Blue Sky Orthopaedic

Quality Report

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Syston Health Centre
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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

Summary of findings

Letter from the Chief Inspector of Hospitals

Blue Sky Orthopaedic Limited is an independent orthopaedic clinic specialising in hand day surgery. It has no overnight 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 on 28 and 29 June 2017. As a result of our findings we issued a warning notice served under Section 29 of the Health and Social Care Act 2008.

The full report of this inspection can be found on the CQC website: http://www.cqc.org.uk/location/1-2860593165

In order to follow up on progress against this warning notice we carried out a short notice announced focused inspection on 29 November 2017.

As this inspection was a focused inspection, we looked at the well-led domain only.

Services we do not rate

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

We found the provider had partially met the requirements of the warning notice. There were still some areas that required further improvement:

- Continuing to embed the new governance framework and understanding of the new protocols and policies
- Agreeing an internal and external audit plan which informs the service about areas to celebrate or improve, including a proposed NICE guidance audit.
- Reviewing management capacity and cover for the registered manager.

However we also found the following areas of good practice:

- Blue Sky Orthopaedic had developed a governance and policy framework, which included a strengthened approach to clinical governance.
- Leadership meetings were formatted so that important aspects of governance could be regularly monitored.
- Blue Sky Orthopaedic started to monitor their own dashboard of safety and quality measures, monthly. This included patient feedback, infection rates, process complaints and audit outcomes and management.
- Policies and procedures to support medicines management and stock control were in place.
- Processes for incident reporting, investigating and sharing learning had been developed and were well understood.
- The service had arrangements in place for identifying, recording, managing and mitigating risk and monitored these at their leadership meeting.
- Clinicians systematically used the World Health Organisation Five Steps to Safer Surgery checklist.
- Safeguarding policy guidance was in place and staff had received safeguarding training
- The service had its own appraisal forms and carried out appraisals in line with its own objectives.Training and appraisal files we reviewed were complete.
- There were new policies for consent, duty of candour and the Mental Capacity Act 2005 and Deprivation of Liberty safeguards and staff understood and had received training on these topics.
- The provider had audits in place for patient outcomes and the quality of sutures (stitches).

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.

Summary of findings

Heidi Smoult

Deputy Chief Inspector of Hospitals (Central), on behalf of the Chief Inspector of Hospitals

Summary of findings

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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 is 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, and surgical procedures and treatment of disease, disorder and injury.

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

Our inspection team

The team that inspected the service comprised a CQC lead inspector and one other CQC inspector. Simon Brown, Inspection Manager, oversaw the inspection team.

Why we carried out this inspection

We carried out this inspection to follow up on actions we requested from the provider as a result of their comprehensive inspection in June 2017.

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

• 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 percentage 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. During the inspection, we visited the main surgical clinic in Syston.

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

We conducted a comprehensive inspection in June 2017. This led to enforcement action and we issued a warning notice. This listed governance issues which the Blue Sky Orthopaedic had to improve. It highlighted breaches of Regulation 17 (Good Governance), in particular, a lack of management systems or meetings for identifying and

Summary of this inspection

learning from incidents, addressing risks, monitoring performance and learning from audits. The provider also had an underdeveloped approach to safeguarding and did not provide an interpreter for consent purposes. There were very few policies underpinning how Blue Sky delivered care. Full details are available in our report of the June 2017 comprehensive inspection.

Since then, Blue Sky Orthopaedic developed an action plan for these improvements and monitored its own progress.

We re-inspected in November 2017 to check that the provider had complied with the warning notice. The inspection was unrated.

Surgery

Safe	
Effective	
Caring	
Responsive	
Well-led	

Are surgery services safe?

- We did not inspect how safe surgery was at this inspection.

Are surgery services effective?

- We did not inspect the effectiveness of surgery at this inspection.

Are surgery services caring?

- We did not inspect how caring surgery was at this inspection.

Are surgery services responsive?

- We did not inspect the responsiveness of surgery at this inspection.

Are surgery services well-led?

Leadership / culture of service related to this core service

- Our June 2017 inspection found that no-one was taking the lead for clinical governance in the organisation. The clinical governance policy statement that this person would be responsible for promotion of quality care within the organisation, provide clinical governance leadership and advice and keep up to date with research and governance recommendations and communicate these accordingly. However, this was not in place at the time.
- When we returned in November 2017 we found that Blue Sky had a nominated clinical governance lead and a governance framework. The service also had a clinical governance policy which committed to important activities such as clinical audit, evidence based patient treatment and a patient participation group. The plans outlined in the policy were in the early stages and had not been fully implemented or embedded.

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

- After our comprehensive inspection in June 2017 we took enforcement action and issued a warning notice. We asked the service to improve a range of governance issues. We returned in November 2017 to do a follow up inspection. Our findings are listed below:
- The service had started to develop audits but did not have a fully developed programme of internal and external audit. They audited outcomes in terms of patient feedback, needs for further surgery, any issues/ revisions from elsewhere and known infections post surgery. The audits from July and August 2017 showed no infections, and this trend continued until one possible infection occurred in October 2017. Clinicians also carried out an audit of each other's suture work (stitches) which showed that out of 12 sutures, nine were high quality and three were medium quality. They planned to agree a programme of audit of clinical and administrative processes at their next leadership meeting.
- In June 2017, Blue Sky did not have any quality, safety or performance measures in place. In addition to the monthly report to their commissioners, the service started to monitor its own dashboard of measures which included patient feedback, infection rates, process compliance and audit management and outcomes. The service planned to use the audit process to inform its ongoing development of key performance measures.

Surgery

- The service had developed a governance framework when we returned in November 2017. This included a comprehensive range of policies and leadership meetings. The monthly executive (leadership) meetings had a standard agenda and reviewed key aspects of the governance structure – risk management, clinical governance, incident management and complaints, infection control, human resources and compliance monitoring. The service held a new style leadership meeting in November 2017, and planned to hold the leadership meetings on a monthly basis. The service had started these meetings when we inspected but this practice needed to be embedded.
- Blue Sky had a range of relevant policies meeting the requirements of the service and regulations. There were clear arrangements in place for review and version control. The policies were discussed and approved at the leadership meeting. Blue Sky also introduced a safety alert policy so that clinicians reviewed alerts at leadership meetings.
- The service made progress on risk management. It had a risk management protocol in place which defined risk categories. A risk register was in place that identified key risks to the service. This included risks such as surgical risks, non-compliance to regulations and potential lack of administrative cover. The document included measures to mitigate and manage the risks. The leadership meeting assigned responsibilities for the management of risks and ensured risks were reviewed regularly.
- When we inspected in June 2017, the service did not use the World Health Organisation (WHO) Five Steps to Safer Surgery checklist to manage risk in the operating theatre. When we returned in November 2017 the service had improved their approach and used the WHO Five Steps systematically to mitigate risk. We saw completed checklists to confirm this was the case. The service had not set up a formal observational audit for the checklist, however, the registered manager reviewed every checklist straight away.
- Staff had a a clear understanding of what should be reported as an incident. This was underpinned by appropriate NHS guidance, a Significant Adverse Events Policy, which gave guidance on what type of event could be defined as an incident, and a new significant adverse event form. The service had a system to investigate incidents (adverse events) and shared the learning at leadership meetings. Meeting minutes from November 2017 showed a review and discussion of recent incidents, for example, the wrong operation had been listed on a waiting list slip in October 2017.
- The service implemented a service continuity plan in September 2017. This document included a range of identified hazards and risks and clarified roles and responsibilities. The service had an escalation plan in case of a clinical incident which set out its arrangements to support the registered manager when they gave advice over the phone. It outlined the action consultants would take in medical emergencies, and transfer to specialists. There was a protocol for transfer for on and off-site emergency transfers.
- The service had a medicines management policy which set out the rules for storing, prescribing, supplying, recording, administering, transporting, and destroying medicines, in accordance with regulations. It had a medicines management protocol supporting this policy which contained information on dose levels and risks for medications used. There was also a policy which set out the rules for transportation, stock control and storage of drugs in fridges, and a book which to monitor arrival dates and expiry dates of drugs. This met the requirements of the warning notice.
- Our June 2017 inspection showed that Blue Sky's policies for obtaining consent were not in line with best practice. When we re-inspected we found that the service had a new consent and treatment protocol, which was comprehensive enough to cover it for future service development. It explained different types of consent such as implied consent and expressed consent, as well as 'Gillick' competency, which allows young people under the age of 18 years to consent for themselves. The service had agreed a Mental Capacity Act and Deprivation of Liberty Safeguarding policy. This was supported by training so staff had a better understanding.
- When we inspected in November 2017 the service had developed a two stage policy for consent. Patients received information about their operation at their clinic consultation. The consultant would ask for their consent at this stage and again just before the operation. It had not yet had the time to audit whether clinicians were asking for patient's consent in line with its policy. Blue Sky did not provide interpreters for consent, relying on the patient to bring suitable people to interpret for them if necessary. This was not in line with best practice.

Surgery

- The service had a training matrix to monitor mandatory training completion by members of staff. We reviewed training and appraisal files and found that the files were complete and up to date with evidence of training and appraisals, professional insurance and disclosure barring scheme checks.
- Staff had completed training on the duty of candour regulation, and the service had agreed a policy which gave guidance on the duty. Blue Sky had not reported any incidents which meant they had to comply with duty of candour, however, they understood what they needed to do in these circumstances.
- The service had improved its infection control processes in November 2017 and had taken advice from an infection control expert from its commissioner. It carried out hand hygiene audits and had a procedure for legionella control. It had a procedure for two person work flow in theatre which explained various theatre procedures for example, who should dispose of sharps and how they should do it.
- Our original findings showed that safeguarding was not supported by a policy in line with intercollegiate guidance. This meant that it did not include guidance on FGM and child sexual exploitation. Key staff members of staff had not had safeguarding training.
- When we returned in November we found Blue Sky service had strengthened its approach to safeguarding. All staff had level two adult and child safeguarding training in September 2017. The team planned to invite the trainer to visit them in 2018 to deliver training tailored to their type of business. The service displayed Leicester, Leicestershire and Rutland key contact lists on the office wall so that they could report a safeguarding incident and access expert advice easily. The service had vulnerable adults and child safeguarding policies in place and nominated a safeguarding lead. However, there was scope to further strengthen the policies because they did not include any guidance on helping patients who were concerned about Female Genital Mutilation (FGM.) We discussed this with the service and they amended their guidance straight away and arranged relevant training. The service reviewed its own action plan to ensure that safeguarding training was ongoing.

Outstanding practice and areas for improvement

Areas for improvement

Action the provider MUST take to improve

- Develop a comprehensive internal and clinical audit programme, including an audit of the WHO Five Steps to Safer Surgery checklist.
- Ensure that its safeguarding policy guidance and training reflects best practice, is comprehensive and that it includes Female Genital Mutilation (FGM)
- Ensure that the governance framework and leadership meeting are embedded and effective.
- Ensure that interpreting services are available for patients to consent to treatment in line with best practice guidance.

Action the provider SHOULD take to improve

- Develop patient engagement through a patient involvement group.

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 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.

Regulated activity	Regulation
Diagnostic and screening procedures Surgical procedures Treatment of disease, disorder or injury	Regulation 17 HSCA (RA) Regulations 2014 Good governance How the regulation was not being met: The provider did not have a programme of internal and clinical audit.

This section is primarily information for the provider

Enforcement actions

Action we have told the provider to take

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