

Save Minds Operational Base

Inspection report

Aura Centre
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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 a short notice announced comprehensive inspection at the registered location of Save Minds Operational Base on 14 July 2022 as part of our inspection programme.

Save Minds Operational Base provides a consultant led outpatient service that assesses and treats patients who are treatment resistant to depression, anxiety and post-traumatic stress disorder. The treatment involves an intravenous infusion using a controlled drug called Ketamine. Patients that approached the service required this type of treatment as other treatments had not been successful in the past.

The consultant anaesthetist was a sole practitioner who led the service but also performed additional roles including chief executive officer and registered manager. 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. The report will refer to this individual as the 'consultant anaesthetist'.

We reviewed a sample of the feedback forms that the provider had collated since opening the service. Comments were positive and described the service as being excellent. All patients said that they would recommend the clinic. Patients we spoke with were complimentary about the service. They described the consultant anaesthetist as being supportive and made them feel at ease. Patients told us that the treatment had vastly improved their quality of their life.

Our key findings were:

- The service provided safe care and treatment. The provider ensured that patients had access to comprehensive assessments for both their mental and physical health prior to treatment.
- Staff understood their responsibilities to manage a medical emergency. The consultant anaesthetist had been appropriately trained in life support through their role in the NHS and had access to emergency equipment on-site.
- The service safely managed medicines. The consultant anaesthetist prescribed and administered medicines to patients in line with legal requirements and current national guidance.
- Staff supported patients to make informed decisions about treatment. The service ensured that patients were given information that included how the treatment works, the rates of success and the costs involved. Patients we spoke with told us that they were given enough time to ask questions before they committed to starting treatment.
- The service used technology to improve treatment and to support patient experience. The provider used a mood monitoring application to track patients' mood during and after treatment. This enabled the service to assess the effect of treatment on patients.

Overall summary

- There was a focus on continuous learning and improvement. The provider had plans in place to use treatment data collected to write a research paper that would be published in a peer review academic journal.
- Access into the service was easy. The provider's website clearly set out how patients could contact the service. The service responded promptly to enquiries and ensured patients were seen in a timely manner.
- The provider had effective governance systems in place that monitored the quality and safety of the service. The consultant anaesthetist recognised the importance of external review and scrutiny and had set up a medical advisory board that met on a quarterly basis. Board members were clinicians.

However:

- Record keeping was not always consistent. Correspondence containing information sent from the service to a patient or other healthcare professionals was not always recorded within the patient's individual electronic record. This meant that the patient records may not always include the most up to date information, which could lead to the patient not receiving safe care and treatment.
- The provider had not completed a Disclosure and Barring Service (DBS) check for a new member of staff prior to employment commencing. One member of staff had not been DBS checked before they had started their role in 2021. The provider could not be assured that the staff member was suitable to the role without knowing if they had a criminal background. At the time of inspection, the provider told the CQC the DBS check had been applied for.
- The provider did not have an exemption certificate in place for the denaturing process that is required before a controlled drug is disposed of. The denaturing process changes the formula of the drug and ensures that it cannot be retrieved or recovered in the waste chain. Whilst there are no risks to patients and their wellbeing, this is a legal requirement under the Misuse of Drugs Regulations 2001. At the time of inspection, the provider confirmed that they would apply for the exemption certificate immediately.
- The service did not have a robust system in place for checking a patient's identity before commencing treatment. Although the consultant anaesthetist required patients to confirm their name, date of birth and address prior to treatment, patients were not required to show photographic ID. This increased the risk of the service treating a person who is not suitable for treatment. At the time of inspection, we raised this concern to the consultant anaesthetist. The consultant anaesthetist confirmed that the service would introduce photographic ID checks immediately.

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

- The provider should ensure that correspondence sent from the service to individual patients and to other healthcare professionals is clearly recorded within the electronic record system.
- The provider should ensure that a Disclosure and Barring Service (DBS) check is completed prior to any member of staff commencing employment.
- The provider should ensure that the service applies for an exemption certificate that covers the denaturing process for controlled drugs before they are disposed of.
- The provider should ensure that there is a robust system in place for verifying a patient's identity when they attend the clinic and before commencing treatment.

Jemima Burnage

Interim Deputy Chief Inspector of Hospitals (mental health)

Our inspection team

Our inspection team was led by a CQC lead inspector. The team included a CQC Inspection Manager and a member of the CQC medicines team. The inspection was led by a CQC inspector who had access to advice from a specialist advisor when required.

Background to Save Minds Operational Base

This service is provided by Save Minds Limited.

Save Minds Limited is registered and the following address. This is the location where our inspection was carried out:

Aura Centre

Charlbert Street

London

NW8 7BT

The service website: <https://saveminds.co.uk>

Save Minds Limited is registered to provide the following regulated activities:

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

Save Minds Operational Base provides assessment and treatment to adults who have treatment resistant depression, anxiety and post-traumatic stress disorder. The treatment involves using a controlled drug called Ketamine that is passed into a person's blood stream via an intravenous infusion. This is known as Ketamine infusion therapy. The treatment is delivered to a patient in a clinical setting and the patient is closely monitored throughout treatment and for a period of time after treatment before being discharged.

An experienced consultant anaesthetist ran the service and delivered the Ketamine infusion therapy. The doctor was supported by external psychiatrists who assessed patients' mental health and their suitability for treatment. Patients were required to complete several assessments prior to treatment including a mental and physical health assessment. Since the service opened in 2020 the service had treated 112 patients.

The evidence base for this type of treatment mainly originates from clinical studies carried out in the United States of America. However, UK based researchers along with an NHS trust in Oxford offer the same treatment as part of a clinical research programme. The consultant anaesthetist had links with the clinicians who ran the research programme.

The service registered with the CQC in November 2020 and has not been inspected before. The service employed a consultant anaesthetist and a chief operating officer. The consultant for this service was a sole practitioner. This meant they did not have a team of colleagues who were employed by the service to provide support and oversight of their work. However, the service did have a medical advisory board in place that provided external scrutiny and the lead consultant attended annual appraisals that included a review of their clinical practice.

Save Minds Operational Base opened when an assessment or treatment was booked in. The clinic was based within a dental practice and had access to their clinic rooms between 8am and 7.30pm Monday to Friday and 9am to 3pm on a Saturday. The service was closed on a Sunday.

How we inspected this service

During the inspection visit to the service, the inspection team:

- spoke with four patients who had used the service
- reviewed 10 feedback forms
- spoke with the registered manager and chief operating officer
- reviewed six treatment records
- checked how medicines were managed

- reviewed two employment records for the employed members of staff and four board members
- reviewed information and documents relating to the operation and management of the service

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?

We rated safe as Good because:

Safety systems and processes

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

- The provider was based within a building along with a dental practice. The dental practice had overall responsibility to manage the environment and fire safety risks. However, the provider also carried out their own environmental risk assessments to maintain oversight of the environment that their patients accessed.
- The provider had appropriate safety policies in place which were regularly reviewed and communicated to staff. The service had standard operating procedures in place to support the running of the service and treatment being delivered. Staff received safety information from the service as part of their induction.
- The service had systems to safeguard vulnerable adults from abuse. Members of staff had received level three safeguarding vulnerable adults training. Guidance on how to raise a safeguarding alert and who to report a concern to was outlined within the provider's safeguarding adult's policy.
- The provider carried out recruitment checks prior to employment and on an ongoing basis where appropriate. The service was small in size and employed two members of staff which included the consultant anaesthetist and the chief operating officer. We reviewed both of their employment records and found that a proof of identification, employment history and mandatory training was available.
- Whilst the provider carried out most of the required staff pre-employment checks, they had not ensured that a Disclosure and Barring Service (DBS) check had been completed for one employed member of staff prior to employment. 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. This was not in accordance with the provider's own staff recruitment policy which includes 'criminal record and barring checks' as one of the nine pre-employment checks to be carried out prior to employment. Although the staff member did not have face to face contact with patients, the staff member handled patient information. The provider could not be assured that the staff member was suitable to the role without knowing if they had a criminal background. At the time of inspection, the member of staff had applied for a DBS check. The provider told the CQC that they had subscribed to a recognised online company who carry out pre-employment checks for employers. Going forward all staff including board members would be expected to have an up to date DBS check completed as part of their work with Save Minds Operational Base.
- All permanent staff received up-to-date mandatory training appropriate to their role. They knew how to identify and report concerns. Staff were required to complete a range of mandatory training courses including information governance, mental capacity training and basic life support.
- There was an effective system to manage infection prevention and control. The provider carried out monthly infection control audits to ensure the environment their patients had access to adhered to infection control principles. The provider had an infection control policy in place to guide staff.

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 chief operating officer booked appointments when required.
- There was an effective induction system for staff tailored to their role. Due to the small size of the service, one member of staff had received an induction. This included how to use the electronic patient record system, mandatory training and the general running of the service.

Are services safe?

- 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. The service had a medical emergency policy in place that guided staff in how to respond to an unwell patient. The service had recognised that the defibrillator they had access to on-site was adequate for supporting a person in cardiac arrest but not adequate for a person with an irregular heartbeat. The consultant anaesthetist had purchased a new defibrillator that could meet this need.
- There were appropriate indemnity arrangements in place. Indemnity arrangements covered the consultant anaesthetist and their individual clinical practice as well as insurance indemnity cover for the provider.
- Patient risk was assessed at the point of referral into the service and during the assessment stage. In all six records reviewed, patients had received a physical health and mental health assessment prior to treatment commencing. Patients received a full psychiatric assessment by one of the external psychiatrists and a physical health check that included an electrocardiograph (ECG) and blood tests by the consultant anaesthetist. Patients were required to be medically cleared prior to treatment starting.
- The provider had a system in place to monitor patients' mental wellbeing and mood after treatment. Patients were required to complete a daily mood monitoring questionnaire via a mobile application that enabled the service to track the patient's mood. This was partly to assess whether the treatment was effective and to also engage with the patient after treatment. Staff contacted individual patients if their score was lower than expected or if they had not responded to the questionnaire. The consultant anaesthetist had an emergency contact for each patient if the patient was not contactable.

Information to deliver safe care and treatment

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

- Whilst staff ensured that individual care records were written in a way that kept patients safe, the records did not always demonstrate the correspondence that had been sent to individual patients, their GP or other healthcare professionals involved in their care. In all six records reviewed we found that the records did not include the introductory emails that had been sent from the service to the individual patients. At the time of inspection, the provider told us that the introductory email and patient information leaflet was sent via email but not saved into the patient's individual record. The service showed CQC an example of the email template that was sent to patients. We also found in two out of six records that the service had not ensured that correspondence sent to other healthcare professionals had been saved into the individual patient records. After the inspection, the consultant anaesthetist shared with the CQC a copy of the correspondence emails that had been shared with the other healthcare professionals. The inconsistent record keeping meant that staff may not be able to rely on a patient record for accurate and up to date information, which could lead to a patient not receiving safe care and treatment.
- The service had systems for sharing information with staff and other agencies to enable them to deliver safe care and treatment. The consultant anaesthetist could only do this when the patient had given consent to sharing their information. In six records reviewed, all patients had given consent for their personal information to be shared. The consultant anaesthetist recognised the associated risks for when a patient declined for their information to be shared with other health professionals but they assured themselves that they would undertake all of the necessary assessments and tests to keep the patient safe before, during and after treatment.

Safe and appropriate use of medicines

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

Are services safe?

- The service managed medicines safely, including controlled drugs and emergency medicines. The provider had a comprehensive medicines management policy in place to ensure staff adhered to local policy and national guidance. During the inspection, we identified that the service did not yet have a Home Office licence. However, they had undertaken all of the necessary steps to apply for one to ensure that they were able to obtain and store Ketamine as a stock medicine, in compliance with the law.
- The provider managed the waste of medicines safely. Although the service had the right protocols in place to safely manage the disposal of controlled medicines, the provider did not have an exemption certificate in place for the denaturing process that is required before a controlled drug is disposed of. The denaturing process changes the formula of the drug and ensures that it cannot be retrieved or recovered in the waste chain. Although this is a legal requirement under the Misuse of Drugs Regulations 2001, there are no risks to patients and their wellbeing. At the time of inspection, the provider confirmed that they would apply for the exemption certificate immediately.
- Whilst staff prescribed and administered medicines to patients in line with legal requirements and current national guidance, the provider did not record the batch numbers and expiry dates of medicines that had been administered. Maintaining records of medicines administered ensures that in the event of a drugs recall, the provider would be able to refer back to the medicines the service had administered and take action if required.
- The service carried out medicines audits to ensure prescribing was in line with best practice guidelines for safe prescribing. The service regularly audited the use of controlled drugs administered to ensure adherence to legislation.
- The clinic provided an off-label medicine (one used in a way that is different from that described in the licence). Staff ensured that patients were aware of this before they consented to treatment.
- The service prescribed Schedule 2 controlled drugs (medicines that have the highest level of control due to their risk of misuse and dependence). They did not prescribe schedule 3, 4 or 5 controlled drugs.
- The consultant anaesthetist carried out physical health monitoring checks prior to prescribing and administering medicines to patients. We reviewed six treatment records and found that the consultant anaesthetist had ensured that a patient's physical health was monitored before, during and after treatment. Physical health checks included the monitoring of blood pressure, heart rate and breathing rate. In all six records reviewed, all patients had received the required physical health checks.
- The provider did not have a robust system in place to check patients' identity. Whilst the service requested patients to confirm their name, date of birth and address prior to treatment, the service did not require patients to show photographic ID. Without a robust verification system in place there was an increased risk of the treatment being given to people who are not suitable for treatment. We raised this to the consultant anaesthetist at the time of our inspection who confirmed that the service would introduce photographic ID checks immediately.

Track record on safety and incidents

The service had a good safety record.

- There had been no serious incidents reported at the service. The service had appropriate policies and procedures in place to manage an incident if they were to occur.
- The service monitored and reviewed their activity. The service had a medical advisory board that met every three months and discussed the running of the service including any incidents that had occurred.

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.

Are services safe?

- There were adequate systems for reviewing and investigating when things went wrong. The service learned and shared lessons, identified themes and took action to improve safety in the service. In 2021 the service had received a complaint about a patient's care and treatment. The complaint was investigated by the General Medical Council and it was decided that no further action would be taken. The medical advisory board was sighted on the complaint raised.
- 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. The provider had a duty of candour policy in place that guided staff in how to ensure the duty of candour principles are upheld.
- 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. The medical advisory board was the main forum in which safety alerts would be discussed and recorded. The consultant anaesthetist received correspondence from the Medicines and Healthcare products Regulatory Agency as well as through their NHS work. At the time of inspection, the consultant anaesthetist had not received any recent medicine safety alerts.

Are services effective?

We rated effective as Good because:

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)

- Staff appropriately assessed patient need and delivered care in line with the most reliable and up to date evidence based research available. Patients were assessed and treated in line with National Institute for Health and Care Excellence (NICE). Although the evidence base for using Ketamine as a treatment for treatment resistant depression, anxiety and post-traumatic stress disorder is still in its infancy in the UK, the consultant anaesthetist was involved in conversations about the treatment with UK based researchers and experts in the field.
- Patients' immediate and ongoing needs were fully assessed. Where appropriate this included their clinical needs and their mental and physical wellbeing. Suitability for treatment was assessed by experienced doctors to ensure the service had enough information about the patient before treatment was given.
- We saw no evidence of discrimination when making care and treatment decisions. In the six records we reviewed, we did not see any evidence of discrimination.
- The service used technology to improve treatment and to support patient experience. Prior to treatment all patients were required to complete a range of questionnaires about their mental health, previous treatments and quality of life. This gave the doctors a baseline. After the Ketamine infusion treatment patients were required to provide daily mood scores via a mobile phone application. The consultant anaesthetist used the results to monitor treatment effectiveness. At the time of inspection, the consultant anaesthetist showed us examples of the mood monitoring application working in practice and the positive effects the treatment had on patients. The provider had recently employed an external consultant psychiatrist to support the analysis of the patient data collected by the mood monitoring application so far. The provider was preparing to write a research paper that could be formally published in a peer-review academic journal later in 2022.

Monitoring care and treatment

The service was actively involved in quality improvement activity

- The service used information about care and treatment to make improvements. The service made improvements through the use of completed audits. There was clear evidence of action to resolve gaps in care and improve quality when they were identified. The service carried out regular audits that included patient records, management of medical emergencies, infection control and clinical governance. The medical emergency audit that had been carried out in June 2022 identified that the algorithm that guides staff in how to respond in an emergency was not displayed correctly. The provider resolved this and ensured the algorithm was easily accessible. In a separate audit the provider had identified that in the event that staff were required to assist in moving a patient, they would not be able to do so as they did not have the right equipment. As a result of the audit, the provider purchased a wheelchair that could support patients and their needs.

Effective staffing

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

Are services effective?

- All staff were appropriately qualified. The provider had an induction programme for all newly appointed staff. The consultant anaesthetist was registered with the General Medical Council and was up to date with revalidation. The consultant anaesthetist was also employed by the NHS had extensive experience in their speciality.
- 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.

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 such as GPs and other healthcare professionals when appropriate.
- Before providing treatment, the consultant anaesthetist ensured they had adequate knowledge of the patient's health, any relevant test results and their medicines history. In all six records reviewed we found the consultant anaesthetist had access to patients' previous treatments and medical records. We saw evidence that the external psychiatrist had reviewed the medical history at the point of assessment and made treatment recommendations based on this.
- 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 consultant anaesthetist told us that they it was rare for a patient to decline their information to be shared. The consultant anaesthetist told us that they would not carry out treatment on patients who did not give consent to share information with their GP or another healthcare professional. Where patients agreed to share their information, we saw evidence of correspondence sent to their registered GP in line with GMC guidance.
- The provider had risk assessed the treatment they offered. The consultant anaesthetist ensured that patients completed various tests that included an assessment of a patients physical and mental health. The outcomes of these assessments were reviewed by the external psychiatrist and the consultant anaesthetist. The consultant anaesthetist took overall responsibility for the delivery of the ketamine infusion therapy.
- Patient information was shared appropriately, and the information needed to plan and deliver care and treatment was available to relevant staff in a timely and accessible way.
- The service monitored the process for seeking consent appropriately. The provider monitored consent as part of the clinical record audit.

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. The service provided patients with information on how to integrate the treatment into their lives and suggested activities that supported this such as yoga, reflection and healthy eating.
- Risk factors were identified and highlighted to patients and where appropriate to their normal care provider. During the assessment process any risks relating to the patients physical or mental health would be taken into account before treatment was considered. The consultant anaesthetist used a recognised physical health classification scale that patients were required to meet before treatment would be given.

Consent to care and treatment

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

Are services effective?

- Staff understood the requirements of legislation and guidance when considering consent and decision making. At every assessment and prior to treatment the consultant anaesthetist required the patient to give consent. In all six records reviewed we found evidence that patients had consented to treatment.
- Staff supported patients to make decisions. Where appropriate, they assessed and recorded a patient's mental capacity to make a decision. When a patient first enquired about the service staff ensured that patients understood the criteria for treatment. The consultant anaesthetist also provided patients with a presentation about the background to the treatment and its effectiveness. The consultant anaesthetist told patients that there was a 60% to 70% success rate for patients who have eight to 10 treatments. All patients we spoke with told us that they were given enough time to ask questions and make their decision about the treatment.

Are services caring?

We rated caring as Good because:

Kindness, respect and compassion

Staff treated patients with kindness, respect and compassion.

- The service sought feedback on the quality of clinical care patients received. The service asked patients to complete a feedback form after treatment or share their experience with the service via email. Patients were positive about the way staff treated people. Patients described the service as being supportive, transparent and that the treatment they had received provided them with a better quality of life.
- 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. Patients told us that the service was flexible in their approach. One patient told us that the service respected their wishes to not go ahead with treatment immediately and ensured they had time to make their decision.

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. Patients were advised that if an interpreter was required the service would need to book this in advance. The consultant anaesthetist told patients there could be an additional charge for interpretation services.
- All patients we spoke with reported that they felt listened to and supported by staff and had sufficient time during consultations to make an informed decision about the choice of treatment available to them.
- Staff involved patients in the assessment and planning of care and treatment. Patients told us that clinicians were contactable for further advice and support outside of the appointment time.

Privacy and Dignity

The service respected patients' privacy and dignity.

- Staff recognised the importance of people's dignity and respect. Patients told us that staff were kind and made them feel at ease.
- Patients were treated in a dedicated treatment room within the building. After treatment, patients remained in the room to recover until they were discharged by the consultant anaesthetist.

Are services responsive to people's needs?

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 consultant anaesthetist understood the needs of their patients and supported their needs. Staff were aware that patients attending the service had not been successful in treating their mental health condition in the past and that some patients were at risk because of this. The consultant anaesthetist ensured that the daily mood monitoring results were reviewed and followed up promptly if a patient had a lower score or did not input a score.
- The facilities and premises were appropriate for the services delivered.
- Reasonable adjustments had been made so that people could access and use services on an equal basis to others. The provider had assessed their environment to ensure that patients who used a wheelchair could access the treatment room.

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, test results and treatment.
- Waiting times, delays and cancellations were minimal and managed appropriately. As the service was small and employed one doctor, the service did not have a formal target for scheduling initial assessments. The service aimed to assess patients promptly after they had completed the pre-consultation questionnaires and shared their medical history.
- Patients with the most urgent needs had their care and treatment prioritised.
- Patients reported that accessing the service was easy. Patients told us the service offered an initial call soon after they had enquired about treatment.

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 in the patient information leaflet. The provider had received one complaint from a patient about the side effects of treatment. The complaint was investigated by the GMC and no further action was taken.
- The service had complaint policy and procedures in place. The service aimed to provide an initial response to a complaint within 24 hours and a final response within 28 days.

Are services well-led?

We rated well-led as Good because:

Leadership capacity and capability;

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

- The consultant anaesthetist was knowledgeable about issues and priorities relating to the quality and future of services. They understood the challenges and were addressing them. The service held a medical advisory board meeting every three months to ensure the service had medical oversight and external scrutiny. The board members were all experienced doctors.
- Leaders were visible and approachable. Due to the small size of the service, the service employed two members of staff, the consultant anaesthetist and the chief operating officer. Both members of staff worked closely together to make sure they delivered a good quality service.

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. The aims of the service were outlined within the clinics policies and procedures. The consultant anaesthetist's long-term goal was to set up a second clinic, but this was dependent on investment opportunities.
- The service developed its vision, values and strategy jointly with staff and the medical advisory board. Staff told us that it was their aim to deliver a service to people that can improve their overall quality of life.

Culture

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

- Staff felt respected, supported and valued. They were proud to work for the service.
- The service focused on the needs of patients. Staff recognised that the patients who approached the service were vulnerable as they had not yet found a successful treatment for their mental health condition.
- Openness, honesty and transparency were demonstrated when responding to incidents and complaints. At the time of inspection, the service had received one complaint, and this had been investigated by an external organisation. The consultant anaesthetist 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 need. This included appraisal and career development conversations. Due to the small size of the service, there were two members of employed staff who required an annual appraisal. At the time of our inspection, the consultant anaesthetist was arranging for an external member of staff to carry out the appraisal for the chief operating officer. This was an opportunity to discuss their performance and wellbeing. The consultant anaesthetist had received an appraisal in December 2021 through their role in the NHS and was up to date with GMC revalidation.
- There was a strong emphasis on the safety and well-being of all staff. The provider ensured staff had received health and safety training as well as fire safety training. The consultant anaesthetist had risk assessed the environment and working practices to ensure staff were kept safe whilst at work.
- The service actively promoted equality and diversity. Staff had received equality and diversity training.

Are services well-led?

- There were positive relationships between staff.

Governance arrangements

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

- Structures, processes and systems to support good governance and management were clearly set out, understood and effective. The governance arrangements in place included quarterly medical advisory board meetings. The meetings had a set agenda which included clinical governance, service risks, incident management and business continuity. The consultant anaesthetist was keen to ensure that the service had a level of external scrutiny due to the service being the first of its kind in the London region.
- Staff were clear on their roles and accountabilities
- The consultant anaesthetist had established proper policies, procedures and activities to ensure safety and assured themselves that they were operating as intended. Policies available included the management of a new patient, a medical emergency, medicines and controlled drugs as well as safeguarding vulnerable adults.
- The service had systems in place to submit data or notifications to external organisations when required. Since the service registered with the Care Quality Commission, we had not received any statutory notifications from the provider. The provider told us that there had been no incidents or safeguarding referrals that would warrant a notification.
- There were arrangements in line with data security standards for the management of patient identifiable data. The provider had been issued with a certificate from the Information Commissioners Office from September 2020 to 2022 which demonstrated that the service's processing of personal data is compliant with UK General Data Protection Regulation.

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 quarterly medical advisory board ensured that all board members maintained oversight on the general running of the service including safety alerts, incidents, and complaints. We reviewed the medical advisory board meeting minutes for 2021 and 2022 and found that the board members monitored service information and challenged the consultant anaesthetist when required.
- The service had processes to manage current and future performance. The service collated patient feedback and used this to monitor patient experience. The consultant anaesthetist was working with an external psychiatrist to review treatment data and planned to use the data to understand the effectiveness of treatment.
- Clinical audit had a positive impact on the quality of service delivered. The service carried out clinical audits that included the management of medical emergencies, care records and infection control. There was clear evidence of action taken to improve the service. For example, the service had identified during an audit for medical emergencies that the service did not stock two emergency drugs used for when a person has an irregular heartbeat. The medicines were recommended by the Resuscitation Council UK. The provider ensured that the medicines were ordered and readily available to staff. The provider had always stocked medicines to support patients experiencing a cardiac arrest and anaphylaxis.
- The provider had plans in place in the event that the service could not open at short notice.
- The consultant anaesthetist had a contingency plan in place with another consultant anaesthetist who had been trained in the delivery of ketamine infusion therapy. If the provider had to close permanently the service planned to transfer patients in treatment back to their GP or to another provider who could carry out the same treatment in the UK.

Are services well-led?

Appropriate and accurate information

The service acted 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 medical advisory board were sighted on clinical matters.

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 patients, staff and external partners and acted on them when required. At the time of inspection, the patients we spoke to and the feedback we reviewed was positive and complimentary about the service.
- Staff could describe to us the systems in place to give feedback. Due to the small size of the service, a staff survey was not carried out. Both the consultant anaesthetist and chief operating officer communicated on a regular basis.

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 consultant anaesthetist was working with an external psychiatrist to review the patient data from the service's mood monitoring application. Patients undergoing treatment were required to complete a mood survey on the application on a daily basis whilst receiving treatment. The consultant anaesthetist planned to use the data outcomes to write a research paper that would be published in a peer review journal. The consultant anaesthetist had been approached from a colleague in the field to be involved in creating a national Ketamine registry that will allow the use of prescribed Ketamine to be monitored more closely.