

# The London Eye Hospital

## Quality Report

4 Harley Street

London

W1G 9PB

Tel: 0207 060 2602

Website : <http://www.londoneyehospital.com/>

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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

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 4 Harley 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 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 patients 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 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, we identified areas of poor practice where the service needs to make improvements:

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

# Summary of findings

- 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 our inspection. Having a registered manager is a condition of registration with the Care Quality Commission.

Following the inspection we told the provider that it should take some action to help improve the service even though a regulation had not been breached. The details are at the end of this report.

Importantly the provider should:

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

**Amanda Stanford**

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

# Summary of findings

## Our judgements about each of the main services

### Service

#### Outpatients and diagnostic imaging

### Rating Summary of each main service

Outpatient appointments were the main activity at this hospital. Staff saw patients for consultations for lens implant surgery and other forms of eye surgery. Staff also saw patients post operatively to check the outcome of surgery. Staff performed surgery at another location separate to this 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 (three out of 16) had completed safeguarding training. Staff subsequently completed this training. 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 staff monitoring the seven-day 'cooling off' period or discussing it with patients.

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 - 4 Harley Street

**Services we looked at:**

Outpatients and diagnostic imaging

# 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. The hospital is open Monday to Friday 9am to 5.30pm.

Staff do not perform any surgery at this site. The location at 29a Wimpole Street is the surgical site where all surgical procedures take place.

## 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

We carried out this unannounced inspection in response to concerns received in August 2017 about 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 the Wimpole Street location following consultation at this hospital. An unannounced inspection was also carried out at the surgical site and the findings relating to 29a Wimpole Street 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.

## How we carried out this inspection

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 also took into account various documents provided to us such as evidence of staff training, policies, ten patient records and ten complaints.

## Information about The London Eye Hospital

The main activity at this location is outpatient services. Patients who consult at this location have their

## Summary of this inspection

procedure/s performed at another location managed by the provider (London Eye Hospital, 29a Wimpole Street, London). No surgery takes place at 4 Harley Street. The hospital is registered to provide diagnostic and screening procedures.

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.

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.



# 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 had not completed mental capacity 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.

### 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:

- 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.
- Staff sought patients' consent and explained risks of surgery at various stages of the consultation process.

### 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 consultation.

# 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 the service did not provide minutes of the clinical governance meetings.
- There was no registered manager at this hospital at the time of our inspection.

# Outpatients and diagnostic imaging

Safe	
Effective	
Caring	
Responsive	
Well-led	

## Summary of findings

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.

Our key findings were:

- 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, we found the following areas where the service needs to improve:

- Staff had not completed mental capacity training at the time of our inspection. They subsequently completed this training.
- 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 provide minutes of clinical governance meetings.
- The service did not have a registered manager at the time of our inspection. Having a registered manager is a condition of registration with the Care Quality Commission.

# Outpatients and diagnostic imaging

## Are outpatients and diagnostic imaging 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 this 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 subsequently completed this 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 outpatients and diagnostic imaging 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.

- 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.
- 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 hospital 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.

### 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.

# Outpatients and diagnostic imaging

- Staff 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 them opportunities to ask questions.
- An information pack containing a copy of the consent form was sent to patients enquiring about lens implant surgery prior to the day of the consultation. We reviewed this information and saw it included information about the risks involved in the surgery, for example, the possibility of vision becoming worse.
- During consultation for lens surgery staff discussed the consent form with the patient. The patient and consultant discussed whether the patient was suitable for the lens implant and the risks involved. The consent form was signed on the day of the surgery at the location where surgery took place.
- 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. During each consultation, the consultant told the patient there was no guarantee the lenses if implanted would restore vision and that results varied with each patient. We observed that the consultant gave patients and relatives the opportunity to ask questions regarding risks.
- Consultants assessed patients' suitability for lens implant surgery. If a patient was deemed a suitable candidate staff provided them with information about the surgery including a copy of the consent form, the hospital's terms and conditions, and information about the lens implant and associated risks. The service had a checklist which patients signed to confirm they had received and understood all this information.
- 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 AMD and other sight-impairing conditions.
- We reviewed ten patient records and found that in all ten records patients had signed to confirm they had received all the documents and information. We also found all ten patients had signed and dated consent forms.
- 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.

## Are outpatients and diagnostic imaging 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 outpatients and diagnostic imaging 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

# Outpatients and diagnostic imaging

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.

- 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 was 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.
- Four of the ten complaints we looked at had not been responded to within 20 working days in line with the hospital's policy. Staff were not able to comment on the delay investigating three of the complaints because the manager who had dealt with these complaints was no longer employed by the service. For the remaining complaint, the delay was caused by changes in management personnel while the complaint was still being investigated.
- 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' practising 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 these 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.

## Are outpatients and diagnostic imaging services well-led?

### Governance, risk management and quality measurement

# 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 should ensure there is a seven-day 'cooling off' period for patients consulting for lens implant surgery.