment or a counselling appointment if they wished to discuss any concerns that they may have.

All patients received detailed and clear information about their proposed treatment which enabled them to make an informed decision. This included the risks and benefits of treatment. The information regarding the cost of the procedures for those patients who were self funding was available.

Privacy and Dignity

The practice respected and promoted patients' privacy and dignity.

- Staff recognised the importance of patients' dignity and respect.
- The practice complied with the Data Protection Act 1998. All confidential information was stored securely.
- The minor surgery room was located away from the main waiting area. Staff told us that patient privacy and dignity was maintained at all times.

Are services responsive to people's needs?

(for example, to feedback?)

Our findings

We found that this service was providing responsive services in accordance with the relevant regulations.

Responding to and meeting people's needs

The service provided a range of procedures including excision of clinically benign lumps, joint injections, and vasectomy and carpal tunnel decompression services for patients in a community setting close to their home. Although the provider was registered to provide services from two sites, all procedures were currently carried out at Blakenall Village Centre.

The service was commissioned by NHS Walsall Clinical Commissioning Group through an Any Qualified Provider contract for Walsall CCG's Minor Surgery Service.

The facilities and premises at Blakenall Village Centre were appropriate for the services delivered. The service had a lift to provide access to the first floor.

Timely access to the service

Patients were able to access care and treatment from the practice within an acceptable timescale for their needs. Clinics were provided weekly on Tuesdays and Saturdays, although there was flexibility to see patients on other days. All patients were seen within eight weeks from contacting

the service through the NHS e-referral system. The nursing provider told us they contacted patients by telephone or text to remind them of their appointment. Consequently, the service had very few patients who did not attend for appointments.

Listening and learning from concerns and complaints

The practice took complaints and concerns seriously and responded to them appropriately to continually improve the quality of care.

- The complaint policy and procedures were in line with recognised guidance.
- There was a designated responsible person who handled all complaints about the service.
- The service had received two complaints during the previous 12 months.
- Complaints were a standing agenda item for staff meetings.

Neither complaint had been received directly by the service. The provider had responded to one of these complaints and the other was ongoing. As a consequence the provider had amended the consent form to include evidence that that patient had received and understood the complaints procedure. The complaints procedure was on display in the waiting area.

Are services well-led?

(for example, are they well-managed and do senior leaders listen, learn and take appropriate action?)

Our findings

We found that this service was not providing well-led services in accordance with the relevant regulations.

Leadership capacity and capability

Leaders had the capacity and skills to deliver effective services. They recognised that if the service was to expand, then additional staff would need to be recruited to the staff team.

Vision and strategy

The provider had a clear vision and strategy to deliver high quality, sustainable care.

- The mission statement for the service was to promote person centred local anaesthetic surgery within community settings as a speciality in its own right.
- There was a clear vision and set of values.
- Staff were aware of and understood the vision, values and strategy and their role in achieving them.

Culture

The two members of staff worked very closely with each other, and both told us they were able to discuss any issues as they arose. Observations made and feedback gained from staff and patients showed the culture of the service actively encouraged candour, openness and honesty.

There were processes for providing all staff with the development they needed. This included an annual appraisal although the process was informal. The medical director was supportive of the nursing director developing their skills to enable them to carry out some of the procedures.

Governance arrangements

There were clear responsibilities, roles and systems of accountability to support good governance and management.

- Staff were clear on their roles and accountabilities. For example; the medical director was the safeguarding lead and the nursing director was the infection prevention and control (IPC) lead.
- Policies and protocols were regularly reviewed and accessible to all staff.

Managing risks, issues and performance

There were limited processes for managing risks, issues and performance.

- There were limited processes to identify, understand, monitor and address current and future risks including risks to patient safety. For the areas used by the service we found that health and safety risk assessments had not been completed to identify hazards and mitigate potential risks at the site.
- The practice had limited processes to manage current and future performance.
- The medical director had oversight of incidents, and complaints in addition to external alerts, such as the Medicines and Healthcare products Regulatory Agency (MHRA) alerts that may affect patient safety.
- There was little evidence to support that clinical audit had a positive impact on quality of care and outcomes for patients.

Appropriate and accurate information

We noted that not all information about the service was up to date and accurate. The website and printed literature advertised procedures that the service did not currently provide, for example circumcision. The provider was advised to ensure that information about the service was up to date and accurate.

Although the provider obtained feedback from patients, there was little information regarding the clinical performance of the service, for example, post operative infection rates or sterility rates following vasectomies. The provider submitted patient satisfaction survey results to the Association of Surgeons in Primary Care (ASPC), who collated the information and produced an annual report.

The provider had recently invested in information technology systems to monitor and improve the quality of care. The consultations and surgical procedures were recorded electronically, although paper records were also maintained.

There were robust arrangements in line with data security standards for the availability, integrity and confidentiality of patient identifiable data, records and data management systems.

Engagement with patients, the public, staff and external partners

The provider encouraged and valued feedback from patients. Immediately after the operation and a week

Are services well-led?

(for example, are they well-managed and do senior leaders listen, learn and take appropriate action?)

post-operatively patients were invited to complete a satisfaction survey asking for their feedback about the service they had received. Staff told us that the comments were reviewed and any issues discussed informally.

The medical director discussed their future plans, which included expanding the business by increasing the staff team and providing additional services and optimising IT functionality.

Continuous improvement and innovation

The medical director was affiliated to a number of Royal Colleges and Associations including the ASPC. Both the medical director and nursing director attended the annual conference and training events as appropriate.

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
Surgical procedures Treatment of disease, disorder or injury	<p>Regulation 12 HSCA (RA) Regulations 2014 Safe care and treatment</p> <p>How the Regulation was not being met:</p> <p>The registered persons had not done all that was reasonably practicable to mitigate risks to the health and safety of service users receiving care and treatment. In particular:</p> <ul style="list-style-type: none">• Risk assessments in relation to safety issues in the area of the building used by the service had not been completed.• A risk assessment in relation to the range of emergency medicines available to staff had not been completed.• The process used to check the expiry dates of single use items was not effective. <p>This was in breach of regulation 12 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014.</p>
Regulated activity	Regulation
Surgical procedures Treatment of disease, disorder or injury	<p>Regulation 17 HSCA (RA) Regulations 2014 Good governance</p> <p>How the Regulation was not being met:</p> <p>There were limited systems or processes that enabled the registered person to evaluate and improve their practice in respect of the processing of information obtained throughout the governance process. In particular:</p> <ul style="list-style-type: none">• The programme of quality improvement activity and review of the effectiveness and appropriateness of the care provided needed to be further developed.

Requirement notices

The registered provider had systems or processes in place that operated ineffectively in that that they failed to enable the registered person to assess, monitor, and mitigate the risks relating to health, safety and welfare of service users and others who may be at risk. In particular:

- A formalised system for undertaking recruitment checks on staff who worked on an adhoc basis was not in place.
- Relevant recruitment information, including indemnity arrangements, professional registration and revalidation for the clinical staff employed on an ad hoc basis had not been obtained.

This was in breach of regulation 17 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014.