

The London Eye Hospital

Quality Report

29a Wimpole Street

London

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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

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

The London Eye Hospital is a private hospital providing a range of eye treatments and surgical procedures to adults. All patients are self-funding. Although they offer treatments for a wide range of eye conditions, they specialise in lens implants and cataract treatment. One of the procedures carried out as part of the service is lens implants for patients with age-related macular degeneration (AMD) which is a progressive disease of the macula (the central area of the retina) and a cause of sight loss. The total number of lens implant surgeries carried out between September 2016 and September 2017 was 379.

The London Eye Hospital is operated by The London Eye Hospital Limited. There are two locations linked to London Eye Hospital Limited, namely 4 Harley Street and 29a Wimpole Street. Both locations are named The London Eye Hospital. Number 4 Harley Street provides the outpatient service for the hospital where pre and post-operative consultations take place. Number 29a Wimpole Street is the site where all the surgical procedures take place. This report relates to 29a Wimpole Street only.

We carried out this inspection in response to concerns received in August 2017 about the type of lens implanted in surgery between 2014 and 2015 at the Wimpole Street location and some aspects of pre and post-operative care and treatment provided at this hospital. We responded to these concerns by carrying out an unannounced inspection on 11 and 16 October 2017. The inspection did not address all our key lines of enquiry but focused only on the issues raised by the information received. The inspection focused on safeguarding, consent, complaints, patient outcomes, and governance arrangements. Prior to this responsive inspection, we had carried out a comprehensive inspection of the service in December 2016.

Summary of the information triggering the responsive inspection.

In August 2017, we received information raising concerns about aspects of treatment and care provided at the London Eye Hospital (both locations). These concerns were about:

- The safety of the type of lens patients consulted on at this location and had implanted at the Wimpole Street location where surgery takes place.
- Failure to seek patients' consent to care and treatment in line with legislation and guidance by staff at the hospital.
- Patients not being informed of the risks related to the lens implant surgery.
- A lack of systems and processes to allow people using the service to make complaints.
- Failure to monitor patient outcomes at the hospital.
- Staff failing to observe patients' privacy during pre-operative checks.

Inspection findings

- The service had stopped implanting the type of lens we had received concerns about in August 2015.
 - There was evidence staff sought patients' consent and explained the risks of surgery prior to surgery taking place.
- Staff informed patients of the risks related to the lens implants at various stages of consultation.
- The hospital had a complaints procedure in place and information about how to make a complaint was available to patients attending the hospital.
- There was some monitoring of patient outcomes using both audits and post-operative appointments.
- Staff observed patients' privacy during consultation and post-operative checks.

However:

- Staff had not completed mental capacity training at the time of our inspection. They subsequently completed this training.

Summary of findings

- There was no indication in patients' records that the service monitored compliance with the seven day 'cooling off' period or that it had been discussed with patients.
- Although there were systems and processes to protect people using the services from abuse and improper treatment, three out of 16 staff had not completed safeguarding training. The three staff completed training following our inspection.
- There was some monitoring of patient outcomes but there was no routine measurement of whether the service was effective.
- The hospital did not respond to four out of ten complaints within 20 working days as per their policy.
- The service did not have a registered manager at the time of or inspection. Having a registered manager is a condition of registration with the Care Quality Commission.

Amanda Stanford

Deputy Chief Inspector of Hospitals, on behalf of the Chief Inspector of Hospitals

Overall summary

The London Eye Hospital is a private hospital providing a range of eye treatments and surgical procedures to adults. All patients are self-funding. Although they offer treatments for a wide range of eye conditions, they specialise in lens implants and cataract treatment. One of the procedures carried out as part of the service is lens implants for patients with age-related macular degeneration (AMD) which is a progressive disease of the macula (the central area of the retina) and a cause of sight loss. The total number of lens implant surgeries carried out between September 2016 and September 2017 was 379.

The London Eye Hospital is operated by The London Eye Hospital Limited. There are two locations linked to London Eye Hospital Limited, namely 4 Harley Street and 29a Wimpole Street. Both locations are named The London Eye Hospital. Number 4 Harley Street provides the outpatient service for the hospital where pre and

post-operative consultations take place. Number 29a Wimpole Street is the site where all the surgical procedures take place. This report relates to 29a Wimpole Street only.

We carried out this inspection in response to concerns received in August 2017 about the type of lens implanted in surgery between 2014 and 2015 at the Wimpole Street location and some aspects of pre and post-operative care and treatment provided at this hospital. We responded to these concerns by carrying out an unannounced inspection on 11 and 16 October 2017. The inspection did not address all our key lines of enquiry but focused only on the issues raised by the information received. The inspection focused on safeguarding, consent, complaints, patient outcomes, and governance arrangements. Prior to this responsive inspection, we had carried out a comprehensive inspection of the service in December 2016.

Summary of findings

Our judgements about each of the main services

Service

Surgery

Rating Summary of each main service

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. Staff saw patients for the lens implant surgery. Patients were seen post operatively at another location.

Clinicians sought patients' consent and discussed risks with the patients at various stages of the consultation process. We also found that the hospital had a complaints procedure in place.

We observed that staff maintained patient's privacy and dignity during consultations and post-operative checks.

However, not all staff had been trained in safeguarding. These staff were subsequently trained following our inspection. We also found that although the service saw individual patients post operatively to assess the success of lens implant surgery the service did not routinely monitor patient outcomes to give an overall measure of the effectiveness of the service.

Furthermore, there was no evidence of the seven-day 'cooling off' period being discussed patients or being monitored in patient records.

The hospital did not have a registered manager in place at the time of our inspection.

We did not rate this service because the inspection focused on specific areas of the service and not the service as a whole.

Summary of findings

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The London Eye Hospital - 29a Wimpole Street

Services we looked at:

Surgery

Summary of this inspection

Background to The London Eye Hospital

The London Eye Hospital is a private hospital providing a range of eye treatments and surgical procedures to adults. All patients are self-paying. One of the procedures carried out as part of the service is lens implants for patients with age-related macular degeneration (AMD) which is a progressive disease of the macula (the central area of the retina) and a cause of sight loss. Consultants at this hospital developed a lens implant for patients with AMD.

The London Eye Hospital is operated by London Eye Hospital Limited. There are two locations linked to London Eye Hospital Limited, namely, 4 Harley Street and 29a Wimpole Street. Both locations are named 'The London Eye Hospital'. Patients attend the 4 Harley Street location for an initial consultation, optometry tests and aftercare. Surgery is carried out at this hospital (29a Wimpole Street). The department is open Monday to Friday 9am to 5.30pm.

We carried out this unannounced inspection in response to concerns received in August 2017 about the some aspects of care and treatment provided at this hospital. There were also concerns about the safety of the type of

lens implanted in surgery at this hospital. We also carried out an unannounced inspection of the outpatient (4 Harley Street) and findings will be reported on in a separate report.

Prior to this inspection, we had last inspected the service in December 2016 using our comprehensive inspection methodology.

For the unannounced inspection, we did not carry out a comprehensive inspection but focused only on the issues raised by the information received. We categorised these concerns into safeguarding, consent, complaints, patient outcomes, and governance arrangements.

There had been no registered manager for this service since July 2017 at the time of our inspection. The hospital was in the process of recruiting staff to be registered as the registered manager.

During the inspection, we spoke with four members of staff including a clinical manager, and consultants. We also spoke with three patients, two relatives and observed two consultations. We reviewed ten patient records and ten complaints.

Our inspection team

The team that inspected the service comprised two CQC inspectors. The inspection team was overseen by Nicola Wise, Head of Hospital Inspection.

Why we carried out this inspection

In August 2017, we received information raising concerns about aspects of treatment and care provided at the London Eye Hospital (both locations). These concerns were about:

- The safety of the type of lens patients consulted on at this location and had implanted at the Wimpole Street location where surgery takes place.
- Failure to seek patients' consent to care and treatment in line with legislation and guidance by staff at the hospital.
- Patients not being informed of the risks related to the lens implant surgery.
- A lack of systems and processes to allow people using the service to make complaints.
- Failure to monitor patient outcomes at the hospital.
- Staff failing to observe patients' privacy during pre-operative checks.

Summary of this inspection

How we carried out this inspection

We visited the service for a unannounced inspection on 11 and 16 October 2017. We gathered further information from data provided by the service.

During the inspection, we spoke with four members of staff including a clinical manager, and consultants. We also spoke with three patients, two relatives and observed two consultations. We reviewed ten patient records and ten complaints.

Information about The London Eye Hospital

The main activity at this location is surgery. Patients have consultations for surgery at the 4 Harley Street location but surgery is carried out at this hospital.

There were no special reviews or investigations of the hospital ongoing by the CQC at any time during the 12 months before this inspection. The hospital has been inspected once before and the most recent inspection took place in December 2016.

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?

We did not rate this service. The inspection focused only on the issues raised by the information received by us in August 2017. The inspection did not look at all our key lines of enquiry but focused on specific aspects of the service.

We found the following:

- Three out of 16 staff had not completed safeguarding training at the time of our inspection. Staff subsequently completed this training following the inspection.
- Staff we spoke with during the inspection demonstrated knowledge of safeguarding and escalating concerns.
- Staff had not completed mental capacity training at the time of our inspection. Staff subsequently completed this training following the inspection.

Are services effective?

We did not rate this service. The inspection focused only on the issues raised by the information received by us in August 2017. The inspection did not look at all our key lines of enquiry but focused on specific aspects of the service.

We found the following:

- Staff sought patients' consent and explained risks of surgery at various stages of the consultation process.
- The hospital had a consent policy and staff explained the risks involved in lens implant surgery to patients at various stages of care and treatment.
- There was no routine monitoring of patients' outcomes to give an overall measure of effectiveness.
- There was no indication in patients' records that the service monitored compliance with the seven-day 'cooling off' period or that it had been discussed with patients.

Are services caring?

We did not rate this service. The inspection focused only on the issues raised by the information received by us in August 2017. The inspection did not look at all our key lines of enquiry but focused on specific aspects of the service.

We found the following:

- Staff maintained patients' privacy and dignity during consultations.

Summary of this inspection

Are services responsive?

We did not rate this service. The inspection focused only on the issues raised by the information received by us in August 2017. The inspection did not look at all our key lines of enquiry but focused on specific aspects of the service.

We found the following :

- The service had a system for identifying, receiving, recording, handling and responding to complaints, however, not all complaints had been responded to within 20 working days as per the hospital's policy.

Are services well-led?

We did not rate this service. The inspection focused only on the issues raised by the information received by us in August 2017. The inspection did not look at all our key lines of enquiry but focused on specific aspects of the service.

We found the following:

- Leadership were aware of the information triggering this inspection and had already made some changes to address some of the concerns.
- The hospital had a Medical Advisory Committee (MAC) who met every six months. Staff told us they had clinical governance meetings between the MAC meetings, however we did not receive minutes of the clinical governance meetings.
- There was no registered manager at this hospital at the time of our inspection.

Surgery

Safe

Effective

Caring

Responsive

Well-led

Information about the service

The main activity at this location is surgery. Patients have consultations for surgery at the 4 Harley Street location but surgery is carried out at this hospital.

There were no special reviews or investigations of the hospital ongoing by the CQC at any time during the 12 months before this inspection. The hospital has been inspected once before and the most recent inspection took place in December 2016.

Are surgery services safe?

Safeguarding

- Safeguarding adults and children training was part of the mandatory training expected of staff at the London Eye Hospital.
- Staff had completed adult safeguarding training at level two. However, three out of 16 staff had not completed this training at the time of our inspection. The three staff subsequently completed training.
- The hospital did not treat patients under the age of 18. However, consultants had level three children safeguarding training and all other staff had level two children safeguarding training. At the time of our inspection three out of 16 staff had not completed children safeguarding training.
- Staff we spoke with during the inspection were able to tell us what might constitute a safeguarding concern and knew how to escalate safeguarding concerns. This included escalating to the safeguarding lead or to the local authority.
- The hospital had safeguarding adults and safeguarding children policies which staff said they had access to. The policies were in date.

- There had been no safeguarding referrals in the 12 months preceding the inspection.

Are surgery services effective?

Patient outcomes

- Staff told us the service monitored outcomes for lens implant surgery as part of the post-operative care provided. Patients had post-operative appointments scheduled a week after each eye surgery. Further post-operative appointments were arranged depending on each patient's case. Staff told us the success of surgery was measured by checking the patient's visual acuity post operatively and at each post-operative visit.
- Although the service checked for improvements in patients' sight following surgery, patients' treatment outcomes were not routinely monitored. Outcomes were measured post operatively at individual patient level but information was not collated to give an overall measure of effectiveness.
- At the past inspection the hospital had shared an audit of their lens implant. This was a sample of 61 patients and showed significant improvements in near and distance vision. However, these results could not be benchmarked because the lens was an innovation, developed by the hospital and not in the public domain.
- In July 2015, the hospital carried out a retrospective audit of 150 procedures where patients had been fitted with the lenses which had given rise to our initial concerns. The purpose of this audit was to determine the short to medium term safety of the lenses. The audit found that the lenses appeared to be safe in the short-to-medium term. At the time of our inspection these lenses had been updated to the version we found being used at the time of our inspection.

Surgery

- During the inspection we were provided with a piece of research published in the European Journal of Ophthalmology in September 2017. Two consultants from the hospitals were involved in this research. The research related to patients who had undergone lens implant surgery using the type of lens which was on offer to patients at the time of our inspection. The case study looked at the results of 244 eyes where the lenses had been used. The study concluded that the lens appeared safe in the short and medium term and that improvements in visual acuity exceeded those observed with standard implants.
- The practice manager told us patients would then book a consultation to discuss the lens. The consultation included an eye examination with the hospital's diagnostic technician who carried out scans on the eyes. This was followed by a full eye examination and then a consultation with the consultant who carried out a second eye examination. During the consultation the patient and consultant discussed whether the patient was suitable for the lens implant and discussed the risks involved.

Consent, Mental Capacity Act and Deprivation of Liberty Safeguards

- Staff had not completed Mental Capacity Act 2005 (MCA) training and this was not part of the mandatory training at the hospital. However, following our inspection, staff completed MCA training and the provider sent us evidence of this.
- The London Eye Hospital had a consent policy which was in date. The consent policy referred to relevant national legislation and to the Department of Health guidance on obtaining patient consent.
- The consent policy set out the protocol to be followed by staff where patients were deemed to lack capacity to consent to surgery. For example, the policy included circumstances when an assessment of whether the treatment would be in the patient's best interests might be considered. Staff were able to tell us what they would do if a patient lacked capacity or if they felt a patient did not understand what was being explained to them.
- Staff we spoke with demonstrated an understanding of the requirements of the MCA. They told us they always ensured patients understood the information that was being shared with them and gave patients numerous opportunities to ask questions.
- Consent forms were given to patients on numerous occasions so they could consider this prior to the procedure. If a patient called to enquire about the lens an information pack was sent to the patients in the post. This included a copy of the consent form and information about the lens implant. We reviewed this information and saw it included information about the risks involved in the surgery included the risk of vision becoming worse.
- Professional standards relating to eye surgery recommend a seven day 'cooling off' period to allow patients time to reflect between agreeing to go ahead with a procedure and surgery being performed. We reviewed ten patient records and found that there was no indication that the seven day 'cooling off' period had been discussed with the patient. Following the inspection we asked the hospital for information about the 'cooling off' period and staff told us the lead time for surgery was between two and six weeks and that there was therefore sufficient cooling off time. However, there was no evidence of the service monitoring compliance with the seven day 'cooling off' or discussing it with patients.
- We observed two consultations on the day of our inspection and saw risks were suitably discussed with patients and relatives. Patients were told the lens was not going to restore their vision and that results were varied. The consultant gave patients and relatives the opportunity to ask questions regarding risks.
- If patients were suitable for the lens implant surgery they were provided with all the key information including a copy of the consent form, terms and conditions and information about the lens implant and associated risks. The service had a checklist which patients signed to say they had received and understood all this information.
- If a patient opted to have the surgery a consent form was signed on the day of the surgery by both the patient and the doctor performing the surgery.
- We reviewed 10 patient records and found all patients had signed to say they had received all the documents and information. We also found all 10 patients had signed and dated consent forms.

Surgery

- We spoke with three patients and two relatives and all of them told us the risks of the lens implant surgery had been explained to them. Patients were told the surgery was not a solution but a way of working around the disorder.
- At the time of our inspection a new consent form had been drafted and was awaiting approval by the hospital's Medical Advisory Committee (MAC). The form had a larger font to make it more easily read by patients with age-related macular degeneration (AMD) and other sight-impairing conditions.
- As part of the inspection we reviewed ten complaints. All ten complaints had been investigated and responded to. The service responded to patients who had not been satisfied there had been an improvement in vision following surgery by demonstrating there had been objective improvements in vision. They did this by including eye charts with results of patients' visual acuity before and after surgery in their complaint responses.
- Staff told us that in future they would manage patients' expectations of lens implant surgery by highlighting that there is a risk of not noticing an improvement in vision following surgery due to the nature of age-related macular degeneration (AMD). Staff also said they would make patients aware that in some cases there may be deterioration in vision after surgery due to the natural progression of the condition as opposed to the lens not working.

Are surgery services caring?

Compassionate Care

- Prior to the inspection, we received information informing us there had been instances where staff spoke with patients in public areas failing to respect their privacy. However, during our inspection we observed two patient consultations which took place in consultation rooms where conversations could not be overheard.
- Patients and relatives we spoke with said staff respected and maintained their privacy and dignity.

Are surgery services responsive?

Learning from complaints and concerns

- The service had a system for identifying, receiving, recording, handling and responding to complaints made by people using the services. The service also had a complaints policy which was in date.
- An information pack with details on how to make a complaint was visible in the waiting area of the hospital. The pack included details about how long the hospital would take to respond to complaints.
- Between September 2016 and September 2017, London Eye Hospital (both locations combined) received 84 complaints overall. Of these, 16 related to lens implanted before August 2015 and seven related to lens implanted after August 2015. The main theme was patients not being satisfied there had been an improvement in vision following lens surgery

Are surgery services well-led?

Leadership and culture of service

- A medical director and a clinical manager led the service. The London Eye Hospital did not have a registered manager at the time of our inspection. It is a condition of Care Quality Commission registration that there be a registered manager in place.
- The leadership were aware of the information triggering this inspection and had made some changes to improve the service. For example, the new consent form to aid better understanding of risks for patients undergoing surgical procedures.

Governance, risk management and quality measurement (medical care level only)

Surgery

- We found there had been recent changes in the governance of the service with a recent appointment of a consultant as the medical director in September 2017.
- The hospital's medical advisory committee (MAC) was responsible for granting consultants' practicing privileges and carrying out consultant appraisals. We saw evidence of the MAC carrying out its responsibilities in relation to granting practicing privileges.
- The MAC met every six months in line with hospital's terms of reference for the MAC. We saw minutes for the meetings which showed attendance by consultants and the clinical manager. Incident reporting, complaints, infection control and consent were some of the topics discussed at the MAC meetings.
- Staff told us the hospital had a clinical governance committee made up of the same members as those making up the MAC. They also said the hospital had regular clinical governance meetings but did not provide us with the minutes for the meetings.
- There was poor communication between management in relation to complaints investigation. For example, when the manager responsible for investigating complaints left the organisation, other managers were unable to comment on why there had been delays in investigating three of the ten complaints we looked at.
- The hospital's risk register identified areas of risk and mitigating factors. For example, the log identified there was a risk related to managing patient expectations in relation to the results of lens implant surgery. The log stated that this was mitigated by the fact that the old version of the lenses (which triggered our concerns) was no longer being implanted and a recent update to the consent form to make it more informative.

Outstanding practice and areas for improvement

Areas for improvement

Action the provider SHOULD take to improve

- The provider should have a registered manager for the service.
- The provider should routinely collect and measure patient outcomes in order to assess the overall effectiveness of the service.
- The provider should ensure mental capacity training is part of the mandatory training for staff.
- The provider should ensure all staff are trained in safeguarding (adults and children) to the appropriate level.
- The provider should record minutes of clinical governance meetings.
- The provider should ensure effective communication between management in relation to complaints investigation and any delays.
- The provider must ensure there is a seven-day 'cooling off' period for patients consulting for eye surgery.