Dr John Revill

Lowedges Clinic

Inspection report

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Overall summary

We carried out an announced comprehensive inspection on 26 July 2018 to ask the service the following key questions; Are services safe, effective, caring, responsive and well-led?

Following this inspection we took enforcement action to cancel the registration of the provider. This means the provider will no longer be able to operate the service.

Our findings were:

Are services safe?

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

Are services effective?

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

Are services caring?

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

Are services responsive?

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

Are services well-led?

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

Background

We carried out this inspection under Section 60 of the Health and Social Care Act 2008 as part of our regulatory functions. This inspection was planned to check whether the service was meeting the legal requirements and regulations associated with the Health and Social Care Act 2008.

Lowedges Clinic provides treatment to adults with a history of alcohol and opiate substance abuse. The clinic offers insertion of the naltrexone implant under the skin during a minor surgical procedure using local anesthetic. It does not offer a detoxification service and does not see people under the age of 18. The clinic does not employ any staff and is owned by a retired GP who is supported by three volunteers who assist with the procedure and perform administrative duties. Patients must come with a carer who stays with them when the procedure is carried out.

The provider, Dr John Revill, is registered with the Care Quality Commission to provide services at Lowedges Clinic, 7 Low Edges, Chesterfield Road , Sheffield, S8 8LW. The clinic is located between Sheffield and Chesterfield in a converted residential building. It consists of a reception/waiting room and treatment room downstairs with an accessible toilet to the rear of the building, in the back yard. There is a consulting room and treatment room on the first floor accessed via a steep stair case. There is free on-road parking.

Summary of findings

The clinic holds a list of registered patients who are self referred to the service. The clinic is available to patients who reside in England and from other countries who require the services.

As part of our inspection we reviewed seven Care Quality Commission comment cards where patients shared their views and experiences of the service. All of the seven comment cards we received were positive about the service experienced. Patients said the clinic offered an excellent service and staff were sensitive, professional, very caring and treated them with dignity and respect.

The clinic is open on Tuesdays from 12 noon to 6pm. Treatment is by appointment only and patients can contact the doctor via a telephone messaging service at other times. The provider is not required to offer an out of hours service and those who need emergency medical assistance outside of the clinic opening hours are requested to seek assistance from alternative services such as their own GP, the NHS 111 telephone service or accident and emergency.

Our key findings were:

- The clinic did not have safety systems, processes or procedures to keep patients safe and reduce the risk of avoidable harm or abuse. The doctor and volunteers had not undertaken adequate safeguarding training. The were no systems in place to mitigate the risks of the health and safety and welfare of patients and others.
- Patients' care and treatment did not reflect current evidence-based guidance, standards, practice or technology. The information needed to plan and deliver effective care and treatment and support was not available at the right time and was not appropriately shared with other care providers.
- Volunteers who supported the doctor were not adequately inducted into or trained for their role.
- Services were not planned or delivered in a way that met patients' needs.
- The delivery of high quality care is not assured by the leadership and governance of the clinic.

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

- Ensure care and treatment is provided in a safe way to patients.
- Ensure patients are protected from abuse and improper treatment.
- Establish effective systems and processes to ensure good governance in accordance with the fundamental standards of care.

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

Summary of findings

The five questions we ask about services and what we found

We always ask the following five questions of services.

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

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

- The provider did not have robust arrangements in place to keep people protected and safeguarded from abuse.
- Staff did not assess, monitor or manage risks to people who use the services. Concerns, incidents or near misses were not recognised or reported consistently.
- There were ineffective infection prevention and control measures in place.
- Medicines were not managed safely.

Are services effective?
We found that this service was not providing effective services in accordance with the relevant regulations.

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

- Care and treatment did not reflect current evidence-based guidance, standards or practice.
- There was very limited monitoring of the outcomes of care and treatment.
- Volunteers were not equipped with knowledge and skills to enable them to support the doctor.
- The clinic offered a reactive, rather than proactive service, to support people to live healthier lives, and those who need extra support were not identified.

Are services caring?
We found that this service was not providing caring services in accordance with the relevant regulations.

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

- The seven CQC patient comment cards reported positive experiences using the service.
- Patients emotional, social, cultural or religious needs were not always viewed as important or reflected in their care, treatment and support.

Are services responsive to people's needs?
We found that this service was not providing responsive care in accordance with the relevant regulations.

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

- Services were planned and delivered without consideration of patients' needs and preferences.
- The facilities had been modified to meet peoples' needs but required further attention.

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

Summary of findings

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

- The clinic is offering a service in isolation to other substance misuse services. There was little or no attention to succession planning, the clinic does not open if the doctor is unavailable.
- The governance arrangements were absent and there was no process to review key items such as the strategy, values, objectives, plans or the governance framework.
- There was little understanding or management of risks and issues, and there was significant failures in performance management, audit systems and processes. Risk or issue registers and action plans, if they exist at all, were rarely reviewed or updated.

Are services safe?

Our findings

Safety systems and processes

The clinic did not have clear systems to keep patients safe and safeguarded from abuse.

- The clinic did not have a suite of safety policies including adult and child safeguarding policies. The doctor and volunteers did not receive safety information for the clinic.
- The clinic did not have a system to highlight or keep a risk register of those whose circumstances may make them vulnerable.
- The doctor and volunteers did not receive up-to-date safeguarding and safety training appropriate to their role. The doctor had not undertaken child safeguarding training in the last three years in line with the Safeguarding children and young people: roles and responsibilities Intercollegiate document 2014. Volunteers we spoke with had not undertaken any adult or child safeguarding training and did not know how to report concerns other than to report them to the doctor. This meant the provider was not ensuring that patients, their families and carers were protected from abuse.
- Disclosure and Barring Service (DBS) checks were not undertaken where required. (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). A risk assessment had not been completed in the absence of DBS checks for the volunteer role.
- There was an ineffective system to manage infection prevention and control. National guidance states 'Prevention of exposure to infection is of prime importance' (Drug misuse and dependence: UK guidelines on clinical management [orange book], Department of Health [DH], update 2017). The service did not undertake infection control audits in accordance with national guidance (Health and Social Care Act 2008: code of practice on the prevention and control of infections and related guidance, 2015). Spray to clean the surgical instrument tray and worktops had expired in May 2018. Sharps bins were not dated when first used and spots of blood were visible around the lids. Volunteers told us they recapped used needles before disposal in the sharps bin. The provider did not have an infection prevention and control policy or any associated procedures. Urine and vomit spillage kits were not available on the premises to clean up high risk body fluids.
- The immunisation status of the volunteers was not known. Guidance within the Immunisation of healthcare and laboratory staff: the green book, chapter 12 was not followed.
- There was a system for managing healthcare waste via a contracted company.
- The clinic did not ensure that facilities and equipment were safe and areas were cleaned regularly. We saw there was a cleaning schedule however records of areas cleaned were not kept. This meant that there was no system for ensuring that all parts of the building were cleaned regularly.

Risks to patients

There were no adequate systems to assess, monitor and manage risks to patient safety.

- Volunteers working at the clinic had worked there since the clinic opened in 2014 and did not have an induction or undertake any ongoing training updates.
- The clinic was not equipped to deal with medical emergencies and volunteers were not trained in emergency procedures. The doctor had undertaken basic life support training, however volunteers were not trained.
- Volunteers told us they would alert the doctor to any emergencies on the premises and emergency services would be called, if necessary.

Information to deliver safe care and treatment

The clinic did not have the information they needed to deliver safe care and treatment to patients.

- Individual patient care records were hand written and the records we saw showed not all information needed to deliver safe care and treatment was available to the doctor. The patient record did not capture whether the patient had any allergies, whether they were receiving treatment from another care provider or include an assessment of their mental health. Records only relating to the procedure were kept. Records of telephone calls with the patient were not kept.
- Prior to attending the clinic, patients were sent an information pack which contained, details about the

clinic, the procedure and a pre-procedure letter to give to the patient's own GP. Patients were asked to visit their own GP, before their appointment, to have a blood test and bring the results to the clinic. Not all patients had this test performed. The patient's urine was tested in the clinic prior to the procedure for traces of illicit drugs. We observed the urine dipsticks had expired in June 2018.

- Following the procedure, patients were given another letter, which included the date of the procedure, information about the implant and aftercare advice to give to their own GP. A copy of this letter was not kept for each patient. They were also given a medical identity card, to keep in their wallet, containing the clinic contact details, the name of the implant used and date inserted. Patient's were also give a stitch cutter to take to a health professional to remove the stitches that closed the wound.

Safe and appropriate use of medicines

The clinic did not have reliable systems for appropriate and safe handling of medicines.

- The clinic did not have adequate systems in place for managing, storing and checking medicines. A stock list was not kept and expiry dates of medicines not checked. This included emergency medicines which were not checked in line with the Resuscitation Council UK guidance.
- The clinic did not have oxygen or a defibrillator on site. A risk assessment had not been completed to assess why these were not required. Equipment was not kept to monitor the patient's blood pressure and temperature prior to, during and after the surgical procedure.
- We saw that the medicine refrigerator used to store Octreotide solution for injection had not been calibrated since 2013. Octreotide for injection, used to treat severe watery diarrhoea, should be stored in a refrigerator between 2 and 8 degrees Celsius. Checks on the temperature of the medicine refrigerator were not undertaken. A carton of apple juice was stored in the medicine refrigerator along with the medicines.
- The doctor supplied and administered medicines to patients relating to the procedure. The surgical implants used were unlicensed for use by the Medicines and Healthcare products Regulatory Agency (MHRA) in the United Kingdom. A medicine used outside of the terms of its license, or that has no recognised license for use in the UK, is known as 'unlicensed'. Unlicensed medicines can be prescribed if the appropriate practitioner concludes "for medical reasons, that it is necessary to do so to meet the specific needs of the patient" (General Medical Council 2013) and gave advice on medicines in line with legal requirements. The doctor informed the patient that the medicine was unlicensed during a pre-procedure consultation and it was also documented in the clinic information leaflet.
- Best practice guidance (DH, 2017) states "prescribers, dispensers and those administering medicines must take precautions to ensure that the use of 'off label' or 'unlicensed' medications is managed properly. There should be local safety standards and arrangements in place to monitor the use of unlicensed and off label medicines." The provider did not have systems or arrangements in place to monitor the use of unlicensed medicines. Other medicines used were antibiotics, anti-sickness and anti-diarrhoea medicines, a sedative and a local anaesthetic.
- Following the procedure the patient's health was not routinely reviewed by the clinic. Patients were provided with aftercare instructions and instructed to contact the clinic if they had any further queries or questions.
- Patients were routinely given a course of antibiotics to take after insertion of the implant to reduce the risk of infection complication.
- The doctor did not provide prescriptions. All medicines were given to the patient when they attended the clinic. Oral naltrexone tablets could be posted to the patient when the implant became less effective.

Track record on safety

The practice did not keep any records to demonstrate a safe track record.

- Comprehensive risk assessments in relation to safety issues had not been completed. For example, a health and safety risk assessment of the premises had not been completed in the previous two years. Fire safety risks had not been assessed. Fire extinguishers had not been serviced since 2013. A legionella risk assessment had not been completed. Window blinds in the waiting room were not securely tied back to prevent danger of entanglement and a risk assessment had not been completed. Substances hazardous to health were stored on top of an unlocked cupboard in a toilet used by patients.

Are services safe?

- The clinic did not monitor and reviewed activity as part of the delivery of the service. A lot of the changes to the running of the practice and procedures were as a result of custom and practice which was not documented or evidenced.

Lessons learned and improvements made

The clinic did not have established processes to learn and make improvements when things went wrong.

- Volunteers told us they would report any concerns or near misses to the doctor. This was not documented. The clinic did not have a procedure to follow when reporting and investigating incidents or events.
- There had been no significant events, incidents or complaints received or recorded in the last three years.
- The clinic did not have a system to receive and act on safety alerts. The doctor told us he kept himself up to date through membership of a professional group and by attending conferences.

Are services effective?

(for example, treatment is effective)

Our findings

Effective needs assessment, care and treatment

The clinic did not have systems to keep clinicians up to date with current evidence-based practice. Email alerts about medicines and medical devices from the MHRA were not received.

Care and treatment was not delivered in line with current legislation, standards and guidance. The clinic administered a three month and a nine month Naltrexone implant. The implants are not currently approved for the treatment and management of opioid dependence by the National Institute for Health and Care Excellence (NICE) or licensed for use by the Medicines and Healthcare Products Regulatory Agency (MHRA). A review by NHS National Institute for Health Research 2014 recommended, pending further research, Naltrexone implant use should be limited to clinical trials. The clinic was not currently engaging in any clinical trials.

Clinical pathways and protocols were not available to the doctor, therefore not used or followed. We saw evidence that a brief assessment of each patient took place before the implant was recommended. This included any medicines the patient was taking (both prescribed and illicit) and the details of the patient's carer. The patient's medical history, blood pressure, involvement with other services and mental health was not documented. The doctor told us they checked for contraindications to treatment such as thrombosis, though this was not recorded in the patient record. A urine test was performed to detect amphetamines, benzodiazepines, cocaine, marijuana, methadone, methamphetamines and opiates. Due to the lack of protocols in place to set out clear thresholds for treatment it was not clear what parameters were followed. The doctor told us treatment could be given if there were traces of non-opioid drugs in the patient's urine.

Monitoring care and treatment

The clinic did not have a comprehensive programme of quality improvement activity and did not routinely review the effectiveness and appropriateness of the care provided. Patients were not routinely contacted to review outcomes.

A clinical audit was undertaken in 2016 of 24 patients to assess the length of time and intensity of craving for opiates in patients receiving a nine month implant. It concluded that using cocaine affected the patients cravings and effectiveness of the implant was shorter. Seventeen patients did not experience cravings and stayed opiate free over the nine months and if cravings were experienced relapse was highly likely.

Effective staffing

The clinic did not employ any staff and three volunteers supported the doctor to deliver the service. We found volunteers did not have the skills, knowledge and experience to carry out their roles. For example, volunteers and the doctor whose role included infection prevention and control and safeguarding vulnerable adults did not undertake specific training in these areas.

The doctor who worked at the clinic had not undertaken any specialist training managing opioid dependence. There were no records showing the doctor had undertaken any continuing professional development (CPD) in this area of practice. The doctor had recently undergone revalidation with their professional body.

Coordinating care and treatment

Patients were asked to give their GP a letter prior to treatment and have blood tests performed and then given a second letter to give to their GP following the surgical procedure. The clinic did not capture whether the patient agreed with this and left it with the patient to liaise with their own GP. We were told the doctor would contact the patient's GP at the request of the patient or GPs could contact the service directly, which they told us, some did.

There was a risk that patients may have developed physical health problems, which could affect the treatment received, but because the clinic did not have regular contact with a patient's GP they did not know about them or adjust the treatment in response.

The clinic did not establish whether the patient was receiving treatment from other services to help them manage their addiction, care was not coordinated.

Helping patients to live healthier lives

Are services effective?

(for example, treatment is effective)

The doctor discussed care and treatment with patients and their carers prior to, during and after the procedure. Patients were directed to their own GP for symptoms not related to the procedure.

Consent to care and treatment

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

- The doctor understood the requirements of legislation and guidance when considering consent and decision making.
- Clinicians supported patients to make decisions. Where appropriate, they assessed and recorded a patient's mental capacity to make a decision.
- The practice monitored the process for seeking consent appropriately.

Are services caring?

Our findings

Kindness, respect and compassion

The seven Care Quality Commission comment cards we received were positive about the service experienced. We were told the doctor and the volunteers treated patients with kindness, respect and compassion. If patients wanted to discuss sensitive issues they could offer them a private room to discuss their needs.

Involvement in decisions about care and treatment

The systems in place to help patients be involved in decisions about their care required review. The doctor and volunteers were not aware of the Accessible Information Standard (a requirement to make sure that patients and their carers can access and understand the information they are given):

- The clinic did not have access to interpretation services for patients who did not have English as a first language. Written patient information was only available in the English language.
- The clinic did not have any communication aids.
- Further information about the implants was available in the clinic and on its website. However, signposting and access to other community and advocacy services was not available.

All patients who attended the clinic for treatment had to be accompanied by another responsible adult or carer. The clinic did not record the caring responsibilities the patient may have.

Privacy and dignity

The practice respected patients' privacy and dignity.

- The doctor and volunteers recognised the importance of patients' dignity and respect.

Are services responsive to people's needs?

(for example, to feedback?)

Our findings

Responding to and meeting people's needs

The facilities had been modified to meet people's needs but required further attention. For example, an outbuilding in the back yard had been refurbished to provide an accessible toilet. However the internal toilet facilities could only be accessed via the ground floor treatment room. The majority of surgical procedures took place in rooms accessed by a very steep staircase.The clinic usually opened on the same afternoon each week which meant patients could usually plan appointments in advance.

The clinic did not provide a hearing loop for patients with hearing difficulties and written information was not available in any other languages except English; the clinic did not have access to interpreter services.

Timely access to care and treatment

The clinic opened Tuesdays from 12 noon to 6pm and attendance was by appointment only. Volunteers checked the answer phone daily for enquiries and appointment bookings. Volunteers responded to telephone messages left on the answer phone and could contact the doctor outside of the normal opening hours to contact the patient if needed.

Listening and learning from concerns and complaints

The provider had a procedure in place for handling concerns and complaints which was displayed on the notice board in the waiting area. We were told there had been no complaints received in the last three years.

Are services well-led?

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

Our findings

Leadership capacity and capability

The provider had a special interest in assisting the rehabilitation of patients to overcome opioid addiction after detoxification. Clinical governance systems were lacking and the service did not operate if the doctor was unavailable. Patients would be expected to seek care from other providers if the service was not available which may pose a risk to the patient if they were not known to or could not access other services. There was the potential for the patient to return to illicit drug taking if they could not access services.

Vision and strategy

The clinic had a mission statement to offer a patient centred confidential approach to care and treatment. Volunteers described the aim of the service as helping patients stay clean of opioid substances which led to improved health outcomes for the patient.

Culture

The clinic did not have a culture of high-quality sustainable care. Volunteers stated they felt respected, supported and valued. However, there was lack of awareness of the requirements of the duty of candour regulation. The doctor and volunteers could not provide examples of when the duty of candour was used as they said the opportunity had never arose. Duty of candour requires the service to be open and transparent with patients in relation to their care and treatment.

Governance arrangements

There were no systems to support good governance and management.

- Structures, processes and systems to support good governance and management were limited or absent and the doctor and volunteers operated following established custom and practice.
- The doctor had established some processes to ensure safety which lacked detail and did not provide assurance they were operated as intended.
- Volunteers were clear on their roles and responsibilities but lacked knowledge in respect of safeguarding and infection prevention and control.

Managing risks, issues and performance

There was no clarity around processes for managing risks, issues and performance.

The provider had no comprehensive assurance systems or performance measures in place, and there was no systematic programme of clinical or internal audit to monitor the quality of the service. The provider did not have an oversight of national and local safety alerts.

Assessing risk was an important part of the patient assessment as previous drug misuse may present specific risks to the patient relating to overdose, taking too many different medicines, alcohol misuse, mental health, unsafe injecting practices and unsafe sex. Assessing the need for safeguarding or other protection actions is also paramount. The provider did not have established systems to assess these risks.

Appropriate and accurate information

The clinic did not have appropriate and accurate information.

- Quality and operational information was not recorded to review and improve performance.
- Meetings with the doctor and volunteers were informal at the end of clinics and notes were not kept.
- The clinic had a website and posted information out to prospective patients. The use of information technology systems was limited to keeping a database of patients. Patient records were paper written and stored in a locked filing cabinet.
- The arrangements for data security standards for the availability, integrity and confidentiality of patient identifiable data, records and data management systems had not been risk assessed.

Engagement with patients, the public, staff and external partners

The views of patients were not routinely sought as the provider told us they historically always had a poor response to any surveys sent. The provider tended to ring the patient if feedback was required. We were told there had been no suggestions for service improvement made in the last 12 months.

Continuous improvement and innovation

There was no evidence of systems and processes for learning, continuous improvement and innovation.

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
Surgical procedures	Regulation 12 HSCA (RA) Regulations 2014 Safe care and treatment Following this inspection we took enforcement action to cancel the registration of the provider. This means the provider will no longer be able to operate the service.

Regulated activity	Regulation
Surgical procedures	Regulation 17 HSCA (RA) Regulations 2014 Good governance Following this inspection we took enforcement action to cancel the registration of the provider. This means the provider will no longer be able to operate the service..