

# Blue Sky Orthopaedic

## Quality Report

Jubilee Medical Practice,  
Syston Health Centre  
Melton Road,  
Syston  
Leicester  
LE7 2EQ  
Tel: 0116 2950600

Date of inspection visit: 28 to 29 June 2017  
Date of publication: 22/09/2017

This report describes our judgement of the quality of care at this location. It is based on a combination of what we found when we inspected and a review of all information available to CQC including information given to us from patients, the public and other organisations

## Ratings

### Overall rating for this location

Are services safe?

Are services effective?

Are services caring?

Are services responsive?

Are services well-led?

# Summary of findings

## Letter from the Chief Inspector of Hospitals

Blue Sky Orthopaedic is an independent orthopaedic clinic specialising in hand day surgery. It has no beds. The company rents the facilities from a local GP practice in Syston, Leicestershire. Facilities include an operating theatre, a consulting room, office, utility and store rooms.

The service provides hand surgery to adults, specialising in carpal tunnel decompression, trigger finger and thumb and Dupuytren's disease surgery.

We inspected this service using our comprehensive inspection methodology. We carried out the inspection on 28th and 29th June 2017.

To get to the heart of patients' experiences of care and treatment, we ask the same five questions of all services: are they safe, effective, caring, responsive to people's needs, and well-led? Where we have a legal duty to do so we rate services' performance against each key question as outstanding, good, requires improvement or inadequate.

Throughout the inspection, we took account of what people told us and how the provider understood and complied with the Mental Capacity Act 2005.

The main service provided by this organisation was surgery. Where our findings on surgery – for example, management arrangements – also apply to other services, we do not repeat the information but cross-refer to the surgery core service.

### Services we do not rate

We regulate surgery but we do not currently have a legal duty to **rate** them when they are provided as a single specialty service. We highlight good practice and issues that service providers need to improve and take regulatory action as necessary.

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

- The service had a limited definition of incident reporting, so trends in incidents were not used to improve safety or quality or for problems solving. There was no detailed procedure on incident procedure to promote a shared understanding
- The service did not systematically use the World Health Organisation Five Steps to Safer Surgery, which have been proven to minimise harm to patients in the operating theatre
- There was no quality dashboard or comparison with other services, so the service did not know how it compared to others, or if it was getting better or worse at patient safety or quality.
- Infection control arrangement in theatre were not formally reviewed and the service did not audit hand hygiene practices to give them information about how consistently staff were washing their hands
- The service lacked evidence to demonstrate, analyse and learn from their post-operative infection rate
- No recent clinical audits had been carried out and there was no audit plan for the current year
- Appraisal and mandatory training systems were not fully in place
- Patient feedback mechanisms did not allow patients to easily give their views after they had left surgery
- There was no evidence of medium term strategic planning, business planning or planning around specific quality objectives
- The service lacked a governance framework including a clinical governance group or programme of internal clinical audit
- The service did not have a strategy to continuously improve quality, safety or infection control, and systems and measures to monitor, analyse or take action on safety, quality, performance were underdeveloped
- Risks to service planning were not formally identified, logged, reviewed or mitigated

# Summary of findings

- The service lacked an agreed, comprehensive definition of incidents. They did not use incident reporting to monitor problem solving or improve patient care
- The service had a limited policy and procedural framework, and some important policies had not been written
- There was no mandatory training system. The service lacked a performance and development system to feed into training plans.

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

- The service used an operating chair rather than an operating table, which made the operating environment seem more comfortable and normal for patients.
- The service used disposable instrument kits for each patient's surgery which helped to minimise the risk of infection.
- The service was initially set up using knowledge gained from evidence based audits and a search for international best practice.
- Clinicians took time to ensure patients understood the alternatives and risks to surgery, and what to expect during and after the treatment.
- Patient feedback obtained immediately after the operation indicated that patients were satisfied with the surgery
- Blue Sky Orthopaedic offered a choice of clinics and times in accessible locations around Leicester and patients had their operations within six weeks of referral.
- The service was easy to access and gave patients a range of appointment options
- The service accepted patients who needed corrective treatment after receiving their operation elsewhere.
- Hand surgery at Blue Sky Orthopaedic was available to a wide range of patients including those with heart problems, cancer or diabetes. The service made adjustments for wheelchair users and patients with guide dogs.

Following this inspection, we told the provider that it must take some actions to comply with the regulations and that it should make other improvements, even though a regulation had not been breached, to help the service improve. We also issued the provider with five requirement notice(s) that affected surgery. We also served a warning notice under Section 29 of the Health and Social Care Act 2008. The provider was failing to comply with the relevant requirements of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014. Details are at the end of the report.

**Heidi Smoult**

**Deputy Chief Inspector of Hospitals**

**Central Region**

## Overall summary

Surgery was the main activity of the hospital. Where our findings on surgery also apply to other services, we do not repeat the information but cross-refer to the surgery section.

The service had a limited definition of incident reporting, and did not use trends in incidents to improve safety or quality or for problems solving. There was no detailed procedure on incident procedure to promote a shared understanding.

The service did not systematically use the World Health Organisation Five Steps to Safer Surgery, which have been proven to minimise harm to patients in the operating theatre.

There was no quality dashboard or comparison with other services, so the service did not know how it compared to others, or if it was getting better or worse at patient safety or quality.

# Summary of findings

The service did not formally review infection control in theatre or conduct hand hygiene audits to give them information about how consistently staff were washing their hands

The service had not carried out any recent clinical audits.

There was an incomplete picture of clinical outcomes due to a lack of post-operative audit and patient feedback mechanisms. This included a lack of information on levels of post-operative pain.

The service lacked a governance framework including a clinical governance group or programme of internal clinical audit.

The service lacked a strategy to continuously improve quality, safety or infection control.

Systems and measures to monitor, analyse or take action on safety, quality, performance were underdeveloped

Risks to service planning were not formally identified, logged, reviewed or mitigated

The service had a limited policy and procedural framework, and some important policies had not been written

However;

The operating theatre was visibly clean and there were effective segregation arrangements for clean and dirty materials and different kinds of waste. Sharps were disposed of separately.

Patient records were written in such a way to ensure patient safety and kept securely locked away

Clinicians took time to fully check patient's readiness to leave after the operation.

Based on limited feedback, complication rates were nil and patients could use their hand and return to work very soon after the operation.

Clinicians took time to ensure patients understood the alternatives and risks to surgery, and what to expect during and after the treatment.

The service had good initial feedback from patients and recorded 100% satisfaction rates on feedback cards. We spoke to four patients who were very pleased with their operation and care.

Staff were kind and compassionate and took time to explain the treatment to patients. They communicated well with patients and relatives.

Blue Sky Orthopaedic offered a choice of clinics and times in accessible locations around Leicester

Blue Sky Orthopaedic treated patients within six weeks of referral.

The service was easy to access and gave patients a range of appointment options

Hand surgery at Blue Sky Orthopaedic was available to a wide range of patients including those with heart problems, cancer or diabetes. The service made adjustments for wheelchair users and patients with guide dogs.

The service had a strong team spirit and a patient centred culture.

# Summary of findings

## Contents

### Summary of this inspection

	Page
Background to Blue Sky Orthopaedic	7
Our inspection team	7
Information about Blue Sky Orthopaedic	7
The five questions we ask about services and what we found	9

### Detailed findings from this inspection

Outstanding practice	24
Areas for improvement	24
Action we have told the provider to take	25

# Blue Sky Orthopaedic

## Services we looked at

Surgery

# Summary of this inspection

## Background to Blue Sky Orthopaedic

Blue Sky Orthopaedics Limited is a limited company formed in 1999. It specialises in hand surgery such as carpal tunnel decompression, trigger finger, trigger thumb and Dupuytren's disease. It outsources nerve conduction tests (neurophysiology). There are five directors – three consultant orthopaedic surgeons, one associate specialist in orthopaedic surgery and one operating nurse specialist. They employ a practice manager and an operating theatre assistant.

The company registered with Companies House in 2003. It moved to its current location in 2008.

It registered with the Care Quality Commission in September 2016 for diagnostic and screening procedures, surgical procedures and treatment of disease, disorder and injury.

The hospital has had a registered manager in post since 1 September 2016.

## Our inspection team

The team that inspected the service comprised a CQC lead inspector, one other CQC inspector, and a specialist advisor with expertise in operating theatre practice. The inspection team was overseen by Simon Brown, Inspection Manager.

## Information about Blue Sky Orthopaedic

The service is registered to provide the following regulated activities:

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

During the inspection, we visited the main surgical clinic in Syston. We spoke with four staff including; the registered manager, the specialist operating nurse, an orthopaedic consultant and a theatre nurse. We spoke with four patients and one relative. We also reviewed Blue Sky Orthopaedics' patient satisfaction cards. During our inspection, we reviewed six sets of patient records.

There were no special reviews or investigations of the hospital ongoing by the CQC at any time during the 12 months before this inspection. This was the service's first inspection since registration with CQC.

Activity (January 2016 to December 2016)

- In the period January 2016 to December 2016, there were 447 episodes of day surgery and 593 outpatient attendances at Blue Sky Orthopaedic Ltd. They do not have overnight beds.
- Blue Sky Orthopaedic opened in 2008, as part of GP plans to move hand surgery from secondary to primary care. The service specialises in treating patients with carpal tunnel syndrome (91%), trigger fingers (6%), trigger thumbs, (2%) and a small percent of patients with ganglions (cysts) of the wrist and early Dupuytren's disease.
- The service carries out day case surgery work for adult patients only.

The service did not employ medical staff under practising privileges. All of the clinical staff working within the company were directors.

Track record on safety between January 2016 to December 2016

- The service recorded zero clinical incidents and 3 non-clinical incidents.
- Zero never events

# Summary of this inspection

- Zero incidences of acquired Meticillin-resistant Staphylococcus aureus (MRSA)
- Zero incidences of acquired Meticillin-sensitive staphylococcus aureus (MSSA)
- Zero incidences of acquired Clostridium difficile (c.difficile)
- Zero complaints



# Summary of this inspection

## The five questions we ask about services and what we found

We always ask the following five questions of services.

### **Are services safe?**

#### **Are services safe?**

We do not currently have a legal duty to rate independent healthcare single speciality surgery service.

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

- The service had a limited definition of incident reporting, so trends in incidents were not used to improve safety or quality or for problem solving. There was no detailed procedure on incident procedure to promote a shared understanding.
- The service did not systematically use the World Health Organisation (WHO) Surgical Safety Checklist and five steps to safer surgery which have been proven to minimise harm to patients in the operating theatre.
- There was no quality dashboard or comparison with other services, so the service did not know how it compared to others, or if it was getting better or worse at patient safety or quality.
- There was no procedure to prevent out of date medicines from arriving in theatre. We pointed this out to the service who responded by starting to put measures in place.
- The service did not formally review infection control in theatre or conduct hand hygiene audits to give them information about how consistently staff were washing their hands
- The service lacked evidence to demonstrate, analyse and learn from their post-operative infection rate.
- Not all members of staff were familiar with the Duty of Candour or safeguarding procedures or what to do about a person at risk. Internal training arrangements were in the process of being developed.

We also found the following areas of good practice:

- The service used an operating chair rather than an operating table, which made the operating environment seem more comfortable and normal for patients
- Medical staffing was at a safe level because a clinician only operated if there was a consultant in a neighbouring room to provide assistance if needed. Clinicians were ready to attend to patients out of normal working hours. They had only needed to do this once.

# Summary of this inspection

- The service used disposable instrument kits for each patient's surgery which helped to minimise the risk of infection.
- The operating theatre was visibly clean and there were effective segregation arrangements for clean and dirty materials and different kinds of waste. Sharps were disposed of separately.
- Patient records were written in such a way to ensure patient safety and kept securely locked away
- Clinicians took time to fully check patient's readiness to leave after the operation

## Are services effective?

We do not currently have a legal duty to rate independent healthcare single speciality surgery service.

We found the following areas of good practice:

- Blue Sky had a team of respected and experienced clinicians who also worked at the local NHS trust
- The service was initially set up using knowledge gained from evidence based audits and a search for international best practice.
- Based on limited feedback, complication rates were nil and patients could use their hand and return to work very soon after the operation.
- Clinicians took time to ensure patients understood the alternatives and risks to surgery, and what to expect during and after the treatment.
- Pain was monitored and managed during the operation.
- It was easy for GPs to refer patients to Blue Sky through the Choose and Book service.

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

- The service had not carried out any recent clinical audits.
- There was an incomplete picture of clinical outcomes due to a lack of post-operative audit and patient feedback mechanisms. This included a lack of information on levels of post-operative pain.
- Patients had to eat and drink as normal before an operation and this was not always effectively communicated to them.
- Appraisal and training systems were in development.

## Are services caring?

We do not currently have a legal duty to rate independent healthcare single speciality surgery service

We found the following areas of good practice:

# Summary of this inspection

- The service had good initial feedback from patients and recorded 100% satisfaction rates on feedback cards. We spoke to four patients who were very pleased with their operation and care.
- Staff were kind and compassionate and took time to explain the treatment to patients. They communicated well with patients and relatives.
- The service displayed posters inviting patients to request a chaperone if they wished.
- Staff gave patients an informative advice sheet in plain English, which explained what to expect after their operation.

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

- The service did not provide pre-surgery information to inform patients about issues such as painkillers to take beforehand and how long the operation would take.
- There were some risks to patient privacy because staff informed clinicians about the next patient by name, in such a way that a patient who was in theatre would overhear.

## Are services responsive?

We do not currently have a legal duty to rate independent healthcare single speciality surgery service

We found the following areas of good practice:

- Blue Sky Orthopaedic offered a choice of clinics and times in accessible locations around Leicester
- Blue Sky Orthopaedic treated patients within six weeks of referral.
- The service was easy to access and gave patients a range of appointment options
- The service accepted patients who needed corrective treatment after receiving their operation elsewhere.
- Hand surgery at Blue Sky Orthopaedic was available to a wide range of patients including those with heart problems, cancer or diabetes. The service made adjustments for wheelchair users and patients with guide dogs.
- The service did not receive any complaints between January 2016 and December 2016.

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

- The service did not monitor indicators such as in-clinic wait times or record patients did not attend (DNA) rates to assess the impact on the service.

# Summary of this inspection

- Patient feedback mechanisms did not easily allow patients to give their views on service after they left the operating theatre.
- The service could not operate on very obese patients or patients with complex mental health needs. They did not provide interpreters for patients who did not speak English.

## Are services well-led?

We do not currently have a legal duty to rate independent healthcare single speciality surgery service.

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

- There was no evidence of medium term strategic planning, business planning or planning around specific quality objectives
- The service lacked a governance framework including a clinical governance group or programme of internal clinical audit
- The service lacked a strategy to continuously improve quality, safety or infection control.
- Systems and measures to monitor, analyse or take action on safety, quality, performance were underdeveloped
- Risks to service planning were not formally identified, logged, reviewed or mitigated
- The service lacked an agreed, comprehensive definition of incidents. They did not use incident reporting to monitor problem solving or improve patient care
- The service had a limited policy and procedural framework, and some important policies had not been written
- Mandatory training and individual performance and development arrangements were not in place.

We found the following areas of good practice

- The service had a strong team spirit and a patient centred culture

## Detailed findings from this inspection

# Surgery

Safe	
Effective	
Caring	
Responsive	
Well-led	

## Are surgery services safe?

### Incidents

- Blue Sky Orthopaedic staff had a limited definition of what should be recorded as an incident, whether clinical or non-clinical. They understood that they should report significant patient safety and health and safety issues. They did not include non-standard clinical cases, staff concerns or barriers to good performance, for example, nerve conduction test delays or patients fainting after surgery.
- The service did not have detailed guidance or training to help staff identify different sorts of incidents. As a result, the service did not use incident reporting to problem solve or to identify trends, or as a tool for quality improvement.
- In the reporting period January 2016 to December 2016, the service recorded no clinical incidents and three non-clinical incidents. Blue Sky Orthopaedic reported no serious incidents, deaths or Never Events between January 2016 and December 2016. Never events are serious patient safety incidents that should not happen if healthcare providers follow national guidance on how to prevent them. Each never event type has the potential to cause serious patient harm or death but neither need have happened for an incident to be a never event.
- Clinicians understood that they needed to record significant clinical incidents. They highlighted that during hand surgery, there is a risk of accidentally cutting a nerve, for example. Blue Sky Orthopaedic had no such incidents between January 2016 and December 2016.
- There were three incidents recorded in their incident book – having to cancel a patient appointment, sickness of a patient's wife and smashed coffee cups.

- Blue Sky did not have a policy on the duty of candour. 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. Clinicians received training through their NHS trust work, but the registered manager and theatre nurse were not trained. We saw them apologising to the patient who was given out of date medication, but this did not happen in a formalised way.

### Clinical Quality Dashboard or equivalent (how does the service monitor safety and use results)

- There was no quality dashboard or comparison with other services, so the service did not know how it compared to others, or if it was getting better or worse at patient safety or quality.

### Cleanliness, infection control and hygiene

- There were no incidents of hospital acquired Meticillin-resistant Staphylococcus aureus (MRSA) or MSSA (Meticillin sensitive Staphylococcus aureus), E-coli or Clostridium difficile (C.difficile) recorded between January 2016 and December 2016.
- The GP practice cleaners routinely cleaned the operating theatre and consulting room. There was a deep clean every Wednesday. We saw that the operating theatre and consulting room were visibly clean. Clinicians used disposable instrument kits for hand operations and this helped to minimise the risk of infection from instruments. Sharps and waste were appropriate segregated.
- Staff were 'bare below the elbow' and wore clean uniforms, gloves and personal protective equipment in the operating theatre.
- We observed that staff did not wash their hands on two occasions before and after patient contact. One staff

# Surgery

member did not wear gloves when disposing of the used instruments and swabs, on one occasion, which put patients and staff at risk. The service did not audit hand hygiene. We highlighted these issues to the service.

- Medical staff told us post-surgery infections were unusual at Blue Sky. This was despite some of the arrangements for sterility in the operating theatre not being formalised.
- The service lacked recorded evidence to show, analyse and learn from their post-operative infection rate. Some patients returned to have an operation on their second hand and gave informal feedback on the first operation. The service did not systematically record or analyse this feedback. They also asked referring GPs to tell them if patients had a post-operative hand infection, because practice nurses often removed sutures (stitches). However, we were told that GPs did not always feed back, so the service could not be sure that there were no infections.

## Environment and equipment

- Blue Sky Orthopaedic had a lockable operating suite with side rooms to separate dirty and clean materials. There was a separate store room and a scrub room. They segregated waste in a locked room and staff from the GP practice removed the waste daily. There was a separate sharps bin. The service had a standard operating procedure agreed in July 2017 which detailed a sharps policy, arrangements for clinical waste and reporting accidents.
- The operating theatre was a large room which contained an operating chair. It did not have a theatre air handling unit. Staff wore theatre attire but patients wore their everyday clothes.
- Resuscitation equipment and oxygen was provided and monitored by the GP practice which managed the building where Blue Sky Orthopaedic was based. They checked the equipment on a weekly basis.
- We checked the resuscitation trolley which showed that the GP practice checked it regularly. The medical gases were within their expiry date.
- The operating theatre had an operating chair so that patients could sit upright. This made the procedure as comfortable as possible for patients. The service had acquired a flat wide trolley for obese patients but would only operate on these patients when it was clinically safe to do so.

## Medicines

- Blue Sky Orthopaedic obtained patient medication from the pharmacy located in the GP practice. Patient medication was kept in a locked fridge in a locked store room. When we inspected the fridge, its temperature was six degrees, within the tolerance of three degrees to seven degrees. The GP practice checked the fridge temperature daily and recorded it on a checklist on the fridge.
- Medical gases were safely stored in a room next to the Blue Sky premises. The GP practice monitored these.
- There was no system in place to monitor medication and identify potential risks for example we did not see a medicine administration policy, medicines audits or systems and processes for medicine stock management. Staff did not have access to a medicines management policy. During our inspection in June 2017 we witnessed an out of date medication which was about to be administered to a patient. The medication had expired in March 2017. We identified that the same medication had been used for the preceding patient on the same day. The service immediately checked any risks with the pharmacist, then rang the patient to explain and apologise.

## Records

- Staff had effective arrangements to keep control of patient records. Over the last three months, no patients were seen without records. The registered manager kept control of records and reminded everyone about the Data Protection policy, which was displayed on the clinic notice board. Staff and patients could read the policy.
- Patient records were stored securely. These were kept in a lockable cabinet in an office, which was locked out of hours. The registered manager transported the records in a locked box to external clinics.
- Clinicians wrote care records which were conducive to patient safety. They carried out a pre-operative assessment at the consultation before surgery and reviewed the patient history provided by the GP. We reviewed six of these and noted that clinicians completed them fully. The assessment covered key patient risks such as anticoagulants with the history of the patient's carpal tunnel syndrome and allergies to local anaesthetics.

# Surgery

- Blue Sky Orthopaedic had a theatre log book which showed times, dates, and nature of operations. This kept a record of patient's treatment. They did not have a surgery monitoring and review process.

## Safeguarding

- Blue Sky Orthopaedic did not have guidelines in place to help all staff identify vulnerable people. We were told the clinicians received safeguarding training at the local NHS trust but received no information on the level or date of training. The registered manager was responsible for dealing with complaints and safeguarding issues, but had not received any safeguarding training.
- Blue Sky Orthopaedic did not report any safeguarding concerns to the Care Quality Commission between January 2016 and December 2016.
- The provider provided us with "Vulnerable Adults" policy dated July 2016. The policy defined different types of abuse but lacked detail of what action staff were to take if they suspected abuse of patients. The policy was not in line with the Safeguarding children and young people: roles and competences for health care staff, intercollegiate document March 2014. The registered manager was the safeguarding lead but had not had any safeguarding training. We did not see the policy included details of other responsibilities such as female genital mutilation and child sexual exploitation. As a result, the service would not be fully prepared if a patient wished to discuss or report these issues.

## Mandatory training

- When we inspected, the registered manager did not have any mandatory training records for staff working in the service. The registered manager told us they relied on staff having completed this at the local NHS trust, but there was no process in place to ensure this had been the case. The provider did not have systems in place to ensure staff were suitably trained and competent to deliver care and treatment safely.

## Assessing and responding to patient risk (theatres, ward care and post-operative care)

- The service was limited to low risk hand surgery. Staff told us they had never had to respond to increased patient risk, but would transfer a patient to the local NHS trust if they had any concerns about a deteriorating patient.

- There was no standardised approach to recognising and acting upon deterioration in a patient. They did not use an early warning scoring system. Following our inspection the service informed us they were writing a policy for the care of deteriorating patients.
- Clinicians assessed risks based on GP information about patients during the initial consultation and before surgery. For example, they monitored a patient's blood pressure if the GP notes flagged it up as high.
- The service did not systematically use the World Health Organisation (WHO) Surgical Safety Checklist and five steps to safer surgery, which have been proven to minimise harm to patients in the operating theatre. They did not have a checklist or policy to follow the five steps of briefing, sign in, time out, sign out and debriefing. Neither was there an instrument count before and after one of the operations we observed. However, they did have a system to check the patient's identity, their dominant hand and the correct hand for surgery.
- Consultants risk assessed patients before the patient left after their operation. They checked sensations in the fingers and encouraged the patient to mobilise their hand. Patients recovered in theatre for up to 20 minutes until they were ready to leave, even if this meant the next operation was behind schedule. This meant the clinician was available if there were any immediate problems.
- There were no protocols in place for transferring patient to the local trust in the case of sudden illness or complications from surgery. The service would initially press the crash (emergency) button for the GP practice resuscitation team and then ring 999 if necessary.

## Nursing and support staffing

- Blue Sky Orthopaedic had two full time nurses/theatre assistants. One of these was a fully qualified nurse practitioner who carried out operations and advised on surgery.

## Medical staffing

- All the medical staff at Blue Sky worked under contracts at local NHS trusts.
- There was sufficient numbers of staff to care for patients. A consultant or the operating specialist nurse operated at the same time there was a consultant clinic running. This ensured there were always two staff with clinical skills in case of an unexpected situation.



# Surgery

- Consultants could attend patients out of hours if needed, but this had only happened once.

## Emergency awareness and training

- Blue Sky's clinic was located in a GP practice. The service complied with the GP practice's fire drills evacuation tests which were held weekly.
- The service had not assessed any potential risks for the planning of their services and no business continuity plans were in place for the regulated activities being carried out. We discussed this with the registered manager and an operating practitioner who said they could move the clinic time and place but it was the GP practice that ran their premises. We were therefore not assured that staff in the service would respond in an appropriate way in the event of a system failure.

## Are surgery services effective?

### Evidence-based care and treatment

- Blue Sky Orthopaedic originally established their service on evidence based care and treatment. We were told the methods involved were based on international best practice in 2007. Blue Sky consultants wrote a number of research papers and carried out clinical audits. They aimed to make carpal tunnel decompression operations as patient-friendly as possible.
- However, the service did not conduct any clinical audits or benchmarking during the three years 2013 to 2016. They did not participate in national audits, for example, for surgical site infections (NICE CG74). They explained that their contracts from the local clinical commissioning group did not exceed one year. This limited the information they collected for some audits, for example on the Boston Hand Score.
- The service followed British Society for Surgery of the Hand guidelines for surgical treatment of trigger finger. They did not audit against these guidelines. The service did not submit any details to the NICE shared learning database or submit details about patient outcomes through surgical quality dashboards.

### Pain relief

- The service suggested that patients took pain relief such as paracetamol two hours before an operation, but not ibuprofen or anti-inflammatories. Staff explained that this was optional because patients were given a local anaesthetic for the procedure in theatre.
- Blue Sky Orthopaedic did not capture patient feedback on pain relief. The clinic did not provide pre-emptive pain relief if patients forgot to take their paracetamol as advised two hours before their operation.
- Clinicians checked pain levels with the patient before going ahead with the operation, and we observed the clinician giving a patient local anaesthetic because their wrist was not numb enough for the operation to take place. Patients told us their pain was well controlled.

### Nutrition and hydration

- Patients did not need to stop eating and drinking before the operation. Patients could maintain their own nutrition and hydration needs.
- A few patients became faint after the operation. One staff member told us that this was usually because they had stopped eating and drinking in preparation for the operation, despite Blue Sky's information on the appointment card telling patients to eat and drink as normal. The service had not asked patients whether there was a more effective way to inform them about this.

### Patient outcomes

- The service originally based its provision around improving outcomes for patients. Procedures were designed to be minimally invasive and to give patients the possibility of using their hand again soon after the operation. This minimised the time they needed to take off work.
- There were no unplanned returns to the operating theatre between January 2016 and December 2016. We did not see any evidence of patient outcomes as the service did not record these.
- Blue Sky Orthopaedic did not proactively collect information about the outcomes of patient care and had an incomplete picture of this from feedback. They told us they did this through patient satisfaction surveys. However, they asked patients to complete a satisfaction card n before they left theatre. This feedback would be too early for patients to feed back about an issue such as pain or infection which might develop a few days later. The patient's local GP practice

# Surgery

nurse removed the stitches and the GP practice would not necessarily inform the service if there was a problem. Some patients who were having operations on both hands reported the outcome of the first operation, but this did not apply to all patients. As a result, the service lacked information to make any improvements based on patient outcomes.

## Competent Staff

- Blue Sky Orthopaedic clinicians performed similar work in the local NHS trust. The service depended on the NHS trust to deliver appropriate clinical training to the consultants although the Blue Sky did not formally record this. The service had no evidence of the operating nurse's or the clinicians NHS training.
- The service had a method for sharing clinical learning. If surgeons or consultants discovered anything unusual or if they adapted a procedure during surgery, they took a photo with their mobile phones with the patient's consent and shared it with their colleagues on a messaging service. However, they had not risk assessed this method of sharing from a data protection or information security point of view. This posed a risk to patient confidentiality and information governance arrangements.
- Medical staff discussed this learning at management meetings. They shared information about a patient who had suspected trigger finger but it turned out to be an extending tendons problem, for example. The service held a management meeting every three months but they had not formalised the agenda.
- Blue Sky did not have a formalised training plan based on identified learning needs. The service did not have full appraisal and training systems in place when we inspected. We did not see evidence to show how the nurse practitioner and nurse were appraised and ensured competencies were up to date. However, the service kept a record of the clinicians' medical revalidation.
- The service did not use practising privileges, as the clinicians were all directors of Blue Sky. The service was planning to expand into other community settings and was considering engaging new consultants under practising privileges.
- Arrangements to manage individual performance were incomplete. The service was in the process of putting appraisals in place for all staff and had carried out appraisals for some staff.

## Multidisciplinary working

- The service worked seamlessly with a variety of local GPs who referred patients through Choose and Book, the NHS on line outpatient appointments system. The service received all necessary information about the patient before their operation. However, not all GPs allowed their practice nurses to remove sutures (take patient's stitches out) and in these cases the patients could return to Blue Sky Orthopaedic to have their stitches removed. They invited feedback from GPs on their service but this was not always given.
- The service worked under contracts provided by the local clinical commissioning group (CCG). They kept a record of activity to ensure they were paid by the CCG. The service also worked with the local NHS trust, which provided nerve conduction studies, which are usually carried out to exclude the possibility that a patient has carpal tunnel syndrome. It had no service level agreement in place for this. .

## Access to information

- The service informed the GP in a timely way, within 24 hours of the patient's discharge. They sent a pink copy of the discharge summary to the GP which ensured continuity of care within the community.
- When patients moved from referral to treatment to discharge, the appropriate information for their care was shared.

## Consent, Mental Capacity Act and Deprivation of Liberty Safeguards

- Blue Sky Orthopaedic staff explained treatment options to patients to ensure that their consent was informed. The service had a brief protocol for consent but this did not cover best practice or legislative guidance and did not include any information on how best to assess consent or mental capacity. The clinician explained the operation and risks at the initial consultation. When the patient arrived for their operation, the operating clinician explained the risks and asked for the patient's consent again. The service did not have a pre-operation information leaflet to explain the operation for patients but started working on this as a response to our inspection.
- We observed a clinician discussing operations and treatment options with the patient to give them a chance to think about their operation. They took time to

# Surgery

explain in plain English what the operation entailed, what the risks were, and the how the patient might feel afterwards. This was done with empathy and ensured that the patient's consent was informed.

- Blue Sky Orthopaedic did not have formal processes in place to aid translation during consent although ethnic minority groups form a significant part of the local population in the Leicester area. They did not have a policy to arrange interpreters themselves. The service encouraged patients who might not easily understand spoken or written English to bring with them an interpreter or family member who could explain the consent document to them. This use of a non-professional interpreter meant that there was a risk of misunderstanding and is against best practice and legislative guidance.
- The service did not have a process to monitor arrangements for consent or to ensure that it met legislation or relevant national guidance.
- The service did not treat patients with complex needs so did not have arrangements to consider the Mental Capacity Act 2005 when asking for patient's consent.

## Are surgery services caring?

### Compassionate care

- In the reporting period (January 2016 to December 2016) the provider collected data for their Friends and Family Test. Staff gave patients a feedback form at the end of every treatment. The service had a response rate of 100% for NHS and other funded patients and achieved a 'would recommend' score of 100% for patients in the last month of the reporting period.
- Staff were compassionate and supportive. They took the time to interact with patients and those close to them. Medical staff were careful to check which the patient's dominant hand was and to advise them on post-operative care. They reacted quickly to any pain that the patient flagged up, giving more anaesthetic where necessary and checking that it had worked well.
- Patients remained dressed in their own clothes throughout the procedure. The service recognised that patients were more comfortable if they did not have to change into theatre gowns. This gave patients more privacy and a feeling of normality.
- Staff occasionally informed the clinician who was operating in theatre that the next patient had arrived

and referred to the patient in friendly terms by either their first name or title and surname. In certain circumstances, this could be detrimental to a patient's need for privacy, because the patient who was already in theatre would have overheard the name of the patient following them.

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

- Staff were friendly and welcoming and introduced themselves to patients and those who accompanied them. They encouraged patients to bring a spouse, partner or friend along to support them and accompany them into the operating theatre. This was reassuring and distracting for the patient, and appeared to reduce their anxiety. It also ensured that there was a second person who heard the surgeon's questions and advice for post-operative care.
- Staff communicated well with patients and those close to them and made sure they understood their care and treatment. They recognised when patients would need additional support and encouraged them to bring people who could support them.
- The service had posters inviting patients to ask for a chaperone if they felt they needed one. As Blue Sky Orthopaedic dealt with hand surgery only, this was extremely rare.
- There were no pre-operation leaflets or other printed information to help patients prepare for the operation. We raised this issue with Blue Sky who responded by producing pre-operation patient leaflets on carpal tunnel decompression and trigger finger/thumb. They had informative post operation leaflets in large print and Arthritis Research patient information on hand conditions.

### Emotional support

- Clinicians understood the impact that treatment might have on patients on wellbeing. For this reason, they designed a low impact procedure so patients could move their hand as soon as possible after the procedure. This ensured that their health and well-being was restored as soon as possible after treatment.
- The service supported patients to self-care with post-operative information explaining what they should

# Surgery

expect in the first week after the operation and some 'do's and don'ts'. It was in large print and plain English and invited patients to contact the service if they had any questions.

## Are surgery services responsive?

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

- Blue Sky Orthopaedic worked with commissioners to deliver services based on local need. The service offered patients around Leicester a choice of location for their treatment in Leicester and the surrounding areas. The service provided the local clinical commissioning group (CCG) with details of patients they treated.
- The service provided flexibility and choice. Blue Sky had a choice of clinics, times and locations. Patients could be seen in the morning, afternoon or evening. The premises and facilities were appropriate for the services delivered. The main clinic had access to a large car park and was on a bus route. The satellite clinics also had car parks and were accessible by bus.
- The service obtained a device which could also test nerve conduction, avoiding the need to attend the local NHS trust. It planned to use this more in future.

### Access and flow

- Patients had timely access to diagnosis and treatment at Blue Sky Orthopaedic. Patients generally had to wait two to three weeks for an appointment if they did not need a nerve conduction study beforehand. Sometimes the service could see and treat them on the same day. The service aimed for a maximum six week turnaround from referral to discharge, which they achieved in all cases which were not referred for nerve conduction study. The local CCG commissioned the nerve conduction studies, for which there was a wait time of up to 15 weeks. This delayed the treatment of some patients at Blue Sky Orthopaedic Limited.
- The appointments system was easy for patients. The consultant explained time and date options to the patients when they had their first consultation.
- The service had an approach to patient access which mirrored that of NHS clinics. Patients received a letter in advance reminding them to attend. Patients could miss one appointment, but if they did not attend on the

second appointment, they were referred back to their GP. The service did not monitor 'did not attend' (DNA) rates but estimated that one patient out of 15 in a clinic did not attend.

- The service told us it did not cancel patient treatment. It offered appointment times on clinic days it knew it could guarantee. In the reporting period (January 2016 to December 2016) Blue Sky responded 'not applicable' in relation to cancelled procedures for a non-clinical reason.
- The service did not monitor when clinics were running late but they tried to ensure that this was never more than 20 minutes. The registered manager went to explain to a patient in the waiting room if a procedure was delayed if the preceding patient felt faint, for example.
- Patients did not automatically have surgery after a meeting with the consultant. Some patients were offered steroid treatment and occasionally splints.
- Blue Sky Orthopaedic were willing to accept patients who needed corrective surgery to hand operations which had been done elsewhere. They told us they reported any need for revision to the originating hospital. Shortly before our inspection, the CCG provided more money for the service to carry out these revisions.
- There were no unplanned transfers, returns to theatre or readmissions between January 2016 and December 2016.

### Meeting people's individual needs

- Blue Sky provided access to treatment for most adult patients with a variety of hand or wrist conditions. They could operate on patients who were taking blood thinning medication or cancer drugs and diabetic patients. The risk of infections was limited for diabetic patients because they could move their hand normally afterwards which kept blood circulating to the affected area.
- Patients with mobility difficulties could access the service. If a patient was a wheelchair user, they could have their operation in their wheelchair without having to transfer to the operating chair. Visually impaired patients and patients with other sensory impairments could bring their guide dogs into the operating theatre. The service had a flatbed trolley which was suitable for some patients who could not use the operating chair.

# Surgery

- The service gave patients an appointment card with the registered manager's telephone number accessible between 8:30 am and 5 pm. The card also reminded patients to eat and drink as normal and not to drive on the day of the operation. The card did not include a reminder to patients to take aspirin or paracetamol. The registered manager reminded patients to contact them after the operation if they had a concern, and arranged for a suitably qualified clinician to contact them if necessary.
- The clinical commissioning group did not contract with the service to see patients under 18. Blue Sky did not see very complex patients or bariatric patients because the risks associated with their treatment could be better managed in the local trust.
- The service did not provide interpreters. One member of staff could speak Hindi and Gujarati so where possible they operated on patients who spoke those languages. Staff in the GP practice could help with British Sign Language. Otherwise, the service wrote to patients who were at risk of not understanding spoken English to suggest they should bring a friend or relative who could interpret for them.
- Written material provided to patients was in English only and the service did not provide alternative versions or formats.
- When we inspected, the operating theatre was uncomfortably warm although the external temperature was 18 degrees centigrade. We discussed this with Blue Sky staff who could not tell us the temperature because there was no thermometer in the room. Ideally, patients should have a stable body temperature (36.5 to 37.5 degrees) during and after a procedure to prevent infection. There was a risk that temperature variation could increase the likelihood of infection. The registered manager responded by putting a thermometer in the theatre so that they could monitor the temperature for each theatre session.

## Learning from complaints and concerns

- Blue Sky Orthopaedic did not receive any complaints from patients between January 2016 and December 2016. It had no record of complaints or customer suggestions, either formal or informal.
- Patients we spoke with knew how to complain and who to complain to, if they needed to. The service informed patients about how to complain and had a complaints policy agreed in July 2016. This stated that the

registered manager, who would respond within 10 days, would deal with a complaint. She would have a face to face meeting with the patient/relative concerned and acknowledge their complaint within three working days. The registered manager would keep everyone informed about the progress of her investigation and the outcome.

- We reviewed 74 customer feedback forms from April to June 2017, across all locations. Customer feedback was 100% positive and patients did not make any suggestions for improvement although the service invited them to. However, the service gave patients the forms and asked them for feedback before they had left the operating theatre. This ensured that patients could feed back, but did not give them a chance to express how they felt after a few days or to report back anything unexpected during their recovery. This limited the service's learning from patients.

## Are surgery services well-led?

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

- The registered manager oversaw the day to day running of the clinic and theatre.
- The service had a nominated clinical lead, but staff explained that they took decisions as a team.
- Blue Sky Orthopaedic was a small organisation and leaders did not focus on developing strong systems to support quality. They instead focused on service delivery and contract fulfilment.
- Blue Sky Orthopaedic staff were a small team who were on good terms and we noted the friendly rapport between them. There were regular discussions between staff. All members had an equal say. The culture appeared open and honest.

### Vision and strategy for this core service

- Blue Sky Orthopaedics vision was to continue being the preferred supplier of minor hand services to the community and to refine the service to improve patient experience.
- There was a clinical governance policy dated July 2016, which envisaged a three year strategic plan and clinical audits, but the service had not implemented them.
- The service did not explicitly state that quality and safety were the top priorities. Their objectives as listed



# Surgery

on the company's statement of purpose provided to the Care Quality Commission were: delivering a diagnostic and treatment service closer to home (an activity shift from acute care to community care); reducing referral to treatment time; providing open access to the patient post operation for six months; and providing a 24/7 cost effective service. These objectives reflected the company's aspirations around responsiveness, access and efficiency, but did not explicitly state any aims concerned with quality.

- The service did not have a medium to long term strategy or business plan with specific objectives or action plans. The local clinical commissioning group (CCG) contracted Blue Sky Orthopaedic to provide hand surgery services for 12 months at a time. The service told us this deterred them from planning for any horizon longer than a year. In summer 2017 the Leicester, Leicestershire and Rutland Alliance took over the commissioning of services. This led to an increase in work for Blue Sky Orthopaedic and the potential to open new clinics, but when we inspected, they had not written action plans for this.
- The service did not have a strategy for quality or safety improvement. Service delivery evolved from an innovative model in 2008 and the company had not developed a safety/ quality plan.
- There were no action plans for improvement of infection control, quality, safety, or performance. The service did not have any stated succession plans but looked to recruit additional clinicians through practising privileges in future.
- Staff at Blue Sky Orthopaedic knew what the organisation's vision and objectives were. This was because the organisation was a small team which communicated well day to day. However, the company had no stated organisational values.

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

- Blue Sky Orthopaedic lacked a governance framework. It held a management meeting approximately every three months. This meeting had no standard agenda to ensure that clinicians and staff reviewed incidents, complaints and clinical audits. There were no other formal meetings or management controls.
- The service did not have an agreed, shared and comprehensive definition of which incidents to report.

There was no agreed policy which defined incidents, how to investigate them or communicate outcomes. As a result, they did not have fully developed systems to record, analyse or learn from the complete range of incidents.

- There was no formal minuted clinical governance group or medical advisory committee responsible for reviewing incidents and patient feedback, agreeing and monitoring clinical procedures, and clinical audits. This meant that there were no resulting actions to improve these aspects of service.
- The service did not have robust systems to monitor, analyse or take action on safety, quality, performance or risk. There were no robust arrangements for identifying, recording and managing risks and mitigating actions or contingency plans. When we explained this, the service responded positively and started to list their clinical and non-clinical risks in a risk register.
- The service had not developed quality, safety or performance measures. They monitored financial performance on their CCG contract and had started to monitor referral to treatment times, but did not have a full suite of quality and performance measures. As a result, quality and performance dashboards were not used to monitor trends or to take action to improve.
- The service did not have formal agreements with some partner organisations. It had no service level agreement with the local NHS trust for the provision of nerve conduction studies, or arrangements for transferring patients who were deteriorating and needed immediate review, or who needed more complex hand surgery.
- The service no longer had a systematic programme of internal and clinical audit. They had an audit programme in 2008 - 2013 but it lapsed when no-one reviewed the audits, including the primary care trust which had requested them.
- There were limited policies in place to provide guidance to staff, and those that were in place had not been fully implemented. Prior to our inspection we requested a range of information. As part of the information request we asked the provider to provide us with a list of policies. Where the provider did not send these we asked for the reason for not submitting them. The provider told us that the following policies were not applicable, risk management, medical records, medicines management, cardiopulmonary resuscitation, infection and prevention control, admissions, patient selection and exclusions policy,

# Surgery

whistleblowing, Mental Capacity Act 2005 and Deprivation of Liberty. These policies are essential in order for the provider to deliver safe care and treatment which protects patients' rights for the regulated activities which they are registered for.

- The limited policy framework in place did not support governance. The service developed some policies in 2016. These included a data protection policy, a quality policy which focused on health and safety, and a clinical governance policy. The Vulnerable Adult Policy was insufficiently clear about action to be taken to safeguard individuals. The service had not developed the detail of these policies or implemented them fully. There was no policy on sepsis or for escalation of deteriorating patients.
- The Clinical Governance SOP dated July 2016 provided to us by the service stated "We will undertake regular clinical audits, record the results, and plan improvements to patient benefit. We will also undertake audit of administrative procedures to ensure that they are working effectively" We did not see any evidence that this process had taken place at the time of our inspection. The policy also stated "We will operate a free system of Significant Event Reporting to encourage review, feedback and learning from incidents in an open and no-blame culture. All significant events will be discussed and documented within the forum of a clinical review / policy meeting." We were not provided with, and we did not find evidence during our inspection to suggest that significant events were discussed and/or documented. We requested information but were not provided with evidence that clinical review or policy meetings had taken place.
- The clinical governance policy stated the name of the person who was the clinical governance lead for the organisation. It stated the person would be responsible for; 'promotion of quality care within the organisation, provide clinical governance leadership and advice, keeping up to date with research and governance recommendations, and communicating these accordingly, to act as an expert resource and advisor in the examination and review of significant events, to initiate and review clinical audits and to oversee the

management of the key Policy provision'. We did not find and were not provided with any evidence to suggest that these responsibilities were being carried out by the provider.

- Following our inspection we were so concerned about the lack of governance processes in place that we served the provider with a warning notice under section 29 of the Health and Social Care Act 2008. This means the provider has until 2 October 2017 to become compliant with Regulations. If the provider fails to achieve compliance with the relevant requirement within this timescale, we may take further action. Further information can be seen at the end of this report.

## Public and staff engagement

- Staff were clear about their roles within the organisation because they worked within a small team. The service had defined board level responsibilities. However, there was scope to develop these roles to better support continuous improvement and clinical governance
- Patient feedback arrangements did not help shape service delivery, despite the service's efforts to obtain feedback. The service asked patients immediately after their operation to give feedback, while they were still in the operating theatre. The satisfaction rates were 100% positive and patients made no suggestions for improvement. This was the only opportunity patients had to give feedback unless they wanted to make a complaint later, and the service had no records of complaints. The method of gathering feedback while still in theatre meant that patients did not have the chance to go away and think about their treatment or the booking process, and did not have the chance to report any subsequent infections or pain issues.
- Staff felt activity engaged in the planning and delivery of services. The service was a small team of seven people and everyone was involved in service delivery.

## Innovation, improvement and sustainability (local and service level if this is the main core service)

- The service lacked quality improvement systems to ensure that it innovated in future

# Outstanding practice and areas for improvement

## Areas for improvement

### Action the provider **MUST** take to improve

- **Action the provider MUST take to meet the regulations:**

- Ensure there is an effective system for reporting, managing, investigating and learning from incidents.
- Ensure staff understand what constitutes an incident and that they know how to report these.
- Ensure that there is an effective process to identify, register, manage and mitigate risk to patients.
- Ensure there is an escalation policy in the event of patient deterioration.
- Ensure staff are suitably skilled and trained to respond to medical emergencies.
- Ensure there are suitable business continuity plans in place and staff are familiar with these and their role within them.
- Ensure that WHO Five Steps to Safer Surgery is carried out in a systematic way and embedded into theatre practices.
- Ensure there are suitable arrangements in place for the management of medication.
- Ensure that infection control procedures in theatre are in line with best practice.
- Ensure hand hygiene compliance is regularly audited.
- Ensure there is a safeguarding policy in place which adopts best practice guidance.
- Ensure up to date and complete mandatory training records are kept.
- Ensure staff are trained in Duty of Candour.
- Ensure staff are trained in safeguarding adults and children at the appropriate level.

- Ensure there is active clinical leadership in place.
- Ensure there is a programme of clinical audits.
- Ensure that patient outcomes of care and treatment are monitored and acted upon.
- Ensure there are sufficient evidence based policies and procedures to comply with CQC regulations and the scope of the service being delivered.
- Ensure monitoring of compliance with policies and procedures is carried out regularly.
- Ensure consent is obtained in line with best and legislative practice.
- Ensure patients can access and that the service provides a fully trained and impartial interpreter for patients whose first language is not English.
- Ensure there is an effective governance framework.
- Ensure there are formal agreements with partner organisations such as the local NHS trust for patient transfer in the case of patient deterioration

### Action the provider **SHOULD** take to improve

- **Action the provider SHOULD take to improve**

- Consider how it will address the privacy concern raised in our report and implement procedures and training to ensure privacy is consistently respected.
- Consider how to improve patient communication arrangements including a pre-surgery information sheet to remind patients to eat before the operation, and gathering feedback post surgery.
- Consider risk-assessing the use of messaging systems for clinical learning.



This section is primarily information for the provider

## 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
Diagnostic and screening procedures Surgical procedures Treatment of disease, disorder or injury	Regulation 20 HSCA (RA) Regulations 2014 Duty of candour  Registered persons must act in an open and transparent way with relevant persons in relation to care and treatment provided to service users in carrying on a regulated activity.  <b>How the regulation was not being met:</b> <ul style="list-style-type: none"><li>• Staff were not aware of their legal responsibilities under the Duty of Candour Regulation.</li></ul>

Regulated activity	Regulation
Diagnostic and screening procedures Surgical procedures Treatment of disease, disorder or injury	Regulation 12 HSCA (RA) Regulations 2014 Safe care and treatment  Care and treatment must be provided in a safe way for service users  <b>How the regulation was not being met:</b> <ul style="list-style-type: none"><li>• There were no policies and procedures in place which covered supply and ordering, storage, dispensing and preparation, administration, disposal and recording of medicines.</li><li>• Infection control practices were not in line with national best practice.</li></ul>

Regulated activity	Regulation
--------------------	------------

This section is primarily information for the provider

## Requirement notices

Diagnostic and screening procedures

Surgical procedures

Treatment of disease, disorder or injury

Regulation 13 HSCA (RA) Regulations 2014 Safeguarding service users from abuse and improper treatment

### How the regulation was not being met:

- Staff had not received safeguarding training
- The safeguarding policy was not in line with best practice guidance.

## Regulated activity

Diagnostic and screening procedures

Surgical procedures

Treatment of disease, disorder or injury

## Regulation

Regulation 11 HSCA (RA) Regulations 2014 Need for consent

### How the regulation was not being met:

- Staff did not obtain consent in line with best practice guidance. They did not use interpreter services for patients whose first language was not English.
- Policies and procedures for obtaining consent were not reflective of current legislation and guidance.

## 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
Diagnostic and screening procedures Surgical procedures Treatment of disease, disorder or injury	<p>Regulation 17 HSCA (RA) Regulations 2014 Good governance</p> <p><b>Regulation 17 HSCA (RA) Regulations 2014 Good governance.</b></p> <p>How the regulation was not being met:</p> <p>The provider did not have a programme of internal and clinical audit.</p> <p>There were no quality, safety or performance measures in place.</p> <p>There was no governance framework in place</p> <p>The provider did not have robust systems to monitor, analyse or take action on safety, quality, performance or risk.</p> <p>There were no robust arrangements for identifying, recording and managing risks and mitigating actions. At the time of our inspection there was no risk register and risks within the service, risks had not been identified therefore they could not be mitigated.</p> <p>The provider was not following nationally recognised best practice to mitigate risks to patients.</p> <p>There was a lack of systems in place to record, analyse or learn from incidents or near misses.</p> <p>The provider had not assessed any potential risks for the planning of their services</p> <p>and no business continuity plans were in place for the regulated activities being carried out.</p> <p>There were no protocols in place for the transfer of a patient to the local trust in the case of complications from surgery or sudden deterioration whilst using the service.</p>

## Enforcement actions

There was no system in place to monitor medication and identify potential risks for example, we did not see a medicine administration policy, medicines audits or systems and processes for medicine stock management.

There were limited policies in place to provide guidance to staff and those that were in place had not been fully implemented.

The registered manager was the safeguarding lead but had not received any specific safeguarding training and the safeguarding policy lacked detail and did not follow national guidance.

At the time of our inspection the registered manager did not have any mandatory training or appraisal records for staff working in the service.

**Regulation 17 (1) (2)(a) (2)(b) (2)(d) (2)(f)**