London Transgender Clinic Limited

The London Transgender 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	Insufficient evidence to rate
Are services safe?	Insufficient evidence to rate
Are services effective?	Insufficient evidence to rate
Are services responsive to people's needs?	Insufficient evidence to rate
Are services well-led?	Inadequate

Summary of findings

Overall summary

We inspected specific parts of this service and rated it as Inadequate for well-led. We served the provider with a warning notice and told them they must make improvements because we found:

- The service had not set up a clear protocol for staff to follow regarding mandatory safety training. Staff were not clear what subject's they were expected to complete relevant to their role. The frequency of required training and at what level was not formally stated. There was no oversight of staff training or monitoring of their completion of training.
- The service did not have a formalised system to report, manage and investigate safety incidents. There was a lack of a documented system for staff to follow for reporting adverse incidents and near misses. The investigative process for incidents was not clearly stated. Because of this, there was a risk that lessons learned from incidents were not being shared. Safety information was not being collected and used it to improve the service.
- The service did not have a well set out governance arrangement or programme of audit to help staff make improvements when and if needed.

However:

- Services were planned and took account of patients' individual needs. People could access the service when they needed to and did not have to wait too long for treatment or follow up care.
- Staff assessed risks to patients, made sure these were acted on and kept good care records to show the pathway of treatment and care, including details related to informed consent. Staff managed the prescribing of medicines well and made arrangements to ensure patients had access to required medicines.

Summary of findings

Our judgements about each of the main services

Service	Rating	Summary of each main service
Outpatients	Inadequate 	Surgery is a small proportion of hospital activity. The main service was diagnostics and screening. Where arrangements were the same, we have reported findings in the main service section. We rated this service as Inadequate for well-led. We found: • The service had not established a clear protocol for staff to follow regarding mandatory safety training. It was not clear what subject's staff were expected to complete relevant to their role, the frequency of this training and at what level. There was no oversight of staff training or monitoring of their completion of training. • The service did not manage safety incidents well as they did not have a documented system for staff to follow for reporting adverse incidents and near misses. The investigative process for incidents was not clearly stated and there was a risk that lessons learned from them were not being shared. Safety information was not being collected and used it to improve the service. • Governance and audit processes had not been fully set up to enable the monitoring of the service and to share learning outcomes with staff. However: • The service planned care to meet the needs of local people, took account of patients' individual needs. People could access the service when they needed it and did not have to wait too long for treatment. • Staff assessed risks to patients, acted on them and kept detailed care records. Patient consent was carried out to a high standard and staff managed the prescribing of medicines well.

Summary of findings

Contents

Summary of this inspection

Background to The London Transgender Clinic

The London Transgender Clinic provides a consultation service to transgender and non-binary individuals with guidance and support related to primary care, reproductive options, voice and communication therapy, mental health services (assessment, counselling, psychotherapy), and hormonal and surgical treatments. Some of these services are arranged with individual professionals working external to the provider location under partnership arrangements.

There is on-site provision for minor surgical procedures under local anaesthetic. Other surgical procedures are carried out by arrangement with an alternative independent hospital.

The service is registered to provide the following regulated activities:

- Treatment of Disease, Disorder and Injury

- Surgical Procedures

- Diagnostic and Screening Procedures

On-site aesthetic procedures, such as hair removal are available but do not come under the regulated activities. Therefore, such services were not inspected.

The registered manager is Mr Christopher Inglefield. Mr Inglefield is a consultant surgeon who has practising privileges at the hospital where surgery is undertaken.

The service has not previously been inspected since its registration in July 2019. This focused inspection was carried out in response to specific concerns which had been brought to the attention of the Care Quality Commission (CQC). We used the inspection methodology for outpatients and only focused on the areas of concern.

The main service provided by this hospital was treatment of disease, disorder and injury. Where our findings on for example disease, disorder and injury, management arrangements – also apply to other services, we do not repeat the information but cross-refer to the main service.

How we carried out this inspection

During the site visit we spoke with the registered manager, the business manager, a member of administration and two members of nursing staff who worked within the hormone prescribing part of the service.

We looked at two electronic patient records, which included completed consent records, psychological and psychiatric assessments. We also viewed information related to shared care and hormone replacement therapies.

Documents were given to us whilst on site to support the information provided to us in our discussions with staff and on request following the visit. The information therein was considered with respect to the areas of concern raised with CQC.

Summary of this inspection

The day after our site visit, we held a telephone discussion with the lead nurse who was an independent prescriber (IP). Independent prescribers are nurses who have successfully completed a nursing and midwifery council (NMC) Independent Nurse Prescribing Course (also known as a v200 or v300 course) and are registered with the NMC as an IP.

You can find information about how we carry out our inspections on our website: https://www.cqc.org.uk/what-we-do/how-we-do-our-job/what-we-do-inspection.

Outstanding practice

We found the following outstanding practice:

- The level of detail contained within psychological and psychiatric assessments was noted to be of a very high standard, with attention to detail and consideration of each individual patient clearly prioritised.
- The range of patient consent forms and completion of these was noted to be of a very high standard. Information, including the risks and benefits were very clearly described, which enabled each patient to make informed decisions about the treatment recommended.

Areas for improvement

Action the service MUST take is necessary to comply with its legal obligations. Action a trust SHOULD take is because it was not doing something required by a regulation but it would be disproportionate to find a breach of the regulation overall, to prevent it failing to comply with legal requirements in future, or to improve services.

Action the service MUST take to improve:

- The service must ensure the arrangements for staff mandatory safety training is clearly stated to all employees through appropriately detailed policies and procedures.
- The service must ensure staff know what training is expected of them, the subjects they are required to undertake, including safeguarding vulnerable adults, the level of training they are required to complete subjects at, and the frequency of these.
- The service must ensure there is an effective system to monitor the staff's completion of mandated training.
- The service must ensure there are suitable arrangements for staff to understand their responsibilities for reporting incidents, accidents and near misses. Such information must be set out in appropriately detailed policies and/or procedures.
- The service must ensure there is an effective system for collecting information related to incidents, that such matters are investigated using appropriate methods and that any learning from the outcome is shared with staff.
- The service must ensure there is a formal process established to enable it to have oversight of incidents and that such information is considered in appropriate risk and governance meetings.

Regulation 17: (2) 9a) (b) (d), Good governance, of The Health and Social Care Act 2008 (Regulated Activities) Regulations 2014

Action the service SHOULD take to improve:

- The service should consider how it can further develop a multidisciplinary approach to internal meetings, for the benefit of patients and its staff.

Summary of this inspection

- The service should formalise its approach to governance and audit practices, so that information is collected at periodic intervals and is subjected to suitable level of scrutiny.
- The service should share learning arising from audit outcome results with staff through the most effective means.

Our findings

Overview of ratings

Our ratings for this location are:

	Safe	Effective	Caring	Responsive	Well-led	Overall
Outpatients	Insufficient evidence to rate	Insufficient evidence to rate	Not inspected	Insufficient evidence to rate	Inadequate	Inadequate
Overall	Insufficient evidence to rate	Insufficient evidence to rate	Not inspected	Insufficient evidence to rate	Inadequate	Insufficient evidence to rate

Inadequate

Outpatients

Safe	Insufficient evidence to rate
Effective	Insufficient evidence to rate
Responsive	Insufficient evidence to rate
Well-led	Inadequate

Are Outpatients safe?

Insufficient evidence to rate

Mandatory training

The service did not provide mandatory training in key skills to all staff and did not have a system for making sure everyone knew what training was required of them. They did not have a well-developed system for the oversight and monitoring of training.

Staff we spoke with did not know exactly what mandatory training was required of them to meet the needs of patients and staff.

We asked to see the training policy for mandatory safety subjects. We were provided with a copy of the staff handbook – headed C &M Health Ltd and dated 18 May 2019. This referenced training in its final section. The information was described as a policy and indicated: 'The Company will provide you with appropriate training to develop the knowledge and skills necessary for you to perform your duties effectively. Wherever possible, the Company will ensure you have every opportunity for career development.' Whilst it had a short paragraph for induction, occupational, internal and external training, it did not go as far as describing any required training, the frequency of this, which staff should complete specific subjects and the level of training they should achieve.

Staff had access to a safeguarding vulnerable adults' policy. This was not dated and did not contain any details to indicate who had written or approved the policy. There was limited information related to the expectations of staff to be trained in safeguarding vulnerable adults and to what level. Training was referred to only in the context of attending induction, which would include an introduction to safeguarding adults. The policy did not contain details of who the lead safeguarding person was and the level of training they had to complete to take on this role.

When we asked the business manager about the level of safeguarding training, we were told "Safeguarding – training depends on level of responsibility; we have a policy." There was no recognition of the lack of content in the policy related to training.

Nursing staff did not receive or keep up to date with mandatory training, as subjects to complete had not been identified to them. The lead nurse prescriber was asked about mandatory training and said she followed Royal College of Nursing (RCN) guidance for safeguarding and that she had completed immediate life support. We would have expected nursing staff to complete a number of safety related subjects as routine, especially staff who had face to face contact with patients.

Inadequate

Outpatients

We were not provided with any documentary evidence to demonstrate what mandatory safety training by role staff were required to complete, despite asking for such information. Information provided to us was limited to a certificate for the registered manager (RM) which showed he had completed safeguarding children and adults at levels 1 & 2 on 17 Dec 2018; two certificates for one staff member showing they had undertaken first aid, fire warden and GDPR training. This same member of staff when asked about mandatory training was not able to tell us what safety related training they had completed.

In our discussion about mandatory training with the business manager, they told us they had an induction programme and shared copy of information given to new staff with us. They told us there was infection prevention and control (IPC), moving and handling training. They were not able to show us any evidence of this or where it was recorded both during the inspection and afterwards. The business manager, who had been in post for no more than three months told us training was an area they would be focusing on, recognising that improvements were needed.

The registered manager (RM) when questioned about mandatory training told us there was IPC, safeguarding and fire safety. They added that "specific training was not really available; we train staff as they join the clinic."

Managers did not monitor mandatory training or alert staff when they needed to update their training. This was because there was no reliable system to enable such activities to be captured and monitored. At the time training was said by the business manager to be dealt with by a third-party provider. It was not possible from the information we received to know how this arrangement was set up and what responsibilities had been agreed.

Records

Staff kept detailed records of patients' care and treatment. Records were clear, up to date, stored securely and easily available to all staff providing care.

Patient notes were detailed and completed to a level which helped the relevant staff understand what had been discussed and agreed between the clinicians and patient. There were detailed psychological or psychiatric assessments, which had been completed by the appropriate experts. Information recorded reflected the standards required -this included for example; general medical and mental health details, with attention to psychosexual health. Records were accessible to only those staff who needed to be able to view the information or contribute to on-going records.

When patients transferred to a new team or for their surgery at a designated location, there were no delays in staff accessing their records. Records were stored securely on an electronic system.

Medicines

The service used systems and processes to safely prescribe medicines in order to meet the needs of the patients.

The service had three nursing staff who had undertaken the required training to practice as independent prescribers (IP). That is, they had completed a nursing and midwifery council (NMC) Independent Nurse Prescribing Course (also known as a v200 or v300 course) and were registered with the NMC as an IP. These nurses were able to prescribe any medicine provided it was in their competency to do so. This included medicines and products listed in the British National Formulary (BNF), unlicensed medicines and all controlled drugs in schedules two - five.

Inadequate

Outpatients

The service had a written medicines management policy. This set out clearly the responsibilities of staff and was written with patient safety in mind. Staff reviewed patients' medicines regularly and provided specific advice to patients and carers about their medicines.

Staff managed medicines prescribing documents in line with the provider's policy, including checks that the current national practice standards were acted upon.

The IP nurses also had access to a document titled 'Shared Care Prescribing Guidance- Treatment of Gender Dysphoria in Trans Male and Non-Binary Transmasculine Patients.' This was a detailed document, which had patient safety and well-being as a priority. It set out the basis of patients attending The London Transgender Clinic in a partnership of care from both their gender specialist and general practitioners. Such arrangements included hormone related medicines.

Incidents

The service did not manage patient safety incidents well. There was no formal system for staff to follow when recognising incidents and near misses or how to report them appropriately.

We asked to see the policy for incident reporting. We were provided with the policy for 'The Management of a Never Event'. This was not dated, or version controlled and there was no indication as to who had written the policy and approved it. The content of the policy suggested it may have been provided by someone not directly aware of the service or how the service worked. We found the policy was lacking detail about the investigative process, what methods would be used to undertake the root-cause analysis, time frames for the investigation and how the outcome would be shared and acted upon.

The service lacked a formal system for recording incidents and for information to guide staff and managers about investigated incidents and how to share lessons learned with the whole team and the wider service.

The incident procedure had not been fully developed and embedded in practice. Incidents were recorded on the patient medical record. There was no separate specifically designed system to capture information at the time of the incident or soon after or to grade the incident.

There was no formal system for reporting other incidents and for investigating these, reporting on the findings and sharing learning, although we were told incidents would be discussed with staff involved and an email would be sent out to the wider team.

We asked if there was a process to enable an incident report to be generated and considered as part of governance processes. We were told they were not sure if this could be done, although the RM indicated he thought there was a way to do this.

Are Outpatients effective?

Insufficient evidence to rate

Multidisciplinary working

Doctors, nurses and other healthcare professionals worked together as a team to benefit patients. They supported each other to provide good care.

Inadequate

Outpatients

Staff in the hormone therapy part of the service held regular and effective multidisciplinary meetings (MDT) to discuss patients and improve their care. Meetings were held at regular intervals and provided an opportunity to discuss complex patient cases. Minutes were taken from these meetings.

There were no formal team meetings where all staff from the different parts of the service came together, either remotely or face to face. This would have provided an opportunity to have clinical supervision and support the sharing of new information, developments and best practice. However, clinical teams were small in size, which enabled them to meet informally during their working days.

Consent, Mental Capacity Act and Deprivation of Liberty Safeguards

Staff supported patients to make informed decisions about their care and treatment. They followed national guidance to gain patients' consent for hormone therapies, surgical procedures and when referred on for associated expertise.

Staff gained consent from patients for their care and treatment in line with legislation and guidance. Information was recorded in detail within consent forms reviewed during the inspection, and these records were stored as part of the patients' medical record. The information detailed discussions around the benefits and risks associated with treatment and care. This enabled patients to make fully informed decisions related to their own choices and preferences.

There was no evidence provided, either within our discussions or documentation or electronic records to show that nursing staff received and kept up to date with training in the Mental Capacity Act and Deprivation of Liberty Safeguards.

Staff always had access to up-to-date, accurate and comprehensive information on patients' care and treatment. Staff had access to an electronic records system that they could all update as required for their respective role.

Are Outpatients responsive?

Insufficient evidence to rate

Service delivery to meet the needs of local people

The service planned and provided care in a way that met the needs of local people and the communities served. It also worked with others in the wider system and local organisations to plan care.

Managers planned and organised their services, so they were able to respond to and meet the changing needs of the respective population it served. The provider and staff were very aware of the lengthy waiting times for the types of services provided both locally and nationally. Wherever possible they accepted patients out of the area to minimise waiting times.

The service minimised the number of times patients needed to attend the clinic, by ensuring patients had access to the required staff, both remotely and face-to-face. Any required tests were organised in a manner which reduced unnecessary return visits.

Facilities and premises were appropriate for the services being delivered. The environment was set up to enable privacy during consultation and treatment.

Inadequate

Outpatients

Patients could access help and support during working hours and if they had undergone surgery, there was access to nursing staff for post-operative wound checks and follow up advice.

Meeting people's individual needs

The service was inclusive and took account of patients' individual needs and preferences. Staff made reasonable adjustments to help patients access services. They coordinated care with other services and providers.

The individual needs of each patient were fully considered and recorded. Records reviewed by us showed evidence of detailed discussion, a full assessment of general medical, physical and mental health interview. We saw information which showed patients choices and wishes were fully considered, along with discussions related to any risks, surgical procedures and on-going treatment options.

There was access to psychological and psychiatric expertise under partnership arrangements, and the resulting reports arising from discussions between said individuals and patients were very detailed. This information assisted in contributing to treatment options and decision making on the part of the patients but also regarding the individual's suitability for such choices.

Once patients had been assessed by the psychologists, they were referred to the service and discussed at a multidisciplinary team meeting (MDT). If the psychologists had any concerns about a patient, they would either see them again or ask another psychologist to undertake a separate review.

The provider had developed working arrangements with other specialists to help manage patients with complex medical histories. Patients were referred onwards to specialists where needed, for example, medical doctors who investigate, diagnose and treat disorders of the endocrine system. (Endocrinologists)

Two separate nursing and an administrative team were available on site. Three nurses managed pre-operative assessments and post-operative follow up care. Another team made up of independent nurse prescribers and administrative staff had a specific responsibility for seeing and managing patients who needed hormone therapies. First contact to this team came via email, phone or via the admin team. Psychologists or psychiatric reports were dealt with by administration before an initial appointment was made with the independent nurse prescriber. Treatment plans took the form of a two-year subscription with regular follow ups and the option to extend the treatment plan, was agreed by the patient and the nurse.

Patients who required additional therapies as part of their treatment had access to a range of options, both on-site and via onward referral. This included for example, voice and communication coaching.

There was access to clinical staff for post-operative care and on-going support. Where interactions with staff took place, information was updated in the patient record to capture this.

Inadequate

Outpatients

Are Outpatients well-led?

Inadequate

Leadership

Leaders had some of the skills and abilities to run the service and were focused on prioritising the needs of patients who used the service. Although they were visible and approachable in the service for patients and staff, they had not developed and embedded practices which fully supported staff to undertake their roles safely and effectively.

The registered manager (RM) had day to day responsibility for the service. They were supported by a recently appointed business manager, other administrative staff and nursing staff. The RM not only provided on-site patient consultations but, undertook minor surgical procedures at the location and complex surgery at another registered hospital location.

The hormone treatment service was run by a suitably skilled independent prescriber, and they ensured their team were supervised and kept up to date with relevant information.

From the information we saw and were provided with, we found the provider had not fully recognised and established systems and processes as expected to meet some of the required standards. This was particularly evident regarding the lack of provision and monitoring of mandatory safety training and the incident process.

There were no formal team meetings where all staff came together, either remotely or face to face. Clinical teams were small in the number of staff, which enabled them to meet informally to discuss relevant matters; however, the lack of a joined approach presented missed opportunities for sharing information such as the discussion of incidents, audit outcomes and learning.

Policies and procedures had not been written and developed specifically for this service, as a result some information was missing or was not relevant. Staff did not have a suitable level of information to direct them related to training and incidents, as a result there were risks to patient and staff safety.

Vision and Strategy

The service had a clearly stated vision, and this was underpinned by the principles of the guidelines for the standards of care for transgender, trans-individuals set out by the World Professional Association for Transgender Health (WPATH).

Governance

Leaders did not operate a fully developed and effective governance processes, throughout the service. Staff at all levels did not have regular opportunities to meet, discuss and learn from the performance of the service.

The service did not hold an on-site Medical Advisory Committee (MAC) meeting or similar, where information related to for example; performance activities, patient outcomes, risks and audit were discussed. Staff who spoke with us confirmed there were no formal governance meetings held at the location, which required either staff to attend or the submission of information for review. We were told there was no formalised audit programme for on-site activities.

Inadequate

Outpatients

There is an expectation that services undertaking gender reassignment surgery participate in clinical audit activity on an annual basis and submits data to local and national audits and any others as required.

We were told by the RM that they collected outcome data for breast surgery; however, we were not able to locate this as we would expect to via the external data collection agency.

There was a governance arrangement with partner organisations. The RM told us they participated in the MAC at the independent hospital where surgery was carried out on patients under his care. We were told the meeting considered and reviewed of patient outcomes and any feedback from them.

Management of risk, issues and performance

The management of risks, issues and performance had not been effectively set up and embedded in everyday practice.

Incident procedures had not been developed fully and was limited to recording incidents on the patient medical record, rather than a separate system. Although we were shown the progress of an incident, which involved joint investigation between the service and the location where surgery took place, we were concerned that by recording the information only in the patient medical record, the details would not be captured and considered fully as part of the governance processes.

There was no formal system for reporting other incidents and for investigating these, reporting on the findings and sharing learning, although we were told incidents would be discussed with staff involved and an email would be sent out to the wider team.

Although there was an induction process, it was limited by not having associated mandatory training tailored to their role before or soon after they started work. As a result, there was a risk staff did not fully understand their responsibilities or how to minimise risks to those who used the service.

This section is primarily information for the provider

Enforcement actions

Action we have told the provider to take

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

Regulated activity	Regulation
Treatment of disease, disorder or injury	Regulation 17 HSCA (RA) Regulations 2014 Good governance The provider had not established sufficient systems and processes to enable them to identify, assess, monitor and mitigate the risks relating to the health, safety and welfare of service users and others who may be at risk which arise from the carrying on of the regulated activity. The provider did not maintain securely such other records as are necessary to be kept in relation to— persons employed in the carrying on of the regulated activity, and the management of the regulated activity.