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

### Ratings

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Overall summary

This service is rated as **Good overall.**

This service was previously inspected 26 July 2018.

The key questions are rated as:

- Are services safe? – Requires improvement
- Are services effective? – Good
- Are services caring? – Good
- Are services responsive? – Good
- Are services well-led? – Good

We carried out an announced comprehensive inspection at Modality Circumcision Service - Birmingham to follow up on breaches of regulations we identified in our inspection in July 2018.

CQC inspected the service on 26 July 2018 and asked the provider to make improvements to ensure that care and treatment of patients is only provided with the consent of the relevant person and to establish effective systems and processes to ensure good governance in accordance with the fundamental standards of care. We checked these areas as part of this comprehensive inspection in May 2019 and found the service had acted on the issues we had identified.

The service is rated good overall with requires improvement for providing safe services. This is because the service did not have effective processes for the management of medicines used off label and patients were at risk of harm.

This service is registered with CQC under the Health and Social Care Act 2008 in respect of the provision of advice or treatment for minor surgical procedures including circumcision to private (fee paying) patients.

The service had a registered manager since April 2012. 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 received 17 Care Quality Commission comment cards. All comments were positive. For example, people using the service felt the service was good, staff had explained everything well, staff were kind, professional and caring.

**Our key findings were:**

- We found while the provider had responded appropriately to our concerns and improved their systems and processes for keeping people safe. The clinic did not have effective processes for the management of medicines used off label and patients were at risk of harm. On becoming aware, the provider responded appropriately to our concerns and took immediate action to minimise the level of risk.
- The clinic had improved their processes around safeguarding and infection control. These were embedded amongst staff.
- The clinic had improved their processes to monitor performance including the collection of patient feedback and monitoring post-operative complications.
- Patient feedback was positive about clinical and non-clinical staff.
- The provider had made improvements to their governance structure, this included the employment of a governance manager for its independent health services. The governance manager had clear oversight of staff training.
- The leadership team demonstrated they were experienced and capable in managing the service.

The areas where the provider should make improvements are:

- The provider should review and monitor their processes for medicines used off label.
- The provider should review their processes for communicating with the patient’s usual GP after the procedure.

**Dr Rosie Benneyworth BM BS BMedSci MRCGP**
Chief Inspector of Primary Medical Services and Integrated Care
Our inspection team

Our inspection team was led by a CQC lead inspector. The team included a GP specialist adviser.

Background to Modality Circumcision Service - Birmingham

Modality Medical Services Limited is the registered provider of Modality Circumcision Service – Birmingham. The clinic also known as Birmingham Circumcision Clinic is an independent healthcare provider located in Birmingham. The service operates from accommodation based at Laurie Pike Health Centre. 2 Fentham Road, Aston, Birmingham B6 6BB. More information about the service can be found on their website www.circumcisionbham.co.uk.

The clinic provides circumcision to fee-paying patients. The service provides circumcision to children and adults for medical, cultural and religious reasons under local anaesthetic.

The clinic had carried out 1251 circumcisions between January and December 2018. Unpublished data provided by the service showed 69% of circumcisions carried out by the clinic were on children under 3 months of age.

Laurie Pike Health Centre is a purpose-built building, with free parking. The circumcision clinic has access to two minor operation rooms, a waiting area and a private recovery room within the health centre.

The service is registered with Care Quality Commission (CQC) to provide the following regulated activities:

- Diagnostic and screening procedures.
- Surgical procedures.
- Treatment of disease, disorder or injury.

The clinic is open Monday to Friday 9am to 5pm. The provider employs two doctors (one male and one female) and two healthcare assistants to cover this clinic as well as other services under the provider. The clinic uses the health centre’s reception staff to greet patients.

The provider employs a clinic manager and governance manager for all the provider’s independent health services. They are based at the provider’s head office. Administration staff are based centrally and cover all community services. Administration staff book appointments and manage aftercare calls.

The clinic does not provide out of hours cover. Staff explain to people when aftercare information is given, they can call the service between 9am and 5pm Monday to Friday and a doctor will call them back with 24 hours during the clinics opening hours. After 5pm or on a bank holiday or weekend, they will need to contact the service back on the next working day or if it is an emergency they need to attend A&E.

How we inspected this service

Before the inspection we reviewed any existing information, we held on the service and the information the provider returned to us.

The methods that were used, for example interviewing staff, observations and review of documents.

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.
We rated safe as Requires improvement because:

During our inspection in July 2018 we found the service was not providing safe care in accordance with the relevant regulations. The provider’s policies and processes for managing significant events, and infection prevention and control (IPC) were not well embedded.

The provider did not have a process to establish if children were known to be on a safeguarding register, there was confusion amongst staff who the safeguarding lead was and processes for checking parental responsibility were not always effective.

During this inspection in May 2019 we found the service had taken appropriate action to improve their systems and processes to keep patients safe. However, is rated requires improvement due to the ineffective arrangements for the management of medicines used off label.

Safety systems and processes

The service had clear systems to keep people safe and safeguarded from abuse.

- The service had improved their systems to assure staff that the adult’s accompanying a child had parental authority.
- The service had improved their systems to manage infection prevention and control (IPC). Healthcare assistants monitored IPC standards and cleaning of the areas they utilised within the health centre and completed daily checklists. We saw the lead clinician checked that checklists were completed at random intervals to monitor IPC standards.
- We observed the minor surgery rooms where the procedure was undertaken. These rooms, the recovery room and the waiting area appeared to be clean and were in good overall condition.
- All staff had received IPC training in line with the provider’s mandatory training policy.
- The clinic utilised the services provided by the health centre for clinical waste disposal.
- The staff told us pre-packed, sterilised, single-use instruments were used for all circumcision procedures. We saw evidence to confirm this on the day of the inspection.
- We saw the clinic had access to an up to date risk assessment for Legionella (Legionella is a bacterium which can contaminate water systems in buildings) that had been carried out by an external company. We saw evidence of monthly checks as recommended by the external company.
- The clinic provided records to show facilities and equipment were safe and that equipment was maintained according to manufacturers’ instructions.
- The clinic had access to the health centre’s latest fire risk assessment and policy. We saw all identified actions had been completed.
Are services safe?

- We saw clinic staff had received fire safety training and the health centre had carried out a fire drill in January 2019. The drill had not raised any concerns.

Risks to patients

There were systems to assess, monitor and manage risks to patient safety.

- There were arrangements for planning and monitoring the number and mix of staff needed.
- Staffing for the service was planned around the scheduled patient appointments. We were told more clinics would be scheduled if demand dictated.
- The service was equipped to deal with medical emergencies and staff were suitably trained in emergency procedures.
- Staff understood their responsibilities to manage emergencies on the premises and to recognise those in need of urgent medical attention. Clinicians knew how to identify and manage patients with severe infections including sepsis.
- Clinicians had suitable professional indemnity arrangements.
- All appointments were pre-booked.
- The clinic did not use locum staff.

Information to deliver safe care and treatment

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

- Individual care records were written and managed in a way that kept patients safe. The care records we saw showed that information needed to deliver safe care and treatment was available to relevant staff in an accessible way.
- The service had systems for sharing information with staff and other agencies to enable them to deliver safe care and treatment.
- The clinicians provided all patients with a letter and requested the patient hand it in to their own GP. For any patient that was registered with a GP practice within Modality Partnership, their records from the circumcision clinic were accessible to their usual GP. For patients that were not registered with a Modality Partnership GP practice, the clinic relied on the patient or parent to hand the letter in to their GP.

The service had reliable systems for appropriate and safe handling of medicines.

- The systems and arrangements for managing medicines, including emergency medicines and equipment generally minimised risks. However, we found on a small number of patients, the clinician had administered a licensed medicine, off label. The clinician had not gained the parents’ consent or explained the reason and benefits of using the medicine in this way. We discussed this with the clinician and the management team during the inspection. They informed us they would review their processes around the management of medicines used off label. After the inspection, they sent us evidence to show they had taken immediate action to minimise risks.
- The service kept prescription stationery securely and monitored its use.
- Patients received appropriate aftercare advice including pain relief.

Track record on safety and incidents

The service had a good safety record.

- The clinic had access to health and safety risk assessments that had been completed by the health centre and provided evidence during the inspection of risk assessments that were specific to the clinic. For example, to ensure children remained safe during the procedure and post procedure when being transferred into the recovery room.
- Staff told us since the previous inspection, regular meetings had been set up for clinic staff to discuss any learning from complaints and safety incidents.

Lessons learned and improvements made

The service learned and made improvements when things went wrong.

- There was a system for recording and acting on significant events. Staff understood their duty to raise concerns and report incidents and near misses. Leaders and managers supported them when they did so.
- Since our previous inspection, the service had acted to improve their systems for reviewing and investigating when things went wrong. The service learned and shared lessons identified themes and acted to improve safety in the service.
Are services safe?

- 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 had systems in place for knowing about notifiable safety incidents.

When there were unexpected or unintended safety incidents:

- The service gave affected people reasonable support, truthful information and a verbal and written apology.
- They kept written records of verbal interactions as well as written correspondence.

The service acted on and learned from external safety events as well as patient and medicine safety alerts. The service had an effective mechanism in place to disseminate alerts to all members of the team.
We rated effective as Good because:

During our inspection in July 2018 we found the service was not providing effective care in accordance with the relevant regulations. The clinic was unable to provide accurate data regarding post-operative complications and the providers’ processes for assessing patients’ suitability pre-operatively and for obtaining feedback from patients regarding aftercare services were not effective.

During this inspection in May 2019 we found the service had taken appropriate action to improve their systems for monitoring performance. The service is now rated as good for providing effective services.

Effective needs assessment, care and treatment

The provider had systems to keep clinicians up to date with current evidence based practice. We saw evidence that clinicians assessed needs and delivered care and treatment in line with current legislation, standards and guidance (relevant to their service).

• Patients’ immediate and ongoing needs were fully assessed. Where appropriate this included their clinical needs and their mental and physical wellbeing.
• Staff told us administrative staff collected medical information from patients/parents before the procedure at the time of booking an appointment. Records we viewed confirmed this.
• The clinic gave us evidence that showed during October 2018 and March 2019 two procedures were cancelled by the clinic on the day of the operation because medically it was inappropriate. This had improved from 10 procedures being cancelled in a similar time in 2017.
• We saw no evidence of discrimination when making care and treatment decisions.
• The clinics website contained useful information about the service, however the service had not updated it to reflect changes to their aftercare process or to reflect changes in the clinical team. After the inspection, the provider sent us information to show these changes had been made.
• Staff gave appropriate advice to patients on pain management and advised patients what to do if their condition got worse and where to seek further help and support.
• Feedback from CQC comments cards we reviewed, was positive about information they received before and after the procedure.

Monitoring care and treatment

The service was actively involved in quality improvement activity.

• Since our inspection in July 2018 the service had improved its systems and processes for monitoring patient outcomes and experience.
• The clinicians continued to review patients records six to eight weeks after their procedure to see if the patient had been in contact with the service to report any post-operative complications.
• In addition to this the management team had carried out an audit and contacted every patient that attended for the procedure in December 2018 and January 2019 to establish the number of complications and gather patient feedback about the service. By doing this the management team could determine if the results of their audit were reflective of the clinician’s individual audits.
• In March 2019 the provider’s central administration team contacted 122 patients by telephone, 76 patients responded to the survey questions.
• 75 out of 76 patients were satisfied with the treatment.
• 74 patients were satisfied with the aftercare support. One patient complained of post-operative complications and required access to hospital/urgent care services.
• 74 out of 76 patients were satisfied with the procedure outcome.
• From the clinician’s audits for December 2018 and January 2019 we saw no complications were reported for December 2018 and one reported in January 2019 which required the patient to attend A&E.
• The management team told us initially they had planned on carrying out their audit twice a year. However, having carried the audit out, they had decided to carry it out at more regular frequencies.
• The service also collected patient feedback from every parent/patient after the procedure.
• During January 2018 and December 2018, 469 people using the service responded to the survey. (37% response rate). Results showed 96% of those people that responded rated the reception/administration staff as excellent and 99% rated the doctor as excellent.
• When compared to the results from the previous year (2017) we saw the response rate had significantly improved and patient satisfaction with clinical and non-clinical staff had also improved.
Patients were informed they could contact the clinic between 9am and 5pm Monday to Friday for aftercare advice. Outside of these hours, if it was an emergency, patients were advised to attend A&E.

Effective staffing

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

- All staff were appropriately qualified. The provider had an induction programme for all newly appointed staff.
- Medical professionals were registered with the General Medical Council (GMC) and were up to date with revalidation.
- The provider understood the learning needs of staff and provided protected time and training to meet them. Up to date records of skills, qualifications and training were maintained. Staff were encouraged and given opportunities to develop.

Coordinating patient care and information sharing

Staff worked with other organisations, to deliver effective care and treatment.

- The clinic provided all patients with a letter after the procedure, and asked the patient to deliver it to their GP. For any patient that was registered with a GP practice within Modality Partnership, their records from the circumcision clinic were accessible to their usual GP.
- Parents were asked to bring in the child’s red book to confirm the patient’s identity. The clinic did not routinely document in the red book, unless the patient was weighed during their appointment.

Supporting patients to live healthier lives

Staff were consistent in supporting patients to manage their own health and maximise their independence.

- Staff provided patients with appropriate aftercare information.

Consent to care and treatment

The service mostly obtained consent to care and treatment in line with legislation and guidance.

- Staff understood the requirements of legislation and guidance when considering consent and decision making. From records we viewed, consent was sought appropriately for the procedure. However, clinicians were unable to demonstrate that they provided patients, parents or legal guardians with sufficient information about medicines they proposed to prescribe off label or explain alternatives available as well as reasons for doing so to allow them to make an informed decision. We discussed this with the clinician and management team during the inspection. Following the inspection, the service sent us evidence to show they had taken appropriate action to review and amend their processes around the use of licensed medicines off label.
- Staff supported patients to make decisions. Where appropriate, they assessed and recorded a patient’s mental capacity to make a decision.
- The service monitored the process for seeking consent appropriately and had carried out an audit of 19 records completed between October 2018 and March 2019 to monitor consent was sought in line with their policy. The audit showed the procedure was only carried out if both parents had consented.
- Since the previous inspection, the clinic had improved their processes for gaining consent and confirming the legal status of children.
We rated caring as Good because:

Kindness, respect and compassion

Staff treated patients with kindness, respect and compassion.

- Feedback from patients was positive about the way staff treat people
- Staff understood patients’ personal, cultural, social and religious needs. They displayed an understanding and non-judgmental attitude to all patients.
- The service gave patients timely support and information.
- We received 17 Care Quality Commission comment cards. All the comments were positive about the way staff treated them and people commented staff were helpful, kind, professional, and good at explaining advice.
- The clinic invited all patients to complete a patient survey after their procedure. During January 2018 and December 2018, the clinic had issued 1251 surveys and received 469 responses (37% response rate). Results showed 96% of those people that responded rated the reception/administration staff as excellent and 99% rated the doctor as excellent.

Privacy and Dignity

The service respected patients’ privacy and dignity.

- Staff recognised the importance of people’s dignity and respect.
- Staff knew that if patients wanted to discuss sensitive issues or appeared distressed they could offer them a private room to discuss their needs.
- Staff ensured doors were closed during consultations and conversations taking place in these rooms could not be overheard.
- Patients could recover in a dedicated private area.

Involvement in decisions about care and treatment

Staff helped patients to be involved in decisions about care and treatment.

- Interpretation services were available for patients who did not have English as a first language.
- The clinic sent each patient an information pack before their appointment. The pack contained detailed information about the procedure and the consent process. Staff told us the pack was available in English, however they could produce it in a different language if it was required.
- Staff told us they discussed in detail the procedure, any possible side effects and aftercare advice with patients/parents on the day of the procedure. Patient feedback on CQC comments cards we received confirmed this.
We rated responsive as Good because:

Responding to and meeting people's needs

The service organised and delivered services to meet patients' needs. It took account of patient needs and preferences.

• The provider understood the needs of their patients and improved services in response to those needs. The provider had recognised almost a third of their patients attended the clinic from a nearby city Walsall. In response to this the provider planned on opening an additional circumcision clinic in Walsall. Registration forms had been submitted to CQC at the time of this inspection.
• The facilities and premises were appropriate for the services delivered.
• Laurie Pike Health Centre from which the clinic operated was accessible to those with mobility difficulties, or those who used a wheelchair. Patients received treatment on the ground floor.
• Interpreters were available for those patients that needed them. Administration staff checked with patients at the time of booking an appointment if an interpreter was required. Staff told us written information including consent forms and the restraint policy were routinely sent out to patients in English. However, if patients requested, they would be produced in an alternative language.
• The service offered longer appointments for those patients that needed them.
• The service was accessible to any person who chose to pay for it and if they were deemed suitable to receive the procedure.

Timely access to the service

Patients were able to access care and treatment from the service within an appropriate timescale for their needs.

• Patients had timely access to initial assessment, treatment and post-operative advice.
• The clinic had a target of seeing private patients within four weeks of first contact.
• Staff told us patients generally received an appointment within six days. Data the clinic provided showed between October 2018 and March 2019, the clinic had met the provider's target each month, with majority of patients being seen within four days.
• Patients booked an appointment through a dedicated appointment line.
• The clinic was open Monday to Friday 9am to 5pm and operated seven sessions per week.
• The clinic gave us data that showed between January and December 2018 they had cancelled one clinic, this was due to staff sickness on the day of the clinic.
• The clinic management team told us from patient feedback they had received, people using the service had experienced difficulties in telephone access. Following this the provider had arranged to have dedicated administration staff for this clinic and increase the number of administration staff for this service.

Listening and learning from concerns and complaints

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

• Information about how to make a complaint or raise concerns was available. Staff treated patients who made complaints compassionately.
• The service informed patients of any further action that may be available to them should they not be satisfied with the response to their complaint.
• The service had a complaint policy and procedures in place. We saw the service discussed complaints and shared any learning with all staff involved in the service to improve the quality of care.
• The service had amended their policy to record verbal complaints as well as written ones.
• The service had received two written and two verbal complaints from April 2018 to March 2019. From records we viewed, complaints were dealt with appropriately.
Are services well-led?

We rated well-led as Good because:

During our inspection in July 2018 we found that this service was not providing well-led services in accordance with the relevant regulations. The provider did not have appropriate governance arrangements in place in relation to policies and procedures.

During this inspection in May 2019 we found the service had taken appropriate action to improve their governance processes. The service is now rated as good for providing well-led services.

Leadership capacity and capability;

Leaders had the capacity and skills to deliver high-quality, sustainable care.

- Leaders were knowledgeable about issues and priorities relating to the quality and future of services. They understood the challenges and were addressing them.
- Leaders at all levels were visible and approachable. They worked closely with staff and others to make sure they prioritised compassionate and inclusive leadership.
- Since our previous inspection the provider had made significant changes to the way this service was organised and managed, this included the employment of a governance manager for its independent health services.

Vision and strategy

The service had a clear vision and credible strategy to deliver high quality care and promote good outcomes for patients.

- This clinic was part of Modality Medical Services Limited. The provider had overall responsibility for ensuring the clinic was operating in line with their policies and strategy.

Culture

The service had a culture of high-quality sustainable care.

- Staff felt respected, supported and valued.
- Clinic leaders told us they encouraged staff to be open and honest. The provider was aware of and had systems to ensure compliance with the requirements of the duty of candour.
- There were processes for providing all staff with the development they needed. This included appraisal and career development conversations. All staff had received an appraisal in the last year. Staff were supported to meet the requirements of professional revalidation where necessary.
- Staff had received equality and diversity training.
- There were positive relationships between staff and management.
- Since our inspection in July 2018 the service had begun to hold regular meetings with all staff to keep all staff informed of issues relating to the clinic.
- The clinical leads of the provider’s community services met monthly to discuss performance and any significant events or complaints.
- The service also held weekly administration meetings to share learning.

Governance arrangements

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

- Since our inspection in July 2018 the provider had reviewed their governance structure and arrangements.
- This included the employment a governance manager for its independent health services. The governance manager had clear oversight of staff training records.
- The provider had put into place a formal arrangement with the GP practice it operated out of. This set out clear roles and responsibilities of the clinic staff and the GP practice staff.
- We found all staff were clear on their roles and accountabilities and we found policies such as infection control, complaints and significant events were embedded amongst staff.
- The provider had responded appropriately after our previous inspection and amended processes around confirming the identity and legal status of children and improved processes around consent.
- We found the service did not have effective processes for managing medicines used off label. Following the inspection, the service sent us evidence to show they had taken appropriate action to review their governance arrangements.

Managing risks, issues and performance

There were clear and effective processes for managing risks, issues and performance.
Are services well-led?

- There was an effective, process to identify, understand, monitor and address current and future risks including risks to patient safety.
- The service had processes to manage current and future performance. Performance of clinical staff could be demonstrated through audit of their consultations, prescribing and referral decisions. Leaders had oversight of safety alerts, incidents, and complaints.
- Clinical audit had a positive impact on quality of care and outcomes for patients. There was clear evidence of action to change services to improve quality.
- The provider had plans in place and had trained staff for major incidents.
- Staff met at regular intervals to discuss issues such as performance, complaints and significant events.

### Appropriate and accurate information

**The service acted on appropriate and accurate information.**

- Quality and operational information was used to ensure and improve performance. Performance information was combined with the views of patients.
- Quality and sustainability were discussed in relevant meetings where all staff had sufficient access to information.
- The service submitted data or notifications to external organisations as required.
- 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.
- The clinic carried out audits to monitor complication rates, consent, infection prevention and control standards, the number of people not attending their appointments and how many clinics/or appointments the clinic had to cancel and the reason why.

### Engagement with patients, the public, staff and external partners

**The service involved patients, staff and external partners to support high-quality sustainable services.**

- The service encouraged and heard views and concerns from the patients, staff and external partners and acted on them to shape services and culture.
- The clinic included in their initial contact letter to people using the service, that they may be contacted to provide feedback or information related to post-operative complications.
- All staff working for the provider had been asked to complete a staff survey. The management team told us in response to feedback from staff, the provider had reorganised staffing to ensure there was a dedicated team of healthcare assistants for this service, and had plans to recruit a senior nurse. The nurse would be responsible for overseeing the healthcare assistant team and supporting their training and development.

### Continuous improvement and innovation

**There was evidence of systems and processes for learning, continuous improvement and innovation.**

- The service had responded appropriately to the concerns that we raised during our previous inspection, this resulted in improved outcomes for patients.
- We found there was a greater focus on continuous learning and improvement.
- The service made use of internal and external reviews of incidents and complaints.
- Learning was shared with all clinic staff and used to make improvements.
- The service took immediate action and responded appropriately to the concerns raised during this inspection to improve quality of care for patients.