

Optimale Southampton Clinic

Inspection report

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

Ratings

Overall rating for this location		Good	
Are services safe?		Good	
Are services effective?		Good	
Are services caring?		Good	
Are services responsive to people's needs?		Good	
Are services well-led?		Good	

Overall summary

This service is rated as Good overall.

The key questions are rated as:

Are services safe? – Good

Are services effective? – Good

Are services caring? – Good

Are services responsive? – Good

Are services well-led? – Good

We carried out an announced comprehensive at Optimale Southampton Clinic on 24 October 2022. The service was registered with the Care Quality Commission (CQC) in November 2020 and has not previously been inspected. We carried out this first rated inspection as part of our regulatory functions. The inspection was undertaken to check whether the service was meeting the legal requirements and regulations associated with the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014.

Optimale is an independent men's health company specialising in providing testosterone replacement therapy (TRT) to men in the UK. It also offers treatments for hair loss and erectile dysfunction. The service is registered with the CQC to provide the regulated activity Treatment of disease, disorder or injury.

Optimale's managing director is the CQC registered manager. A registered manager is a person who is registered with the CQC 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 did not meet with patients for this inspection. However, the provider asked patients for feedback, using their survey template, on the day prior to the inspection, specifically to support the inspection process.

This survey resulted in 159 responses and patients were asked to rate a range of questions between 1 and 5. Overall, the patients gave a score of 4.56 when asked how happy they were with the service.

Our key findings were:

- There were clear systems to keep people safe and safeguarded from abuse. The provider had systems for assessing and monitoring patient risks. Staff understood responsibilities to raise concerns and report incidents and near misses.
- Services met patients' needs and followed the British Society for Sexual Medicine (BSSM) guidelines. There was a focus on monitoring the outcome of treatment on patients' health and wellbeing.
- Staff were skilled and kept up to date in their specialist field. All staff were supported with their career development within the service.
- The provider listened to patient and staff comments and feedback from patients was consistently positive. The provider had undertaken detailed patient satisfaction surveys in 2021 and 2022 and feedback highlighted high levels of satisfaction with treatment, knowledge of staff and communications.

Overall summary

- Services were tailored to meet the needs of individual patients. Consultations were offered in a timely way, at times to suit patients. There was a range of advice from staff and from articles on the website to help patients make informed decisions about care and treatment.
- There was a culture of patient-centred care, learning and improvement. There was evidence of effective and compassionate leadership.

We saw the following outstanding practice:

- The provider was committed to improving systems and patient outcomes. It used audit, including clinical audit, to monitor the impact of treatment on patients' health and wellbeing. It sought patient and staff feedback and acted in response to responses.

The areas where the provider **should** make improvements are:

- The provider had oversight of safety alert updates but should keep a log to demonstrate and monitor any actions taken where necessary.

Dr Sean O'Kelly BSc MB ChB MSc DCH FRCA

Chief Inspector of Hospitals and Interim Chief Inspector of Primary Medical Services

Our inspection team

Our inspection team was led by a CQC lead inspector and included a member of the CQC medicines optimisation team.

Background to Optimale Southampton Clinic

The registered provider is Optimale Ltd. It first registered with CQC November 2018, with a location in the north of England. It currently has one location in Southampton, registered in November 2020:

1st Floor, 2 Canute Road, Southampton SO14 3FH.

Optimale Southampton Clinic provides testosterone replacement therapy (TRT), hair loss and treatment for erectile dysfunction. It only treats adults over the age of 18 years. Optimale is registered for the regulated activity Treatment of disease, disorder or injury and services provided are diagnostic tests, face to face and remote consultations with doctors and prescriptions.

The website www.optimale.co.uk provides information about the company, its background, treatments offered and information articles. It includes contact details, terms and conditions for patients and testimonials. The website informs patients on costs and treatment plans.

The clinic is open between 9am and 5.30pm for phone calls and doctor consultations can be made during these hours as well as on Saturdays, depending on patient requests.

The provider also offers patients face to face consultations from a satellite location, on a case-by-case basis. This is a room in a building that offers clinical rooms for rent, at 58 South Molton Street, London, W1K 5SL.

How we inspected this service

Before visiting the location, we looked at a range of information that we hold about the service. During our visit, we interviewed staff, reviewed documents and clinical records, and observed the location. We requested and reviewed further information and documents from the provider.

For this inspection we visited the main location and talked with the directors. There were no patients to interview but the service carried out a patient survey immediately before our inspection to share patient views. We did not visit the satellite location. After the site visit, we spoke with three staff by telephone.

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?

Safety systems and processes

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

- The provider conducted safety risk assessments. It had appropriate safety policies, which were regularly reviewed and communicated to staff. They outlined clearly who to go to for further guidance. Staff received safety information from the service as part of their induction and refresher training.
- The service had systems to safeguard children and vulnerable adults from abuse. The safeguarding policy had been updated to reflect intercollegiate guidance on training levels and to include safety measures for on-line consultations. All staff received up-to-date safeguarding and safety training appropriate to their roles. Those we spoke with knew how to identify concerns and how to report these to the registered manager, who was also the safeguarding lead.
- Staff who acted as chaperones were trained for the role and had received a DBS check.
- There had been no reported safeguarding concerns or referrals in the past 12 months. The service understood it would work with other agencies to support patients and protect them from neglect and abuse.
- The provider carried out staff checks at the time of recruitment and on an ongoing basis where appropriate. Disclosure and Barring Service (DBS) checks were undertaken where required by the service. (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).
- There was an effective system to manage infection prevention and control. The provider had implemented a COVID-19 policy to protect staff and patients from infections. The premises were professionally cleaned weekly, and there were daily cleaning logs in place. The provider had a waste management contract in place.
- The provider ensured that facilities and equipment were safe and that equipment was maintained according to manufacturers' instructions. There were systems for safely managing healthcare waste.
- The provider carried out appropriate environmental risk assessments, which considered the profile of people using the service and those who may be accompanying them.

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. The service had recruited additional doctors and patient support staff in response to an increase in demand for treatments.
- There was an effective induction process for staff tailored to their role. Staff reported they felt well supported into their roles with planned shadowing opportunities and access to a mentor. They said they had the information they needed to care for and treat patients safely.
- The service did not treat patients who were acutely unwell. However, staff understood their responsibilities to manage emergencies and to recognise those in need of urgent medical attention.
- There were suitable medicines and equipment to deal with medical emergencies which were stored appropriately and checked regularly. There was an *automated external defibrillator* (AED) on site. If items recommended in national guidance were not kept, there was an appropriate risk assessment to inform this decision. Equipment was checked daily. Medical staff were trained in basic life support and intermediate life support depending on their roles.
- When there were changes to services or staff the service assessed and monitored the impact on safety. For example, in relation to recruiting new doctors.
- There were appropriate indemnity arrangements in place.

Information to deliver safe care and treatment

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

Are services safe?

- 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. They were stored securely on a cloud-based system, with controlled access.
- The service had systems for sharing information with staff and other agencies to enable them to deliver safe care and treatment. For example, with patients' own GP.
- The service had a system in place to retain medical records in line with Department of Health and Social Care (DHSC) guidance in the event that they cease trading
- Clinicians made appropriate referrals in line with protocols and up to date evidence-based guidance.

Safe and appropriate use of medicines

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

- The systems and arrangements for managing emergency medicines and equipment minimised risks to patients.
- The service utilised secure electronic prescriptions and monitored their use. Prescribed medicines were posted to patients and delivery arrangements were agreed in advance.
- The service did not prescribe Schedule 2 and 3 controlled drugs (medicines that have the highest level of control due to their risk of misuse and dependence). They prescribed schedule 4 controlled drugs and had secure systems to manage these prescriptions.
- Staff prescribed medicines to patients and gave advice on medicines in line with legal requirements and current national guidance. Processes were in place for checking medicines and staff kept accurate records. Where there was a different approach taken from national guidance, there was a clear rationale for this that protected patient safety.
- Most patients received patient information leaflets (PILs) by email. These PILs described the medicine, its indications, side effects, cautions in use and included further links to published guidance and academic papers.
- There were effective protocols for verifying the identity of patients. These were explained by staff we spoke with.
- Some of the medicines this service prescribed were used off-label. Treating patients with medicines off-label from the licensed medicines is higher risk than treating patients with licensed medicines for the license indication. This is because, whilst the medicine is licensed for some indications the off-label indication may have less evidence to support the use. Staff explained to us how they discussed the off label use of medicines with patients and provided patients with PILs explaining the off label use of these medicines.

Track record on safety and incidents

The service had a good safety record.

- There were comprehensive risk assessments in relation to safety issues. For example, medicine supply was monitored, and action taken in response to risks of stock shortages. This helped minimise the risk of a lack of continuity of supply for patients.
- The service monitored and reviewed activity. This helped it to understand risks and gave a clear, accurate and current picture that led to safety improvements, for example in relation to information governance.

Lessons learned and improvements made

The service learned and made improvements when things went wrong.

- The service had a good safety record. There had been no recorded significant events or near misses in the past 12 months. Managers outlined an incident they had responded to previously, and the action they had taken to support the patient and implement learning.

Are services safe?

- The registered manager monitored and acted in response to incidents and significant events. Staff understood their duty to raise concerns and report incidents and near misses. They commented on the open culture to encourage incident reporting. They were confident of the support from leaders and managers when they reported events.
- There were adequate systems for reviewing and investigating when things went wrong or could be improved. This was through the service's clinical governance structure. Clinical review meeting minutes showed the provider sought opportunities to improve care.
- The medical director received and acted on patient and medicine safety alerts. When relevant, these were shared with the registered manager and other relevant staff.
- The provider was aware of and complied with the requirements of the Duty of Candour. The provider encouraged a culture of openness and honesty.

Are services effective?

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).

- The provider assessed needs and delivered care in line with relevant and current evidence-based guidance and standards such as the British Society for Sexual Medicine (BSSM) guidelines. For example, the provider had developed new treatment protocols for TRT, based on BSSM guidelines, to better reflect patients' specific needs and preferences. The medical director had discussed these new treatment guidelines with leaders in the field of men's health.
- Clinicians had enough information to make or confirm a diagnosis and treatment plan. Patients' immediate and ongoing needs were fully assessed. This included their clinical needs and their mental and physical wellbeing. Protocols were in place to assess patients' needs before agreeing treatment plans, based on their medical history, diagnostic test results, symptoms and preferences in terms of medicine administration. The provider required patients to attend for face-to-face consultations and tests if they were over 45 years of age, in order to carry out additional diagnostic tests and risk assessments. Other consultations for younger patients were held remotely via video calls.
- Arrangements were in place to support the ongoing care of patients. The provider had systems to call patients for regular tests and reviews, for example as part of their testosterone replacement therapy (TRT). New patients received additional consultations at the start of treatment to balance medicine levels based on their specific experiences. Patients were followed up at three- and six-monthly intervals for blood tests and a clinical review.
- The provider had protocols to limit the impact of TRT in reducing infertility. This was a topic the provider explored with patients, when agreeing their individual treatment plans.
- Patients were required to submit regular blood tests for monitoring and review purposes, in order to receive their prescribed medicines. Assessment of patients' wellbeing, mood and side effects from medication were an important part of this review process.
- We saw no evidence of discrimination when making care and treatment decisions.
- Patients were sent appointment, blood test and review appointments by email and failure to respond was monitored and followed up.

Monitoring care and treatment

The service was actively involved in quality improvement activity.

- The service used information about care and treatment to make improvements. This included audits and reviews of patient experiences and treatment outcomes.
- Clinical audit had a positive impact on quality of care and outcomes for patients. There was clear evidence of action to resolve concerns and improve quality. The provider had initiated a clinical audit of 50 patients in October 2022, to review the effectiveness of their updated protocol based on BSSM guidance, after six months of treatment. This first cycle of clinical audit had been developed based on a widely used questionnaire used to help assess whether a patient is experiencing low testosterone levels. It was developed to provide a quantitative measure of the impact of treatment. The results of the first audit cycle showed treatment had improved testosterone levels as well as patients' wellbeing.
- The service carried out regular records audits to ensure sufficient information was recorded within the patients' clinical records, by all doctors, to support effective review of treatment. These audits had been undertaken in February 2019, August 2019, March 2020 and August 2020. The initial audit identified some omissions in the records. These findings were shared and a new records system was implemented with automated forms. Successive audit results showed a sustained improvement in completing records in full. In August 2020, an audit of 50 records showed high compliance in maintaining full records and the organisation continued to implement safety nets to minimise the risk of omissions.

Are services effective?

- As part of the system improvements, the provider updated the patient recall system and placed flags on those patients on TRT who had not submitted blood tests, so prescriptions were not automatically generated.
- The provider also added a risk stratification for patients. Doctors risk assessed each patient based on their medical history, lifestyle and previous steroid use, to help audit the care provided to high risk patients.

Effective staffing

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

- All staff were appropriately qualified and skilled for their roles. The provider had an induction programme for all newly appointed staff and staff told us this enabled them to gain the necessary competences and skills for their roles.
- Patient support staff were provided with process guides and were shown these and the Optimale systems during their induction period.
- 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. The provider maintained a human resource system with up-to-date records of staff skills, qualifications, training and appraisals. Staff were alerted when training updates were due. Staff received annual appraisals as well as probationary meetings and informal conversations.
- The provider supported staff with development. This included enabling medical staff to gain additional relevant academic qualifications.

Coordinating patient care and information sharing

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

- Patients received coordinated and person-centred care. Staff referred to, and communicated effectively with, other services when appropriate.
- Before providing treatment, doctors at the service ensured they had adequate knowledge of the patient's health, any relevant test results and their medicines history. We saw examples of patients being signposted to more suitable sources of treatment where this information was not available, to ensure safe care and treatment. For example, patients with underlying medical conditions such as high blood pressure, pre-diabetes and obesity were advised to contact their GPs for review and treatment before embarking on TRT.
- All patients were asked for consent to share details of their consultation and any medicines prescribed with their registered GP on each occasion they used the service.
- The provider had risk assessed the treatments they offered. They had identified medicines that were not suitable for prescribing if the patient did not give their consent to share information with their GP, or they were not registered with a GP. Where patients agreed to share their information, we saw evidence of letters sent to their registered GP in line with GMC guidance.
- Care and treatment for patients in vulnerable circumstances was coordinated within the medical team and other services. For example, the service had a doctor with psychiatric training.
- Patient information was shared appropriately (this included when patients moved to other professional services), and the information needed to plan and deliver care and treatment was available to relevant staff in a timely and accessible way. There were clear and effective arrangements for following up on people who had been referred to other services.
- Risk factors were identified, highlighted to patients and where appropriate shared with their GP for additional support. For example, patients with underlying medical conditions such as high blood pressure, pre-diabetes and obesity. We saw an example where the doctor reviewed a prospective patient's blood results and advised the patient to see his GP for treatment, before considering any treatment by the service.

Are services effective?

Supporting patients to live healthier lives

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

- Where appropriate, staff gave people advice so they could self-care. This was in relation to health and wellbeing.
- The provider helped patients learn how to self-administer medicines. There was an instructional video and if required, the service could arrange the services of a phlebotomist.
- Where patients' needs could not be met by the service, staff redirected them to the appropriate service for their needs.

Consent to care and treatment

The service 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.
- 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.

Are services caring?

Kindness, respect and compassion

Staff treated patients with kindness, respect and compassion.

- The service sought feedback on the quality of clinical care patients received through their own surveys and via an online review platform. The provider used a recognised survey tool for assessing testosterone deficiency in men's health. The survey tool also had space for comments.
- Feedback from patients was positive about the way staff treated people. Patients commented on the helpfulness and kindness of staff. We saw comments where people said the service was tailored to the individual.
- Staff understood patients' personal, cultural, social and religious needs. They displayed an understanding and non-judgmental attitude to all patients. Patients' emotional and relationship needs were seen as being as important as their physical needs.

Involvement in decisions about care and treatment

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

- The service had revised and maintained its website to include a wide range of information for patients, to help them understand the treatments offered. This included information about the treatments, the company's directors and their testimonials, research papers and articles about testosterone and men's health and frequently asked questions.
- Communications were largely by phone/internet. Face to face meetings when required or preferred were held in clinical environments, suitable for this type of service. Interpretation services were available for patients who did not have English as a first language.
- Feedback from patients showed all staff listened to and supported patients, giving them sufficient time to make an informed decision about their treatment. Staff told us they encouraged patients to ask questions and seek reassurance before agreeing to progress with treatment. Patients comments on the professionalism of the team and their knowledge. We saw comments such as receiving being 'life-changing' treatment.

Privacy and Dignity

The service respected patients' privacy and dignity.

- Staff recognised the importance of people's dignity and respect.
- Staff said they were careful to highlight privacy considerations with patients, when undertaking video consultations.

Are services responsive to people's needs?

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 designed and improved services in response to those needs. There was a strong focus on personalised care. For example, the service had reviewed their protocols for administering TRT to reduce patient pain and risk. It had created videos for patients to refer to for taking their own blood samples. It also offered patients a phlebotomy service from a nurse who could visit them in their home, should they prefer this over taking their own blood samples.
- The facilities and premises were appropriate for the services delivered. The provider used premises designed for clinical treatments.
- The provider offered patients the option of the London satellite clinic for face-to-face medical consultations if this was their preference. They could also attend on Saturdays if this was their preference.
- The provider's website provided a wide range of information about the treatments offered. This included details about the frequency of submitting blood samples, reviews and costs. Patient support staff said these were discussed at the outset and they checked patients had a good understanding of the service before progressing to the consultation stage. Feedback indicated patients were not pressured into signing up for treatment and were not obliged to continue. Costs for medicines were explained.
- Reasonable adjustments had been made to support patient access. For example, we were told the provider could accept results of physical diagnostic tests provided by NHS or other private doctors, should the patient prefer this or find it more convenient.
- Patient support staff told us they aimed to provide continuity of care for patients, to help with communication and build positive relationships.

Timely access to the service

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

- Patients had timely access to initial assessment, test results, diagnosis and treatment. Patient support staff explained the process for advising new patients on the eligibility criteria for treatment, blood sampling procedures and frequency of reviews. Patient feedback showed this was clear, timely and patient-centred.
- Optimal offered patients date and time options for their reviews and these were within one or two weeks of the receipt of their blood test results. For ongoing care, patients were able to book onto available review meetings shared by the provider. Waiting times and delays were minimal and managed appropriately.
- Patients reported that patient support staff were helpful and quick to respond to queries. We observed positive feedback about the efficiency and professionalism of communications.

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 we spoke with described how they supported patients with their queries and concerns. They explained how they escalated concerns to the registered manager who monitored and responded to complaints and concerns.
- Staff treated patients who made complaints compassionately and took account of their individual needs.

Are services responsive to people's needs?

- 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 complaints policy and procedures in place. We highlighted this was not readily available on the website and the provider acted on this before the end of the inspection.
- The service learned lessons from individual concerns, complaints and from analysis of trends. It acted as a result to improve the quality of care. For example, there had been a complaint about the frequency of blood tests. The provider responded to the complainant within the timescales stated in its complaint policy, and answered the issues raised. The provider was acting within its stated patient agreement and clinical protocols. The provider updated their communications with patients to give further information about medicines supplies.
- Patient feedback via an online review platform was responded to by the provider. Feedback was mostly positive, however if concerns were raised, the provider gave detailed responses.
- The costs for treatment had been raised as a concern. The provider was aware of this and ensured the rationale for the pricing structure was explained to patients at the outset and on the website.

Are services well-led?

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. These included ensuring there were sufficient staff to meet patient demand and maintaining medicine supplies.
- Staff told us leaders approachable and supportive. They worked with staff to make sure they prioritised compassionate and inclusive leadership. For example, by listening and responding to suggestions and supporting them with training and development.
- The provider had effective processes to develop leadership capacity and skills, including planning for the future of the service. There was a strong focus on implementing systems to improve customer experience and care and learning from advances in this area of healthcare.

Vision and strategy

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

- There was a clear vision and set of values. Leaders had a forward strategy for the company which was regularly reviewed and revised at leadership meeting.
- The service developed its vision, values and strategy jointly with staff (where relevant).
- Staff were aware of and understood the vision, values and strategy and their role in achieving them.
- The service monitored progress and risks associated with delivering the strategy.

Culture

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

- Staff felt respected, supported and valued. Those we spoke with said they were proud to work for Optimale because it provided an important healthcare service and because they were treated well.
- The service focused on the needs of patients. Both patient feedback and staff we spoke with showed the provider considered the wellbeing of the patient and the positive impact of treatment their priority.
- Leaders and managers acted on behaviour and performance inconsistent with the vision and values. For example, they supported staff when patients were abusive or unkind (which was rare). Optimale's recruitment process placed a focus on recruiting staff with suitable communication skills and experience to provide good customer care.
- Openness, honesty and transparency were demonstrated when responding to incidents and complaints. The provider was aware of and had systems to ensure compliance with the requirements of the duty of candour.
- Staff told us they could raise concerns and were encouraged to do so. They had confidence that these would be addressed.
- There were processes for providing staff with the development they needed. This included appraisal and career development conversations. Staff received probationary reviews and regular annual appraisals. They were required to complete the training appropriate to their role. Staff were supported to meet the requirements of professional revalidation where necessary. Medical staff had protected time for professional development and evaluation of their clinical work.
- There was a strong emphasis on the safety and well-being of all staff. Patient support staff were given the equipment they needed for their roles.
- There were positive relationships between staff and teams.

Are services well-led?

Governance arrangements

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

- Optimal had structures and systems to support good governance. There were regular virtual meetings for the patient support staff, and they understood their roles and responsibilities within the company.
- Clinical review meetings were held at least every six months, and were minuted. Minutes showed the meetings were used to discuss good practice examples, areas for development and staffing.
- Leaders had established proper policies, procedures and activities to ensure safety. There was a policy review schedule and the leadership team were assured that policies and procedures were adhered to.
- The service used performance information which was reported, monitored and managed. Staff were held to account and advised of feedback from patients.
- The information used to monitor performance and the delivery of quality care was accurate and useful.
- 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. Staff we spoke with understood the importance of ensuring patient confidentiality.

Managing risks, issues and performance

There were clear and effective processes for managing risks, issues and performance.

- 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 patient records and treatment decisions. There were processes for assessing the performance of patient support staff.
- Leaders had oversight of safety alerts, incidents, and complaints. For example, the MHRA safety alerts were received and managed by the medical director. The provider did not retain a log of safety alert updates to demonstrate action taken where necessary.
- Clinical audit had a positive impact on quality of care and outcomes for patients. There was evidence of action to assess the impact of treatment on patients and service changes to improve quality. For example, in relation to the prescribing of medicines.
- The provider had policies to support business continuity and respond to major incidents, such as loss of computer systems.

Appropriate and accurate information

The service acted on appropriate and accurate information.

- Quality and operational information was used to ensure and improve performance. The provider had implemented information management systems, for organising and communicating appointments and to manage patient records. Performance information was combined with the views of patients which was collected routinely.

Engagement with patients, the public, staff and external partners

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

Are services well-led?

- The service encouraged and heard views and concerns from patients and staff and acted on them to shape services and culture. For example, the provider had undertaken 3 all-patient surveys, and response levels were approximately 25%, (the survey in 2021 resulted in 200 responses). The survey was based on a questionnaire designed specifically to explore the symptoms of low testosterone in men. This was a detailed questionnaire designed to explore improvement opportunities. Feedback was positive in terms of the impact of TRT on patient health and wellbeing, and the provider contacted any patients who returned low responses to investigate what could be done to improve outcomes. A few patients who had only recently started on treatment at the time of the survey said they would prefer an earlier follow up after initiating treatment on TRT. As a result, the provider implemented a task for patient support staff to call new patients 2 weeks after starting treatment.
- The provider also received feedback from patients via an online consumer review platform. At the time of the inspection, the clinic received an excellent score (4.9 out of 5) out of over 300 responses. The provider responded to patient feedback and we noticed that where a patient had reported concerns about the price, the provider responded with a detailed explanation.
- The provider also undertook reviews of clinical effectiveness, for example by assessing changes to testosterone following treatment and the impact on patient wellbeing.
- There were systems to support improvement and innovation. The provider was proud of its information technology to promote effective records management and support reviews of patient care. For example, the practice had carried out an all-patient records review to audit blood tests and it carried out regular patient surveys and acted on findings.
- Staff could describe to us the systems in place for them to give feedback. There had been a survey of staff in September 2022, where staff gave suggestions for service improvements. Some of these suggestions were implemented promptly, such as restructuring the patient support team into two teams; one to support new patients and the other patients having ongoing treatment. They also proposed changes to the communication management system, to improve the management of follow up tasks with patients. Staff told us they felt involved and listened to by leaders.
- The service was transparent, collaborative and open with stakeholders about performance.

Continuous improvement and innovation

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

- There was a focus on continuous learning and improvement. The provider used audits effectively and listened to patients and staff to improve standards. For example, there was evidence of improved record keeping and the service had upgraded its IT systems to remind patients to complete their blood tests when they were due. As well as flagging non-submissions on the patient record, the provider had created an automated system to email patients if they omitted to order their blood sampling kit.
- The service reviewed any incidents, events, feedback or complaints to make improvements. Internal and external reviews of incidents and complaints. Learning was shared and used to make improvements. For example, the provider had introduced a backup payment system following an issue with their payment gateway.
- The provider shared information from external reviews on its website, for example reports from the BSSM, to help inform patients.