

Whitethorn Fields MediClinic Limited

# Whitethorn Fields MediClinic

## Inspection report

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## Overall summary

We carried out an announced comprehensive inspection on 21 September 2016 to ask the service the following key questions; Are services safe, effective, caring, responsive and well-led?

### 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 providing effective care in accordance with the relevant regulations

#### Are services caring?

We found that this service was providing caring services in accordance with the relevant regulations .

#### Are services responsive?

We found that this service was 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.

Whitethorn Fields Medicentre was established in 2012. The clinic offers a consultation service for a wide range of cosmetic surgery treatments to adults. These treatments include aesthetic cosmetic consultations and treatment, cosmetic surgery consultation and minor cosmetic surgical procedures under local anaesthetic.

The provider established the clinic with a colleague and together they work as co-directors. There are two distinct halves to the clinic; one has the main purpose of providing a professional nipple (areola restoration) tattoos service for women following breast surgery and an aesthetic service, such as dermal fillers and laser hair removal. This part of the business was not inspected as it does not fall under the regulations. The second is the one run by Mr Ghosh to provide cosmetic surgery consultations and minor surgical procedures for cosmetic reasons, such as removal of skin tags or warts.

The objective of the company is to provide all patients with an outcome consistent with current best practice guidelines and individual expectations.

# Summary of findings

The provider attends the clinic for one afternoon and evening a week to conduct outpatient services and minor cosmetic surgery. The provider employs a registered nurse to assist with surgical procedures. The clinic only uses localised anaesthetic to perform cosmetic surgical procedures. The provider's other employment is in a local NHS Hospital at other times. The registered nurse works in another healthcare establishment and completes her mandatory training and clinical supervision with this employer to remain current with clinical practice. The service has no beds. Facilities include a clinical treatment room and a consultation room.

We do not currently have a legal duty to rate cosmetic surgery service or the regulated activities they provide but we highlight good practice and issues that service providers need to improve and take regulatory action as necessary.

Mr Sudip Ghosh is the 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 provider told us that the business been served a blight notice to vacate the premises. The provider was planning to close the business within 4-6 months and continue working in the NHS.

We spoke with 15 patients and five family members all of whom provided positive feedback about the service. Patients reported that they had received an excellent service and all staff members in the clinic were professional and caring.

## Our key findings were:

- The clinic was clean, tidy and welcoming with wheelchair access. We saw that good infection control practice was observed such as hand hygiene.
- Patients were positive about their care and treatment. Although the provider did not have a system for collecting patient feedback, in order to use this information to monitor the quality of the service and to drive improvements.
- A chaperone was available and patients were offered this choice. However, these staff members had not received chaperone examination training.

- Equipment and medication that may be required in an emergency were accessible. However, there was no evidence that these pieces of equipment were checked when the clinic was open.
- While there was an effective system for managing those medicine currently being used by the clinic, there was a large amount of medicine and stock consumables items no longer used that had expired and not been disposed of.
- There were no service agreements in place for clinical equipment such as the examination/ treatment couch
- The provider granted practising privileges to a doctor to perform hair transplants. We found the necessary compliance checks had been completed for this doctor; however, the provider was not clear regarding the accountability should something go wrong with this doctor's practice.
- The provider explained clinical procedures to his patients in easy to understand terms.
- The provider followed the Department of Health 2009 guide to consent for examination or treatment and explained risks and benefits and used drawings to explain surgical procedures.
- Advice was given such as reducing weight or cessation of smoking prior to procedures. The provider politely declined requests from patients for surgical procedures that were not considered in the best interest of the patient and gave clear explanation to the patient why the request had been refused.
- The provider continued to work in the NHS and was up to date with mandatory training and could give examples of recent safeguarding and mental capacity act /deprivation of liberty safeguards training.
- There was no formal governance system for the monitoring of the quality of the service

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

- Ensure there is a fully effective stock rotation system that includes the removal and destruction of out of date stock medicine and consumables.
- Introduce a governance framework that uses audits, review of incidents, complaints and patient feedback to review the quality of the service.

There were areas where the provider could make improvements and should:

# Summary of findings

- Review the process for the checking and recording of the check for clinical equipment such as the emergency resuscitation equipment and the medicine fridge temperature.
- Ensure the clinic chaperone has undertaken training so that they develop the competencies required. This training is to include roles and responsibilities and the policy and mechanism for raising concerns.
- Ensure that all clinical equipment is serviced in accordance with the manufacturer's instructions.
- Review the complaints monitoring process and consider implementing a formal written process for handling complaints.

# 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 Requirement Notices/ at the end of this report).

We found the following issues that the service provider needs to improve:

- There were systems for reporting clinical and non-clinical incidents. However, there was limited learning from incidents as there had been so few reported. Systems for the safe management of medicines and checking of equipment were not followed.
- There was no evidence of service arrangements for clinical equipment, to ensure they were maintained according to the manufactures instruction and safe to use.
- A chaperone was available and patients were offered the choice of having a chaperone, however these staff had not received any training to undertake this role.

However, we also found the following areas of good practice:

- The clinic was clean, tidy and welcoming with wheelchair access.
- Infection prevention and control processes were in place and we observed good hygiene practices.
- Plans were in place to respond to medical emergencies.
- Staffs were aware of safeguarding procedures and had received training.
- Staffing levels were sufficient to meet patient demand. Processes were in place to provide cover if staffing fell below expected levels.
- Risks to patients were assessed, monitored and managed daily.
- There were no reported cases of serious infection such as MRSA

Both clinic staff members were aware of the duty of candour and gave clear examples how it could be used in the services that they provided.

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### **Are services effective?**

We found that this service was providing effective care in accordance with the relevant regulations.

We found the following areas of good practice:

- The provider politely declined requests from patients for surgical procedures that were not considered in their best interest and gave clear explanation to the patient why the request had been refused.
- Advice such as reducing weight or cessation of smoking was given prior to procedures.
- Patients were assessed and treated in line with evidence-based practice.
- There were effective consent processes and patients received sufficient information to make decisions about their treatment. All clinical procedures were explained in easy to understand terms.
- The provider followed the Department of Health 2009 guide to consent for examination or treatment and explained risks and benefits of surgical procedures

However, we found the following issues that the service provider needs to improve:

- Clinical staff completed appropriate training to maintain their skills and had completed revalidation. However, the registered nurse had not received a yearly appraisal with the provider.

# Summary of findings

## Are services caring?

We found that this service was providing caring services in accordance with the relevant regulations.

We found the following areas of good practice:

- All staff at the clinic was approachable and friendly.
- Patient verbal feedback was positive about the standard of care they had received.
- Patients said they were treated with dignity and respect and they were involved in decisions about their care and treatment.
- Information for patients about the service was easy to understand and accessible on the up to date clinic website. Patients were given leaflets about relevant treatment options, by the clinical staff.

## Are services responsive to people's needs?

We found that this service was providing responsive care in accordance with the relevant regulations.

We found the following areas of good practice:

- The service was responsive, and reasonable adjustments were made to ensure patients' needs were met.
- All patients told us they found it easy to make an appointment and the clinic provided a relaxed atmosphere.
- Appointment times were managed appropriately.

We found the following issues that the service provider needs to improve:

- The service had no documented system in place for handling complaints and concerns.

## Are services well-led?

We found that this service was not providing well-led care in accordance with the relevant regulations. We have told the provider to take action (see full details of this action in the Requirement Notices/ at the end of this report).

We found the following issues that the service provider needs to improve:

- There were limited governance arrangements. There was some risk assessments for the clinic, however, there was no risk register.
- There were limited policies and procedures to govern activity and there was no programme of audits completed across the year.
- The service did not demonstrate that they encouraged feedback from patients.

However, we also found the following areas of good practice:

- All staff told us that they enjoyed their job and that patient care was the priority. They commented on the good teamwork and support.

# Whitethorn Fields MediClinic

## Detailed findings

### Background to this inspection

We carried out an announced inspection on 21 September 2016.

The team that inspected the service comprised a CQC lead inspector and a specialist advisor with expertise in cosmetic surgery.

During March 2015 and March 2016 the provider performed 122 cosmetic surgery procedures using localised anaesthetic.

The clinics registered to provide the following regulated activities:

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

As part of our inspection, we spoke with the doctor, the nurse and reception staff. We also spoke with 15 patients and five family members all of whom provided positive feedback about the service. With patient consent, we observed 12 consultations. We reviewed policies and procedures and contracts

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.

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- Is it responsive to people's needs?
- Is it well-led?

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# Are services safe?

## Our findings

### Reporting, learning and improvement from incidents

- There had been no never events relating to this service. Never events are a type of serious incident that are wholly preventable, where guidance or safety recommendations that provide strong systemic protective barriers are available at a national level and should be implemented by all healthcare providers.
- There were systems for reporting incidents. This included clinical and non-clinical incidents. There was limited learning from incidents as there had been so few reported. There had been one minor patient falls incident reported between June 2015 and June 2016.
- The duty of candour is a regulatory duty that relates to openness and transparency and requires providers of health and social care services to notify patients (or other relevant persons) of 'certain notifiable safety incidents' and provide reasonable support to that person. The service was aware of duty of candour regulations and the need to provide the patient with an apology and explanation to patients following incidents.

### Reliable safety systems and processes (including safeguarding)

- There were arrangements to safeguard adults from abuse. Both the provider and registered nurse had received recent safeguarding training from an external provider.
- Staff understood the processes to escalate any concerns for vulnerable adults. Treatment was not provided to patients under the age of 18 years, and staff checked the age of patients at initial consultation.

### Medical emergencies

- The provider did not operate out of hours cover (weekend and nights). Patients were advised to contact their general practitioner should the clinical need arise.
- In the rare case of clinical emergency out of hours, the patient was advised to attend the emergency department.
- Risks to patients were assessed, monitored and managed. The provider confirmed if the registered nurse was not available, clinical procedures did not take place.

- All patients were risk assessed as part of the initial assessment for surgery criteria, for risk factor such as asthma and diabetes.
- The protocol for management of deteriorating patients was to call the ambulance as a 999 call. The provider stated the need to call the emergency service ambulance had never occurred since opening the service in 2012.

### Nursing and support staffing

- Staffing levels of a doctor and nurse were sufficient to meet current patient demand. Processes were in place to provide cover if staffing fell below expected levels. The provider confirmed if the registered nurse was not available, clinical procedures did not take place.
- The provider had never used agency or bank nurses since the business opened.
- The registered nurse works elsewhere in a clinical role and maintains her competencies to remain on the nursing register.
- There was no formal contract or job description for the registered nurse, however, the provider satisfactorily completed both documents within nine days following the inspection.
- A chaperone was available and patients were offered this choice. The clinic reception staff acted as chaperone for intimate examinations. However, these staff members had not received chaperone training.

### Infection control

- The clinic was clean, tidy and welcoming with wheelchair access.
- We found in the clinical room a clean and a dirty sink to prevent cross contamination or infection.
- A cleaner cleaned the facilities twice a week. We saw that a colour-coded system was used for mops and refuse for clinical and non-clinical waste.
- There was an infection, prevention and control (IPC) policy. There was hand sanitising gel and liquid soap available for hand hygiene. There was sufficient personal protective equipment such as gloves.
- At the time of the inspection no surgical procedures were being performed therefore we only saw



# Are services safe?

consultation. All physical examinations were performed with staff adhering to the 'bare below elbows' national guidance. During all consultations with patients we saw that good hand hygiene practices were followed.

- The provider did not collect surgical site infection rates at this clinic. If patients expressed a concern that a wound was infected the provider stated that they would see the patient and review the wound for themselves.
- The clinic used single use medical devices such as forceps in line with national guidance.
- There was a contract with an external provider for the removal of hazardous waste. Clinical waste was appropriately segregated and disposed of.

## Premises and equipment

- Systems for the management and checking of equipment were not always followed. We found clinical equipment for example syringes, dressing packs and needles in a locked cupboard that were out of date. We were assured that these items were no longer in use for patient care. However, while they remain in cupboards on the premises there is potential risk of them being used for patient care.
- Emergency medicines (including oxygen) were accessible to staff. The clinic kept an anaphylactic kit on site. We found resuscitation equipment suitable for an adult patient. However, there was no evidence that the equipment was checked.
- We found theatre equipment was clean and working. However, we found clinical equipment such as the clinical examination light had not been serviced regularly and some equipment did not have service agreements for maintenance.

## Safe and effective use of medicines

- We found approximately 20 out of date medicines in a locked cupboard. We were assured these medicines were no longer in use for patient care. It was clear from visual inspection that the cupboard had not been opened in some time. The provider confirmed these were all items thought to be required when the clinic first opened but as the purpose of the business had changed these were no longer required. However, while

they remain on the premises there is potential risk of them being used and the clinic own Medicine Management Policy 2015 which highlights regular audits of medicines had not been followed.

- There was a system to record the ordering, receipt and disposal of medicines in use. There were processes to ensure the safe administration and supply to patients.
- Oxygen was only used for therapeutic purposes, for example in a medical emergency or on prescription from the medical practitioner. We saw evidence that the oxygen cylinders had been serviced.
- There were no controlled drugs kept on the premises.
- The medicine fridge was clean and had a temperature-monitoring device. However, there was no evidence the temperature was monitored on a daily basis and we were told that this did not happen. Therefore there was no assurance that items stored in the fridge were kept at the correct temperature.
- We found local anaesthetic medicine stored in a fridge. This medicine should be stored at room temperature. Other medicines in use were securely stored in a locked cupboard.

## Records

- Records were stored securely in a locked cupboard
- Medical records were paper based; well-ordered and used standard forms. The records we saw were detailed, legible, and covered issues such as medical history, allergies, and clinical advice.

## Mandatory training

- Both the provider and registered nurse were compliant with mandatory training, such as moving and handling and safeguarding training. This training was received elsewhere for additional NHS employment requirements.
- The provider was verbally informed by the registered nurse of the mandatory training updates attended, however, did not retain and could not provide a record of course dates attended.

## Emergency awareness and training



## Are services safe?

- All staff we spoke with had training on fire evacuation plans and stated fire equipment was checked yearly. We saw fire appliances and fire blankets had been recently serviced.

# Are services effective?

(for example, treatment is effective)

## Our findings

### Assessment and treatment

- The provider assessed needs and delivered care in line with the relevant and current evidence based guidance and standards, National institute for health and care excellence (NICE) and British association of plastic reconstructive and aesthetic surgeons best practice melanoma assessment and management guidelines 2015
- The provider documented the five steps to safer surgery, the WHO Surgical Safety Checklist, in the patient's clinical record.
- Clear and comprehensive consideration was given to each patient as to whether to proceed or not proceed with the operation. The operating surgeon along with the patient before surgery assessed clinical risk factors. This included lifestyle such as smoking and alcohol intake and previous psychiatric history.
- The provider completed pre-operative assessments and gave advice such as weight reduction and smoking cessation prior to surgery.

### Staff training and experience

- We saw a copy of the provider's recent medical revalidation from a local NHS hospital.
- We saw a copy of the employer's current liability and indemnity insurance.
- The provider granted practising privileges to a doctor performing hair transplants. We found that necessary compliance checks and indemnity had been completed for this doctor, however, the provider was not clear regarding the accountability of this doctor should something go wrong with this doctor's practice. On further investigation it was confirmed that the doctor rented the facilities for the day.

- There was no evidence that an annual appraisal has been taken place for the registered nurse and this was confirmed by the nurse.

### Working with other services

- If the patient was referred by the general practitioner for pre-operative assessment prior to an operation in the NHS full details of the patient's medical history were sent in paper form. However, if the patient attended for minor cosmetic surgery, without a referral, the provider did not inform the general practitioner. The provider told us this was a private arrangement between the provider and patient.

### Pain relief

- Patients told us that they were given advice regarding pain relief and whom to contact should they require further advice and support.

### Consent to care and treatment

- The provider followed the Department of Health 2009 guide to consent for examination or treatment and explained risks and benefits of surgical procedures.
- There were effective consent processes and patients received sufficient information to make decisions about their treatment. We saw nine consent to treatment forms which were in line with the clinics consent for examination and treatment policy.
- Patients were provided with a two week cooling off/ reflection period to allow them time to ask any further questions or to change their mind.
- The two clinical staff received recent training relating to the Mental Capacity Act 2005.

# Are services caring?

## Our findings

### Compassionate care

- Patients told us that they were treated with dignity and respect and they were involved in decisions about their care and treatment.
- Patient feedback was positive regarding the standard of care they received. Two patients we spoke with said it was the second time they were attending, as they were pleased with past treatment and care received.
- Information for patients about the service was easy to understand and accessible. We saw an up to date website with explanations of clinical procedures explained.
- All 14 patients we spoke with told us that the staff at the clinic were friendly, approachable and promoted a relaxed and welcoming atmosphere.

### Respect, dignity, compassion

- We observed consultation assessments and treatment room doors were closed during consultations. Conversations taking place in these rooms could not be overheard. The windows to the treatment room had blinds at the window so no one could view patients from outside of the building.
- The provider requested one of the clinic non-qualified staff to act as chaperone during examinations, investigations and treatments. To maintain a patient's privacy and dignity, the provider left the room whilst the patient undressed for the clinical examination. However,

there was no additional curtain around the examination couch and when the provider re-entered the room there was the possibility of waiting members of the public seeing the patient on the examination couch.

- The provider did not collect friends and family test results to find out how patients and families viewed the clinical service provided.

### Understanding and involvement of patients and those close to them

- Patients and families told us that they felt involved in decisions about the care and treatment they received.
- Family members were invited into the consultation with the patient's permission and surgical options were explained and diagrams drawn to aid understanding of the procedure. Possible side effects of surgery were fully discussed.

### Emotional support

- The registered nurse told us about the importance of their role of offering emotional support to both the patient and family.
- The provider told us counselling service information were available for patients, should the need arise.
- Patients told us 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. Patients told us they did not feel pressured in any way to undertake treatment.
- Patients were provided with a two week cooling off/ reflection period to allow them time to ask any further questions or to change their mind.

# Are services responsive to people's needs?

(for example, to feedback?)

## Our findings

### Service planning and delivery to meet the needs of local people

- The provider generally worked one afternoon and evening per week at the clinic. Patients told us a consultation date was given between 7 and 10 days from phoning for an appointment.

### Access and flow

- Patients self-referred to the clinic. The service was generally open on a Wednesday afternoon and evening.
- The patient could call the provider out of hours if there was a serious concern and a mobile phone number were given. Routine concerns were referred to the general practitioner. Non-urgent calls were re-directed to the clinic, during usual business hours.
- The clinic used a paper diary system to book appointments. Staff re-scheduled cancelled appointments to suit the needs of the patient.
- There was flexibility in the system to provide urgent appointments if required

### Patient flow

- We saw that for every 10 patients seen for a consultation to consider plastic surgery approximately 4 patients went on to have the cosmetic surgery.

- We saw the admission process however; there was no written exclusion and inclusion criteria.
- The provider did not inform the general practitioner of the cosmetic surgery procedure. The provider told us this was a private arrangement between the provider and patient.
- The provider did not collect cancellation rates of the clinic

### Meeting people's individual needs

- We saw that the clinic was on the ground floor and there were facilities such as a ramp for patients with disabilities to access the building. Toilet facilities were wheelchair accessible.
- The registered nurse discussed the clinic could access interpreters when needed.

### Learning from complaints and concerns

- Details about how to make a complaint was contained in the patient guide and on the website. However, the service had no written procedure in place for handling complaints and concerns.
- The provider said the clinic had, had no written complaints for June 2015 to June 2016. The registered nurse discussed that there was one verbal complaint of a patient concerned about the shape of her earlobe following cosmetic surgery. This complaint resolved itself after the initial surgical swelling had gone down.

# Are services well-led?

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

## Our findings

### **Leadership / culture of service related to this core service**

- The staff at the clinic told us it “was a lovely, friendly place to work and everyone got on with each other well”
- Clinic staff said they had regular coffee meetings to raise concerns or new ideas.
- All clinical staff were aware of the process of escalation in the event of concerns or advice. Clinic staff said they would not hesitate to raise concerns where required and felt these would be acted on.
- Both the provider and registered nurse spoke with confidence about their understanding of the duty of candour.

### **Vision and strategy for this this core service**

- The provider told us that the business served a government blight notice to vacate the premises. The provider was planning to close the business within 4-6 months and that there was no plan to start up a new business in different premises. The provider told us the plan was to continue working as a cosmetic surgeon in the NHS and under practicing privileges at a private hospital.
- The service had a patient promise statement. “We respect you and our time with you. We will listen to your

concerns and will provide the highest level of quality care, advice and treatment. We endeavour to provide an unparalleled level of service throughout your entire experience at whitethorn fields mediclinic.”

### **Governance, risk management and quality measurement (and service overall if this is the main service provided)**

- We saw that there was limited governance processes and arrangements to manage quality and drive improvements in this practice. There was an incident reporting system, however due to the low number of incidents it was not possible to monitor for trends. There was also limited evidence of learning from complaints again due to the low number. There was no audit plan and no evidence that audit had been used to monitor the quality of the service provided.
- There were no risk register for the service. However, we did see recent comprehensive risk assessments of the clinic.
- There were limited policies and procedures to govern activity for the service. Examples of policies we saw include consent for examination and treatment and safeguarding adults policy.

### **Provider seeks and acts on feedback from its patients, the public and staff**

- There was no formal system to gather feedback from patients. We saw cards and letters of appreciation from patients and families for the treatment received.

## Requirement notices

### 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	<p>Regulation 17 HSCA (RA) Regulations 2014 Good governance</p> <p>Regulation 17 1. Systems or processes must be established and operated effectively to ensure compliance with the requirements in this Part.</p> <p>2. Without limiting paragraph (1), such systems or processes must enable the registered person, in particular, to—</p> <ol style="list-style-type: none"><li>1. Assess, monitor and improve the quality and safety of the services provided in the carrying on of the regulated activity (including the quality of the experience of service users in receiving those services);</li></ol> <p>(e) seek and act on feedback from relevant persons and other persons on the services provided in the carrying on of the regulated activity, for the purposes of continually evaluating and improving such services.</p> <p><b>How the regulation was not being met:</b> - There was governance system or audits, or system for gathering patient feed back to monitor the quality and safety of service.</p>

Regulated activity	Regulation
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## Requirement notices

Treatment of disease, disorder or injury

Regulation 12 HSCA (RA) Regulations 2014 Safe care and treatment

Regulation 12 (1) Care and treatment must be provided in a safe way for service users.

(2) Without limiting paragraph (1), the things which a registered person must do to comply with that paragraph include-

(2) (g) The proper and safe management of medicines

**How the regulation was not being met:** The temperature of the fridge where medicines were stored was not being monitored to ensure that medicines were stored at the correct temperature. We found a large quantity of out of date medicines that should have been disposed of.