

Inspection framework: independent acute hospital

Log of changes since last version

Section / Report sub heading	Page number	Detail of update
All	All	The whole framework has been reviewed and updated to reflect the new single assessment framework for health. Hyperlinks were updated where they had broken and where they changed from 2017 to 2018
all		Update reference links as per generic updates to all inspection frameworks: i.e safeguarding, NICEQS15, WRES.

Single specialty service: refractive eye surgery

This inspection framework should be used when inspecting the following types of service:

- Single specialty services providing solely or mainly refractive eye surgery

If refractive eye surgery is not the sole or main service provided but refractive eye surgery is being inspected under the core service inspection framework for surgery, inspectors will find it useful to refer to the additional prompts in this inspection framework.

Refractive eye surgery providers specialise in providing vision correction services, carrying out surgical procedures. This type of service is ordinarily provided for self-referring, self-pay patients. This type of surgery is functional in that the surgery can reduce a person's dependence on spectacles and contact lenses and is mostly elective surgery and not funded by the NHS or private medical insurers. The service may also include corneal surgery, laser eye surgery, refractive lens surgery, refractive lens exchange (RLE) and intraocular lens implants (IOLs).

Refractive surgery providers may also provide treatment of cataracts and vitrectomy which may be funded by the NHS or private medical insurance funding. However, to be included as a single specialty service these other ophthalmic surgery procedures must not be the provider's main purpose.

Providers are mostly corporate organisations, providing services in 'high-street' clinic locations.

This inspection framework includes all refractive eye surgery activities in a hospital or clinic setting, for example, planned (elective), day case and, rarely, emergency surgery. It includes anaesthetic services that are provided alongside the surgery, including local anaesthesia such as topical anaesthesia and or anaesthesia blocks.

All refractive eye surgery, intraocular surgery and any other treatments that are Regulated activities should be included where they are provided by the service.

Areas to inspect*

The inspection team should carry out an initial visual inspection of each area. Your observations should be considered alongside data/surveillance to identify areas of risk or concern for further inspection.

- Pre-operative assessment area or outpatient clinic equivalent
- Pre-admission ward/area (if one is part of the admission pathway for surgical patients) or equivalent clinic area
- Equipment rooms/storage/HSSD(Hospital Sterile Supplies Department) – particularly laser and related equipment
- Recovery
- Post-surgical areas or clinic areas where patients are following initial recovery from surgery.
- Other area where clinical examination may be carried out prior to and following the laser eye surgery

Interviews/focus groups/observations

You should conduct interviews of the following people at every inspection:

- People who use services and those close to them
- Registered Manager
- Nurse Lead or Head of Clinical Services
- Ophthalmic surgeon
- Laser eye surgery lead
- Anaesthesia lead
- Lead optometrist
- Laser Technician/Laser Protection Supervisor

You could gather information about the service from the following people, depending on the staffing structure:

- People who use services (there is likely to be an ideal opportunity to speak to people who use services when they attend pre-assessment appointments). Post-surgical case interviews would be important in understanding people’s care pathways/overall experience
- Surgeon
- Anaesthetist
- Operating Department Practitioner (ODP) – dependent on type of service.
- Registered nurse
- Pre-admission / assessment nurses – this may also be a role undertaken by optometrists in some provider organisations
- Lead nurse
- Technical specialists
- Support staff
- Lead Medical Officer.
- Booking clerk/officer

Safe

By safe, we mean people are protected from abuse* and avoidable harm.

*Abuse can be physical, sexual, mental or psychological, financial, neglect, institutional or discriminatory abuse.

Key lines of enquiry: S1

S1. How do systems, processes and practices keep people safe and safeguarded from abuse?

Report sub-heading: **Mandatory training**

Prompts	Professional standard	Sector specific guidance
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<ul style="list-style-type: none"> • S1.1 How are safety and safeguarding systems, processes and practices developed, implemented and communicated to staff? • S1.5 Do staff receive effective training in safety systems, processes and practices? 	<ul style="list-style-type: none"> • Skills for Health: Statutory/Mandatory Core Skills Training Framework https://www.skillsforhealth.org.uk/services/item/146-core-skills-training-framework 	<ul style="list-style-type: none"> • How often do staff receive refresher training? • Have staff undertaken appropriate life support training and is this updates so that they are able to deal with emergencies? • Are all staff, regardless of role, up to date on mandatory training on safeguarding?
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Report sub-heading: **Safeguarding**

<ul style="list-style-type: none"> • S1.1 How are safety and safeguarding systems, processes and practices developed, implemented and communicated to staff? • S1.2 How do systems, processes and practices protect people from abuse, neglect, harassment and breaches of their dignity and respect? How are these monitored and improved? • S1.3 How are people protected from discrimination, which might amount to abuse or cause psychological harm? This includes harassment and discrimination in relation to protected characteristics under the Equality Act. • S1.4 How is safety promoted in recruitment practice staff support arrangements, disciplinary procedures, and ongoing checks? (For example Disclosure and Barring Service checks). 	<ul style="list-style-type: none"> • Adult Safeguarding: Roles and Competencies for Health Care Staff: First edition: August 2018 https://www.rcn.org.uk/-/media/royal-college-of-nursing/documents/publications/2018/august/pdf-007069.pdf • Safeguarding Children and Young People: Roles and Competencies for Healthcare Staff Fourth edition: January 2019 https://www.rcn.org.uk/-/media/royal-college-of-nursing/documents/publications/2019/january/007-366.pdf • Safeguard Children: A guide to inter-agency working to safeguard and promote the welfare of children July 	<ul style="list-style-type: none"> • Who is responsible for post-operative care? • Who is responsible for follow up? • Are staff trained to recognise adults at risk and supported with effective safeguarding policies and procedures?
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<ul style="list-style-type: none"> • S1.5 Do staff receive effective training in safety systems, processes and practices? • S1.6 Are there arrangements to safeguard adults and children from abuse and neglect that reflect relevant legislation and local requirements? Do staff understand their responsibilities and adhere to safeguarding policies and procedures, including working in partnership with other agencies? • S1.7 Do staff identify adults and children at risk of, or suffering, significant harm? How do they work in partnership with other agencies to ensure they are helped, supported and protected? 	<p>2018</p> <p>https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/779401/Working_Together_to_Safeguard-Children.pdf</p> <ul style="list-style-type: none"> • Female genital mutilation multi-agency practice guidelines published in 2016 • DH Female Genital Mutilation and Safeguarding: Guidance for professionals March 2016 • Guidelines for physicians on the detection of child sexual exploitation (RCP, November 2015) • CQC cross sector DBS guidance. 	
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Report sub-heading: **Cleanliness, infection control and hygiene**

<ul style="list-style-type: none"> • S1.1 How are safety and safeguarding systems, processes and practices developed, implemented and communicated to staff? • S1.8 How are standards of cleanliness and hygiene maintained? Are there reliable systems in place to prevent and protect people from a healthcare-associated infection? 	<ul style="list-style-type: none"> • NICE QS61 Statement 3: People receive healthcare from healthcare workers who decontaminate their hands immediately before and after every episode of direct contact or care. • RC Ophthalmology Ophthalmic Services Guidance 2013 – Theatres • RCOphth Ophthalmic Instrument Decontamination October 2016 	<ul style="list-style-type: none"> • How does the service ensure standards of cleanliness in a laser/clinical treatment room or theatre environment in line with RCOphth professional standards and guidance? • Is intraocular refractive surgery performed within a standard ophthalmic operating theatre environment? • Is laser refractive surgery performed in a
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	<p>https://www.rcophth.ac.uk/standards-publications-research/ophthalmic-services-guidance-2/</p> <ul style="list-style-type: none"> • Decontamination of surgical instruments (CFPP 01-01) • https://www.gov.uk/government/publications/the-health-and-social-care-act-2008-code-of-practice-on-the-prevention-and-control-of-infections-and-related-guidance • NICE QS61 Statement 5: People who need a vascular access device have their risk of infection minimised by the completion of specified procedures necessary for the safe insertion and maintenance of the device and its removal as soon as it is no longer needed. 	<p>minimal access intervention operating environment with a log of temperature and humidity conditions demonstrating that these are being maintained consistently within the range for safe operation of equipment specified by the manufacturers of the lasers being used?</p> <ul style="list-style-type: none"> • How does the service ensure surgical instruments are decontaminated in accordance with Health Technical Memorandum (HTM) 01-01: management and decontamination of surgical instruments (medical devices) used in acute care • How does the service screen new cases for MRSA/C-difficile? • How does the service ensure systems, process and practice reflect relevant elements of NICE guidance regarding surgical site Infection?
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Report sub-heading: Environment and equipment

<ul style="list-style-type: none"> • S1.1 How are safety and safeguarding systems, processes and practices developed, implemented and communicated to staff? • S1.9 Do the design, maintenance and use of facilities and premises keep people safe? • S1.10 Do the maintenance and use of 	<ul style="list-style-type: none"> • RCOphth professional standards for refractive surgery published April 2017 see Point 4.2 on page 7. • RCOphth Ophthalmic Services Guidance 2013 – Theatres • MHRA guidance on the safe use of lasers, intense light source systems 	<ul style="list-style-type: none"> • Are facilities, surgical and anaesthetic equipment including resuscitation and anaesthetic equipment available, fit for purpose and checked in line with professional guidance? • How does the service demonstrate that it complies with optical radiation safety guidance?
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equipment keep people safe?

- S1.11 Do the arrangements for managing waste and clinical specimens keep people safe? (This includes classification, segregation, storage, labelling, handling and, where appropriate, treatment and disposal of waste.)

[and LEDs in medical, surgical. Dental and aesthetic practices](#) Sept 2015 For example;

Laser Protection Adviser duties (p10) e.g. Undertake risk assessments before the laser or IPL is operated, Identification of the Laser Controlled Area, etc.

Local rules content (p21) e.g. Management safety structure, register of Authorised Users, defined region and limits of the Controlled Area

Use of warning signs (p27) e.g. warning signs being placed at each entrance to the Controlled Area.

- [Guidance on Control of Artificial Optical Radiation HSE](#) 2010
- [AAGBI guidelines for checking for anaesthetic equipment / checklist.](#)
- [RCS Good Surgical Practice 2014](#)
- RCOphth [Professional Standards for Refractive Surgery](#) published April 2017
<https://www.rcophth.ac.uk/2017/04/new-refractive-surgery-standards-provide-improved-quality-of-care-and-patient-information-2/>
- [Health and Safety Executive: Management of Health and Safety Regulations at Work Regulations 2006](#)

- Does the service have either a stand-alone optical radiation policy or one that is part of a wider radiation protection policy, as suggested in the MHRA guidance, which follows HSE guidance on Control of Artificial Optical Radiation 2010?
- Is the policy tied into other management policies so that it can be managed in the same way as other activities?

- How does the service demonstrate that it follows guidance from the provider's laser or optical radiation safety committee and feeds back to the committee?
- How does the service demonstrate it undertakes suitable risk assessments that are reviewed annually or sooner if required, such as when equipment is changed or upgraded?
- How does the service ensure the safe use of its lasers in line with [MHRA guidance](#)?
- How does the service demonstrate that a Laser Protection Adviser is consulted and that the LPA's duties are undertaken appropriately?
- How does the service ensure that the

- HSE Maintaining portable electrical equipment
<http://www.hse.gov.uk/pUbns/priced/hsg107.pdf>
- Managing Medical Devices Guidance for healthcare and social services organisations April 2015
https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/421028/Managing_medical_devices_-_Apr_2015.pdf

area around working lasers and intense pulsed light sources is controlled to protect other persons while treatment is in progress, that the **Controlled Area** is clearly defined and not used for other purposes, or access to areas, when treatment is being carried out?

- How does the service demonstrate appropriate use of laser warning signs?
- How does the service demonstrate that it follows and regularly reviews **local rules** that all staff understand them?
- Is the risk assessment drafted by the LPA, LPS and/or other appropriate staff, e.g. Authorised user(s) in line with HSE regulations? Is there evidence of appropriate risk assessment of the Controlled Area being undertaken before laser use?
- **If patients receive intravenous sedation** is there appropriate facilities and equipment in place? For example:
 - o an anaesthetist
 - o an DP/ODA/PA(A)/anaesthetic nurse
 - o IV access
 - o pulse oximetry
 - o non-invasive blood pressure monitoring
 - o ECG

- o resuscitation equipment
- o recovery facilities with level 2 capacity, appropriate nursing staff, and the facility for overnight stay in patients who are slow to recover from the effects of sedation or who experience medical problems during sedation.

Key line of enquiry: **S2**

S2. How are risks to people assessed, and their safety monitored and managed so they are supported to stay safe?

Report sub-heading: **Assessing and responding to patient risk**

Prompts	Professional standard	Sector specific guidance
<ul style="list-style-type: none"> • S2.5 Are comprehensive risk assessments carried out for people who use services and risk management plans developed in line with national guidance? Are risks managed positively? • S2.6 How do staff identify and respond appropriately to changing risks to people who use services, including deteriorating health and wellbeing, medical emergencies or behaviour that challenges? Are staff able to seek support from senior staff in these situations? 	<ul style="list-style-type: none"> • Sepsis: recognition, diagnosis and early management (NICE Guideline 51) • Pre-operative assessment should be in line with NICE guideline NG45 Routine preoperative tests for elective surgery April 2016 • RCoA Guidance on the Provision of Ophthalmic Anaesthesia Services 2019 . <i>Point 3.14. Owing to the risk of life threatening complications, sharp needle-based blocks (e.g. peribulbar or retrobulbar block) should not be administered by non-medically-qualified personnel. Intravenous</i> 	<ul style="list-style-type: none"> • Does the service have an admission/screening policy setting out safe and agreed criteria for admission of people using the service for each procedure they will be undergoing? <ul style="list-style-type: none"> o How does the service assure itself that people are well enough to undergo RES? • How does the service ensure pre-operative assessments has been carried in out in line with NICE guidance? • How does the service ensure patients are selected for treatment in accordance with professional guidelines? • How does the service ensure it administers local anaesthesia in line with

access should be established prior to performing sharp needle blocks and for any patient deemed to be high risk due to severe co-morbidity.

- [Royal College of Anaesthetists and the Royal College of Ophthalmologists 2012: local anaesthesia for ophthalmic surgery](#) sets out the following in section 7 - *With careful selection, explanation, reassurance and a sympathetic approach most patients accept ophthalmic surgery under local anaesthesia. This is greatly facilitated by continuity of staff care at all stages. However, there will remain a proportion of patients who may benefit from sedation. Ideally, the patient undergoing ophthalmic surgical procedures should be fully conscious, responsive, and without anxiety, discomfort or pain`.*
- WHO [Surgical Safety Checklist for Cataract Surgery only.](#)
- [The RCoA Guidance on the Provision of Ophthalmic Anaesthesia Services 2019](#) sets out in 5.7 that `There should be a robust procedure for checking the laterality of the eye to be operated on prior to local anaesthetic block or general anaesthesia. This

RCoA Guidance for Provision of Ophthalmic Anaesthesia Services?

- How does the service ensure compliance with the 5 steps to safer surgery, World Health Organisation (WHO) surgical checklist including marking of the surgical site? (In cases where a local anaesthetic block is used this will include checking the laterality of the eye to be operated on prior to local anaesthetic block being administered)
- In cases where intraocular surgery is carried out is there compliance with the WHO checklist for cataract surgery, such as:
 - What refractive outcome is planned?
 - What lens model and power is to be used?
 - Is the correct lens implant present?
- How does the service ensure that there is an appropriate 24-hour emergency call or hotline arrangements in place following discharge?
- Are there protocols for the transfer of people using services to NHS (or other appropriate facilities) in the event of serious complications?

	<p>should include the eye being marked with an indelible mark by the responsible surgical team prior to admission to the operating theatre. The RCoA/ NPSA 'Stop before you block' protocols should be adhered to.</p> <ul style="list-style-type: none"> • The RCOphth Professional Standards for Refractive Surgery April 2017 sets out that there should be an open line of communication (mobile or 24-hour telephone number) with the operating surgeon or an experienced refractive surgeon on-call. Although calls may be triaged through non-medical staff, immediate onward communication to the surgeon on-call should be available 	
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Report sub-heading: Nurse staffing

<ul style="list-style-type: none"> • S2.1 How are staffing levels and skill mix planned and reviewed so that people receive safe care and treatment at all times and staff do not work excessive hours? • S2.2 How do actual staffing levels and skill mix compare with the planned levels? Is cover provided for staff absence? • S2.3 Do arrangements for using bank, agency and locum staff keep people safe at all times? • S2.4 How do arrangements for handovers 	<ul style="list-style-type: none"> • <u>How to ensure the right people, with the right skills, are in the right place at the right time: A guide to nursing, midwifery and care staffing capacity and capability?</u> National Quality Board • RCOphth: Ophthalmic Services Guidance - Theatres • RCoA Guidance on the Provision of Ophthalmic Local Anaesthesia Services (Section 1) 	<ul style="list-style-type: none"> • Is guidance on staffing levels followed, as set out in The National Quality Board guidance, including consideration of specific guidance on staffing in ophthalmic theatres? • If an anaesthetist is not present is there appropriately trained anaesthetic nurse, ophthalmic theatre nurse or operating department practitioner (ODP) present to monitor the patient during establishment of local anaesthesia?
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<p>and shift changes ensure that people are safe?</p> <ul style="list-style-type: none"> • S2.7 How is the impact on safety assessed and monitored when carrying out changes to the service or the staff? 		<ul style="list-style-type: none"> • If sedation is employed how does the service ensure that there is a dedicated skilled assistance for the anaesthetist provided?
<p>Report sub-heading: Medical staffing</p>		
<ul style="list-style-type: none"> • S2.1 How are staffing levels and skill mix planned and reviewed so that people receive safe care and treatment at all times and staff do not work excessive hours? • S2.2 How do actual staffing levels and skill mix compare with the planned levels? Is cover provided for staff absence? • S2.3 Do arrangements for using bank, agency and locum staff keep people safe at all times? • S2.4 How do arrangements for handovers and shift changes ensure that people are safe? • S2.7 How is the impact on safety assessed and monitored when carrying out changes to the service or the staff? 	<ul style="list-style-type: none"> • Laser Protection Adviser (LPA) refer to: MHRA guidance on laser safety: Point 3.3 guidance for private sector providers on when to consult an LPA. • Public Health England Laser Protection Adviser services • RCoA Guidance on the Provision of Ophthalmic Anaesthesia Services 2019. See summary, point 3.14 • Refer to RCOphth Professional Standards for Refractive Surgery published April 2017, which sets out standards about holding the RCOphth Certificate in Laser Refractive surgery. NB after 1 August 2018 Refractive Surgeons who commence refractive surgery practice should be on the GMC Specialist Register in Ophthalmology and hold the CertLRS entry level qualification.) 	<ul style="list-style-type: none"> • How does the service ensure appropriate Operational Laser Protection Supervisor cover? • How does the service ensure appropriate access to a suitable Laser Protection Adviser (LPA)? • How does the service ensure that there is access to consultant medical input if required in an emergency and post-operatively? • Does the service ensure that surgeons, who have been performing refractive eye prior to 1 August 2018, either hold the CertLRS or be on the GMC Specialist Register in Ophthalmology, and hold evidence in their last revalidation cycle of an established refractive surgery practice? • Does the service ensure that in the (unlikely) event that intravenous sedation is used, that it is administered under the direct supervision of an anaesthetist?

- Does the service ensure that local anaesthetic blocks are only performed by an indemnified practitioner who has been specifically trained? (A trained surgeon or anaesthetist must administer needle-based blocks) Sharp needle blocks should only be performed by doctors.

Key line of enquiry: S3

S3. Do staff have all the information they need to deliver safe care and treatment to people?

Prompts

Professional standard

Sector specific guidance

Report sub-heading: Records

<ul style="list-style-type: none"> • S3.1 Are people’s individual care records, including clinical data, written and managed in a way that keeps people safe? • S3.2 Is all the information needed to deliver safe care and treatment available to relevant staff in a timely and accessible way? (This may include test and imaging results, care and risk assessments, care plans and case notes.) • S3.3 When people move between teams, services and organisations (which may include at referral, discharge, transfer and transition), is all the information needed for their ongoing care shared appropriately, in a timely way and in line with relevant protocols? 	<ul style="list-style-type: none"> • Records management code of practice for health and social care Sets out standards required for the management of records for organisations who work within, or under contract to the NHS in England. • NICE QS15 statement 3; People using adult NHS services experience coordinated care with clear and accurate information exchange between relevant health and social care professionals. • The GMC Guidance for all doctors who offer cosmetic interventions which came into effect on 1 June 2016 sets out in paragraph 40 and 41 	<ul style="list-style-type: none"> • How does the service ensure that its record management policy follows the principles of the Record Management Code of Practice for all NHS-funded care? • How does the service ensure that appropriate pre-operative assessment is recorded? • How does the service ensure that consultant operating records and the patient clinical record is communicated to the GP where necessary? • How does the service ensure that record keeping complies with the GMC guidance for doctors who offers cosmetic
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- S3.4 How well do the systems that manage information about people who use services support staff, carers and partner agencies to deliver safe care and treatment? (This includes coordination between different electronic and paper-based systems and appropriate access for staff to records.)

You must keep records that contain personal information about patients securely and in line with:

- Any data protection requirements
- Our Confidentiality guidance
- Guidance published by the UK health departments, even when the interventions are provided outside the National Health Service.
- [MHRA guidance on the safe use of lasers, intense light source systems and LEDs in medical, surgical. Dental and aesthetic practices](#)
- [RCS Good Surgical Practice 2014 Point 1.2.1](#)
GMC: [Good medical practice about record keeping](#).
- RCoA: Guidance on the Provision of Anaesthesia Services for Day Surgery 2019
<https://www.rcoa.ac.uk/document-store/guidelines-the-provision-of-anaesthesia-services-day-surgery-2019>

surgery?

Note: the GMC have advised Laser and implant based refractive eye surgery is considered to be covered within the scope of this the GMC guidance for doctors who offer cosmetic interventions. http://www.gmc-uk.org/guidance/ethical_guidance/29160.asp

- How does the service ensure that appropriate records are maintained every time the laser is operated?
- Is there a system in place to ensure that medical records generated by staff holding practising privileges are available to staff (or other providers) who may be required to provide care or treatment to the patient?
- How is discharge communicated to GPs, where appropriate, and referring optometrists? How soon after discharge does this occur?
- Are care summaries sent to the patient's GP/optometrist on discharge to ensure continuity of care within the community?
- How does the service ensure that details of the surgery are sent to the patient and to the patient's GP?

Key line of enquiry: **S4**

S4. How does the provider ensure the proper and safe use of medicines, where the service is responsible?

Prompts	Professional standard	Sector specific guidance
Report sub-heading: Medicines		
<ul style="list-style-type: none"> • S4.1 How are medicines and medicines-related stationery managed (that is, ordered, transported, stored and disposed of safely and securely)? (This includes medical gases and emergency medicines and equipment.) • S4.2 Are medicines appropriately prescribed, administered and/or supplied to people in line with the relevant legislation, current national guidance or best available evidence? • S4.3 Do people receive specific advice about their medicines in line with current national guidance or evidence? • S4.4 How does the service make sure that people receive their medicines as intended, and is this recorded appropriately? • S4.5 Are people's medicines reconciled in line with current national guidance on transfer between locations or changes in levels of care? • S4.6 Are people receiving appropriate therapeutic drug and physical health monitoring with appropriate follow-up in accordance with current national guidance or evidence? • S4.7 Are people's medicines regularly reviewed including the use of 'when required' medicines? • S4.8 How does the service make sure that 	<ul style="list-style-type: none"> • NICE QS61 Statement 1: People are prescribed antibiotics in accordance with local antibiotic formularies. 	<ul style="list-style-type: none"> • Are allergies clearly documented in the prescribing document used? • Are nursing staff aware of policies on administration of controlled drugs as per NMC standards for medicines management? • Are there local microbiology protocols for the administration of antibiotics and are prescribers using them? • Do sign-off processes include, where the service uses them, cytotoxic medicines, such as Mitomycin C to reduce post-operative haze other treatments off-licence, such as Lucentis, to treat post-operative macular oedema?

people's behaviour is not controlled by excessive or inappropriate use of medicines?

Key line of enquiry: **S5 & S6**

S5. What is the track record on safety?

S6. Are lessons learned and improvement made when things go wrong?

Prompts	Professional standard	Sector specific guidance
Report sub-heading: Incidents		
<ul style="list-style-type: none"> S5.1 What is the safety performance over time? S5.2 How does safety performance compare with other similar services? S5.3 How well safety is monitored using information from a range of sources (including performance against safety goals where appropriate)? S6.1 Do staff understand their responsibilities to raise concerns, to record safety incidents, concerns and near misses, and to report them internally and externally, where appropriate? S6.2 What are the arrangements for reviewing and investigating safety and safeguarding incidents and events when things go wrong? Are all relevant staff, services, partner organisations and people who use services involved in reviews and investigations 	<ul style="list-style-type: none"> A never event is a serious incident that is wholly preventable as guidance, or safety recommendations providing strong systemic protective barriers, are available at a national level, and should have been implemented by all providers. The event has the potential to cause serious patient harm or death, has occurred in the past and is easily recognisable and clearly defined. <ul style="list-style-type: none"> Revised never events policy and framework (2015) Never events list 2015/16 Never Events List 2015/15 - FAQ Serious Incidents (SIs) should be investigated using the Serious Incident Framework 2015. MHRA guidance on the safe use of lasers, intense light source systems 	<ul style="list-style-type: none"> Are <u>Never Events</u> in the refractive eye surgery clinic monitored? Are Serious Incidents (SI) in the laser eye surgery clinic (including anaesthesia) Investigated by appropriately trained and resourced staff and/or investigation teams that are sufficiently removed from the incident to be able to provide an objective view?. Are infection and complication rates for all laser eye and ophthalmic surgery monitored? How do they ensure such complications which are treated elsewhere (i.e. they go to the NHS) are detected and learning occurs? Are any complications audited? If so, how accessed i.e. adequate follow up to ensure they are identified? How is learning from complaints

<ul style="list-style-type: none"> • S6.3 How are lessons learned, and themes identified and is action taken as a result of investigations when things go wrong? • S6.4 How well is the learning from lessons shared to make sure that action is taken to improve safety? Do staff participate in and learn from reviews and investigations by other services and organisations? • S6.5 How effective are the arrangements to respond to relevant external safety alerts, recalls, inquiries, investigations or reviews? 	<p>and LEDs in medical, surgical. Dental and aesthetic practices: <i>If there is a suspected or actual ocular injury, staff should report the incident to both their employer and LPA. An ophthalmologist should then perform a medical examination within 24 hours of the event, so that the extent of the injury can be identified.</i></p> <ul style="list-style-type: none"> • (NICE QS66 Statement 4): For adults who receive intravenous (IV) fluid therapy in hospital, clear incidents of fluid mismanagement are reported as critical incidents. • Duty of Candour: As soon as reasonably practicable after becoming aware that a notifiable safety incident has occurred a health service body must notify the relevant person that the incident has occurred, provide reasonable support to the relevant person in relation to the incident and offer an apology. 	<p>identified and disseminated?</p> <ul style="list-style-type: none"> • How is a relevant safety alert acted on? • How have staff used learning from an incident(s) to drive improvement in practice. What difference did it make to patient care? • Do surgical (including anaesthetic) reviews feed into service improvement? Are these undertaken monthly, MDT attended, minuted and lessons learnt?
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Report sub-heading: **Safety Thermometer**

<ul style="list-style-type: none"> • S5.1 What is the safety performance over time? • S5.2 How does safety performance compare with other similar services? • S5.3 How well safety is monitored using information from a range of sources (including performance against safety goals 	<ul style="list-style-type: none"> • NICE QS3 Statement 1: All patients, on admission, receive an assessment of VTE and bleeding risk using the clinical risk assessment criteria described in the national tool. • NICE QS3 Statement 4: Patients are re-assessed within 24 hours of 	
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where appropriate)?	admission for risk of VTE and bleeding.	
	<ul style="list-style-type: none"> • Safety Thermometer 	

Effective

By effective, we mean that people's care, treatment and support achieves good outcomes, promotes a good quality of life and is based on the best available evidence.

Key line of enquiry: E1

E1. Are people's care, treatment and support achieves good outcomes, promotes a good quality of life and is based on the best available evidence.

Prompts	Professional standard	Sector specific guidance
Report sub-heading: Evidence-based care and treatment		
<ul style="list-style-type: none"> • E1.1 Are people's physical, mental health and social needs holistically assessed, and is their care, treatment and support delivered in line with legislation, standards and evidence-based guidance, including NICE and other expert professional bodies, to achieve effective outcomes? • E1.2 What processes are in place to ensure there is no discrimination, including on the grounds of protected characteristics under the Equality Act, when making care and treatment decisions? 	<ul style="list-style-type: none"> • RCOphth professional standards for refractive surgery April 2017. RCOphth clinical guidelines for example • Cataract surgery 2010 • Intra-ocular injections by non-medical healthcare professional 2013 • Local anaesthesia in ophthalmic surgery 2012 • GMC pages about refractive eye surgery. • RCS Good Surgical Practice 	<ul style="list-style-type: none"> • How does the service ensure that refractive eye surgery is managed in accordance with professional and expert guidance? Including guidance published by GMC about doctors performing cosmetic interventions? • How does the service ensure that professional guidance is followed on recording and management of ocular device implants? • How does the service ensure that care is managed in accordance with NICE

<ul style="list-style-type: none"> • E1.3 How is technology and equipment used to enhance the delivery of effective care and treatment and to support people's independence? • E1.4 Are the rights of people subject to the Mental Health Act 1983 (MHA) protected and do staff have regard to the MHA Code of Practice? • E1.7 Are people told when they need to seek further help and advised what to do if their condition deteriorates? 	<p>(September 2014)</p> <ul style="list-style-type: none"> • 2015 GMC Guidance for doctors who offer cosmetic interventions. http://www.gmc-uk.org/guidance/ethical_guidance/28688.asp <p>NICE Guidance:</p> <ul style="list-style-type: none"> • IPG164 Photorefractive surgery • CG3 Preoperative tests • QS49 Surgical Site Infection • NG51 Sepsis: recognition, diagnosis and early management • NICE Guidance IPG164 Photorefractive (laser) surgery for the correction of refractive errors March 2006 	<p>guidelines, for example</p> <ul style="list-style-type: none"> ○ IPG164 Photorefractive surgery ○ CG3 Preoperative tests ○ QS49 Surgical Site Infection ○ NG51 Sepsis: recognition, diagnosis and early management. <ul style="list-style-type: none"> • How does the service ensure that people undergoing laser refractive surgery receive appropriate pre-operative assessment and discussion as set out in the GMC Guidance for doctors who offer cosmetic interventions and also the RCOphth professional standards?
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Report sub-heading: Nutrition and hydration

<ul style="list-style-type: none"> • E1.5 How are people's nutrition and hydration needs (including those related to culture and religion) identified, monitored and met? Where relevant, what access is there to dietary and nutritional specialists to assist in this? 		
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Report sub-heading: Pain relief

<ul style="list-style-type: none"> • E1.6 How is a person's pain assessed and managed, particularly for those people where there are difficulties in communicating? 	<p>Joint guidelines from the Royal College of Anaesthetists and the RCOphth Feb 2012: Local anaesthesia for ophthalmic surgery http://www.rcoa.ac.uk/document-store/local-anaesthesia-ophthalmic-</p>	<ul style="list-style-type: none"> • How does the service ensure that patients undergo surgical procedures without experiencing discomfort or pain?
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[surgery](#)

- [Core Standards for Pain Management Services in the UK](#)

Key line of enquiry: E2

E2. How are people’s care and treatment outcomes monitored and how do they compare with other similar services?

Prompts	Professional standard	Sector specific guidance
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Report sub heading: **Patient outcomes**

<ul style="list-style-type: none"> • E2.1 Is information about the outcomes of people's care and treatment (both physical and mental where appropriate) routinely collected and monitored? • E2.2 Does this information show that the intended outcomes for people are being achieved? • E2.3 How do outcomes for people in this service compare with other similar services and how have they changed over time? • E2.4 Is there participation in relevant quality improvement initiatives, such as local and national clinical audits, benchmarking, (approved) accreditation schemes, peer review, research, trials and other quality improvement initiatives? Are all relevant staff involved in activities to monitor and use information to improve outcomes? 	<ul style="list-style-type: none"> • Optional audits suggested by RCOphth: Perceptions by patients of the quality of care provided by the refractive surgery service Re-treatment or treatment enhancement following laser refractive surgery • RCS Good Surgical Practice (September 2014) • NICE interventional procedure guidance 164 Photorefractive (laser) surgery for the correction of refractive errors 2006 <p>Where appropriate: Detection and management of outliers for National Clinical Audits: Implementation guide for NCAPOP providers</p>	<ul style="list-style-type: none"> • How does the service ensure that care bundles are in place to improve patient outcomes e.g. surgical site infections? • Does the service ensure that audit is undertaken in order to identify areas for improved outcomes? • How does the service monitor and ensure that visual acuity outcomes for the people they serve are within expected ranges in line with, for example, NICE guidance? • How does the service monitor and improve patient perceptions of quality of care and outcomes, for example by undertaking optional audits suggested by RCOphth? • does the service investigate why performance was much worse than
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https://www.hqip.org.uk/wp-content/uploads/2018/05/implementation-guide_NCAPOP-suppliers_FINAL-2.pdf

Include the following prompt and national guidance: For statistics audit outliers, and in line with the National Guidance on the management of audit outliers.

expected, and make changes to improve care?

Key line of enquiry: E3

E3. How does the service make sure that staff have the skills, knowledge and experience to deliver effective care, support and treatment?

Prompts	Professional standard	Sector specific guidance
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Report sub heading: Competent staff

<ul style="list-style-type: none"> E3.1 Do people have their assessed needs, preferences and choices met by staff with the right skills and knowledge? E3.2 How are the learning needs of all staff identified? Do staff have appropriate training to meet their learning needs to cover the scope of their work and is there protected time for this training? E3.3 Are staff encouraged and given opportunities to develop? E3.4 What are the arrangements for supporting and managing staff to deliver effective care and treatment? (This includes one-to-one meetings, appraisals, coaching and mentoring, clinical supervision and revalidation.) 	<ul style="list-style-type: none"> Royal College of Ophthalmologists Certificate in Laser Eye Surgery RCOphth Professional Standards for Refractive Surgery April 2017. Refer to section 2 of these standards. MHRA Guidance on the safe use of lasers, intense light source systems and LEDs in medical, surgical, dental and aesthetic practices: <ul style="list-style-type: none"> LPS competencies & Authorised User competencies Training will cover three areas: equipment-based training, safety training and procedural training. 	<ul style="list-style-type: none"> How does the service ensure that consultant surgeons only carry out surgery that they are trained, skilled, competent and experienced to perform? How does the provider ensure that surgeons undertake a minimum of 50 hours of continuing professional development activity (CPD) per year across their whole practice, or 250 hours across the 5-year revalidation cycle? These activities should be relevant to their refractive surgery practice and support their current skills, knowledge and career development. In each surgeons revalidation cycle is there at least one patient feedback exercise from their refractive surgery
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<ul style="list-style-type: none"> • E3.5 How is poor or variable staff performance identified and managed? How are staff supported to improve? • E3.7 Are volunteers recruited where required, and are they trained and supported for the role they undertake? 	<p>The LPS or LPA should ‘talk through’ the content of the local rules with staff to ensure their understanding of the document.</p> <ul style="list-style-type: none"> • NICE guidance: clinicians should have adequate training before undertaking laser refractive surgery IPG164 • The Joint RCoA and Royal College of Ophthalmologists guidelines 2012. NB: The need for ALS training and capability is based on a service where intraocular procedures are planned, or there is any form of sedation or local anaesthetic given by a technique involving injection, in which circumstances the Joint RCoA and Royal College of Ophthalmologists guidelines should be fully applied. The Royal College of Anaesthetists Guidance on the Provision of Ophthalmic Anaesthesia Services 2019 applies where anaesthetists are involved in delivering the care and sets out that sets out that ‘In isolated units, where no anaesthetist or medical emergency team is immediately available, there should be at least one person with advanced life-support training or equivalent. A clear and agreed pathway should be in place for isolated units to enable the patient to receive appropriate advanced medical care, including 	<p>practice and presentation of the results for discussion at appraisal, demonstrating the actions taken and the learning achieved?</p> <ul style="list-style-type: none"> • How does the service ensure that the Laser Protection Supervisor (LPS) and Authorised Users have relevant competencies to undertake their duties? • How does the service ensure that all laser light users have Core of Knowledge training, including when equipment is upgraded or replaced? • Can the service demonstrate that all staff have read and understood the ‘local rules’? • Where the unit is free-standing and there is no immediate access to a formal cardiac arrest team, and where intraocular procedures are planned, or there is any form of sedation or local anaesthetic given by a technique involving injection, is there at least one person with Advanced Life Support or equivalent? • What are the arrangements to ensure staff working on an occasional or infrequent basis e.g. agency staff are competent and skilled to carry out care and treatment that they provide?
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	<p>intensive care, in the event of it being required.</p> <ul style="list-style-type: none"> • Safety: 'Core of Knowledge' courses provide basic knowledge for staff that either work directly with lasers and/or IPL systems, or assist with such equipment. • NICE guideline NG51 Sepsis: recognition, diagnosis and early management 	<ul style="list-style-type: none"> • Are there arrangements in place to make sure that local healthcare providers are informed in cases where a staff member is suspended from duty? • How does the service ensure staff have appropriate training in administration of cytotoxic medicines, such as Mitomycin C, or other treatments, such as Lucentis 'off-licence', if used, to help with any post-operative complications, including preparation where they are not already reconstituted? • How does the service ensure staff maintain their skills in recognising and treating sepsis in a timely way?
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Key line of enquiry: **E4**

E4. How well do staff, teams and services within and across organisations work together to deliver effective care and treatment?

Prompts	Professional standard	Sector specific guidance
Report sub-heading: Multidisciplinary working		
<ul style="list-style-type: none"> • E4.1 Are all necessary staff, including those in different teams, services and organisations, involved in assessing, planning and delivering care and treatment? • E4.2 How is care delivered and reviewed in a coordinated way when different teams, services or organisations are involved? • E4.3 How are people assured that they will 	<ul style="list-style-type: none"> • The Academy of Royal Colleges Guidance for Taking Responsibility: Accountable Clinicians and Informed Patients. • MHRA Device Bulletin Guidance on the safe use of lasers, intense light source systems and LEDs in medical, surgical, dental and aesthetic 	<ul style="list-style-type: none"> • How do staff within the service work together to meet the needs of people? e.g. Team working between optometrists/ophthalmologists staff e.g. sharing information on never events. • Do non-medical staff perform extended roles and how are their training, competencies and adherence to protocols ensured?"

<p>receive consistent coordinated, person-centred care and support when they use, or move between different services?</p> <ul style="list-style-type: none"> E4.4 Are all relevant teams, services and organisations informed when people are discharged from a service? Where relevant, is discharge undertaken at an appropriate time of day and only done when any necessary ongoing care is in place? 	<p>practices. P13: The Clinical Laser Expert / Clinical LPS is expected to work with the Operational LPS.</p> <ul style="list-style-type: none"> RCOphth professional standards for Refractive Surgery – point 7.1 & 7.2 PHSO: A report of investigations into unsafe discharge from hospital Transition between inpatient hospital settings and community or care home settings for adults with social care needs (NICE guideline 27) 	<ul style="list-style-type: none"> How does the service ensure the all members of the care team has appropriate access to well organized records from the provider?
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Report sub-heading: **Seven-day services**

<ul style="list-style-type: none"> E4.5 How are high-quality services made available that support care to be delivered seven days a week and how is their effect on improving patient outcomes monitored? 		<ul style="list-style-type: none"> Are there appropriate protocols in place to refer or transfer patients in an emergency, if required? <p>How does the service a safe mechanism for patients to be looked after out of hours, if needed?</p>
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Key line of enquiry: **E5**

E5. How are people supported to live healthier lives and where the service is responsible, how does it improve the health of its population?

Prompts	Professional standard	Sector specific guidance
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Report sub-heading: **Health promotion**

<ul style="list-style-type: none"> • E5.1 Are people identified who may need extra support? This includes: <ul style="list-style-type: none"> • people in the last 12 months of their lives • people at risk of developing a long-term condition • carers • E5.2 How are people involved in regularly monitoring their health, including health assessments and checks, where appropriate and necessary • E5.3 Are people who use services empowered and supported to manage their own health, care and wellbeing and to maximise their independence? • E5.4 Where abnormalities or risk factors are identified that may require additional support or intervention, are changes to people’s care or treatment discussed and followed up between staff, people and their carers where necessary? • E5.5 How are national priorities to improve the population’s health supported? (For example, smoking cessation, obesity, drug and alcohol dependency, dementia and cancer.) 		
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Key line of enquiry: E6

E6. Is consent to care and treatment always sought in line with legislation and guidance?

Prompts	Professional standard	Sector specific guidance
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Report sub-heading: **Consent, Mental Capacity Act and DOLs**

<ul style="list-style-type: none"> • E6.1 Do staff understand the relevant consent and decision making requirements of legislation and guidance, including the Mental Capacity Act 2005 and the Children's Acts 1989 and 2004 and other relevant national standards and guidance? • E6.2 How are people supported to make decisions in line with relevant legislation and guidance? • E6.3 How and when is possible lack of mental capacity to make a particular decision assessed and recorded? • E6.4 How is the process for seeking consent monitored and reviewed to ensure it meets legal requirements and follows relevant national guidance? • E6.5 When people lack the mental capacity to make a decision, do staff ensure that best interests decisions are made in accordance with legislation? • E6.6 How does the service promote supportive practice that avoids the need for physical restraint? Where physical restraint may be necessary, how does the service ensure that it is used in a safe, proportionate, and monitored way as part of a wider person centred support plan? • E6.7 Do staff recognise when people aged 16 and over and who lack mental capacity are being deprived of their liberty, and do they seek authorisation to do so when they 	<ul style="list-style-type: none"> • RCOphth professional standards for refractive surgery April 2017. Refer to section 5 of these standards which set out a two-stage process in which consent forms are taken away from the consultation at which the procedure recommendation is made by the operating surgeon, and patients are given an open line of communication with their surgeon (email, telephone, or optional repeat consultation) for follow-up questions during a cooling off period. A minimum cooling off period of one week is recommended between the procedure recommendation and surgery. Specifically, patients should not be offered time limited discounts or a refund of the initial consultation fee if they choose to proceed. Rates of conversion to surgery should not be used as a performance measure for surgeons, optometrists or other staff. • Consent: patients and doctors making decisions together (GMC) • Consent - The basics (Medical Protection) • Department of Health reference guide to consent for examination or 	<ul style="list-style-type: none"> • How do staff ensure that <i>informed</i> consent is given by speaking pre and post op to patients about their understanding of their surgery (is there documented evidence of risk assessment and care plans)? • Is there clearly written patient information indicating risks/benefits? • How does the service ensure that staff advise people about all possible costs that will be incurred in a timely manner and check that people understand this information/? • Are processes in place to aide translation during the consent process? • Is the consent process always the responsibility of the surgeon performing the procedure? • How does the service ensure that there is always an adequate cooling off period of at least one week for reflection period between the patient agreeing to undergo surgery and the surgery being performed? How does the service ensure the consent conversation is tailored to fit the patient, aiming to help them make balanced choices, and highlighting any areas of particular risk or benefit for them as individuals?
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consider it necessary and proportionate?	<p>treatment</p> <ul style="list-style-type: none"> • BMA Consent Toolkit • BMA Children and young people tool kit • Gillick competence 	
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Caring

By caring, we mean that the service involves and treats people with compassion, kindness, dignity and respect.

Key line of enquiry: C1, C2 & C3

C1. How does the service ensure that people are treated with kindness, dignity, respect and compassion, and that they are given emotional support when needed?

C2. How does the service support people to express their views and be actively involved in making decisions about their care, support and treatment as far as possible?

C3. How is people’s privacy and dignity respected and promoted?

Generic prompts	Professional Standard	Sector specific guidance
Report sub-heading: Compassionate care		
<ul style="list-style-type: none"> • C1.1 Do staff understand and respect the personal, cultural, social and religious needs of people and how these may relate to care needs, and do they take these into account in 	<ul style="list-style-type: none"> • RCOphth professional standards for refractive surgery April 2017; in particular refer to point 6.2 that sets out that it is helpful to keep up a 	<ul style="list-style-type: none"> • How do staff provide reassuring support in accordance with published professional standards • Do staff ensure that they act in

<p>the way they deliver services? Is this information recorded and shared with other services or providers?</p> <ul style="list-style-type: none"> • C1.2 Do staff take the time to interact with people who use the service and those close to them in a respectful and considerate way? • C1.3 Do staff show an encouraging, sensitive and supportive attitude to people who use services and those close to them? • C1.4 Do staff raise concerns about disrespectful, discriminatory or abusive behaviour or attitudes? • C3.1 How does the service and staff make sure that people's privacy and dignity needs are understood and always respected, including during physical or intimate care and examinations? • C3.2 Do staff respond in a compassionate, timely and appropriate way when people experience physical pain, discomfort or emotional distress? 	<p>reassuring dialogue, talking to patients through the surgery and explaining when they are likely to experience sensations such as pressure in the eye, temporary loss of vision, a bright light, a burning smell, or fluid running over the eye</p> <p>https://www.rcophth.ac.uk/2017/04/new-refractive-surgery-standards-provide-improved-quality-of-care-and-patient-information-2/</p> <ul style="list-style-type: none"> • NICE QS15 statement 1 People using adult NHS services are treated with empathy, dignity and respect • NICE QS15 statement 2 People using adult NHS services understand the roles of healthcare professionals involved in their care and know how to contact them about their ongoing healthcare needs. 	<p>accordance with NICE Quality Statements 1, 2, 3 and 13?</p>
<p>Report sub-heading: Emotional support</p>		
<ul style="list-style-type: none"> • C1.5 Do staff understand the impact that a person's care, treatment or condition will have on their wellbeing and on those close to them, both emotionally and socially? • C1.6 Are people given appropriate and timely support and information to cope emotionally with their care, treatment or condition? Are they advised how to find other support 		

<p>services?</p> <ul style="list-style-type: none"> • C2.7 What emotional support and information is provided to those close to people who use services, including carers, family and dependants? 		
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Report sub-heading: Understanding and involvement of patients and those close to them

<ul style="list-style-type: none"> • C2.1 Do staff communicate with people so that they understand their care, treatment and condition and any advice given? • C2.2 Do staff seek accessible ways to communicate with people when their protected equality or other characteristics make this necessary? • C2.3 How do staff make sure that people who use services and those close to them are able to find further information, including community and advocacy services, or ask questions about their care and treatment? How are they supported to access these? • C2.4 Are people empowered and supported, where necessary, to use and link with support networks and advocacy, so that it will have a positive impact on their health, care and wellbeing? • C2.5 Do staff routinely involve people who use services and those close to them (including carers and dependants) in planning and making shared decisions about their care and treatment? Do people feel listened to, respected and have their views 	<ul style="list-style-type: none"> • NICE QS15 statements 5 People using adult NHS services have their preferences for sharing information with their family members and carers established, respected and reviewed throughout their care • NICE QS15 statement 6, People using adult NHS services are supported in shared decision making. • RCOphth Professional standards for refractive surgery April 2017 And their patient information leaflets: <ul style="list-style-type: none"> ○ Refractive Surgery Patient Checklist April2017 ○ Laser Vision Correction Surgery Patient Leaflet April2017 ○ Phakic Intraocular Lens Implantation Patient Leaflet April2017 ○ Refractive Lens Exchange Patient Leaflet April2017 ○ Roles within the Refractive Surgery Team April2017 • NHS choices about corrective eye surgery 	<ul style="list-style-type: none"> • Are patients given appropriate information about what they should expect from refractive laser eye surgery and realistic expectations about outcomes, in line with the RCOphth guidance? • Do patients have opportunities to discuss their health beliefs, concerns and preferences to inform their individualised care? • Are patients supported by staff to understand relevant treatment options, including risks, benefits and potential consequences, as per RCOphth professional standards for refractive surgery? • Do staff make sure written information is available as published by the RCOphth and NHS Choices website? • Are patients given transparent and accurate information about all costs involved as per regulation 19 of the
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<p>considered?</p> <ul style="list-style-type: none"> • C2.6 Are people’s carers, advocates and representatives including family members and friends, identified, welcomed, and treated as important partners in the delivery of their care? • C3.3 How are people assured that information about them is treated confidentially in a way that complies with the Data Protection Act and that staff support people to make and review choices about sharing their information? 	<ul style="list-style-type: none"> • Regulation 19 of the Care Quality Commission Registration Regulations 2009 	<p>CQC Registration Regulations 2009?</p>
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Responsive

By responsive, we mean that services meet people’s needs

Key line of enquiry: R1 & R2

R1. How do people receive personalised care that is responsive to their needs?
R2. Do services take account of the particular needs and choices of different people?

Prompts	Professional standard	Sector specific guidance
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Report sub-heading: **Service delivery to meet the needs of local people**

<ul style="list-style-type: none"> • R1.1 Do the services provided reflect the needs of the population served and do they ensure flexibility, choice and continuity of care? 	<ul style="list-style-type: none"> • RCOphth Professional standards for refractive surgery April 2017 Pre-treatment information should include a clear explanation of what to 	<ul style="list-style-type: none"> • Does the service ensure all patients have all necessary information and clear explanations of what to expect, before the day of surgery?
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<ul style="list-style-type: none"> • R1.2 Where people’s needs and choices are not being met, is this identified and used to inform how services are improved and developed? • R1.3 Are the facilities and premises appropriate for the services that are delivered? 	<p>expect during the surgery, with instructions about how the patient can help the procedure to go smoothly and reassurance about discomfort or disconcerting lights, sounds or smells which are normal during the surgery.</p> <ul style="list-style-type: none"> • RCOphth professional standards for refractive surgery April 2017. In particular section 6.9 	<ul style="list-style-type: none"> • If the surgeon delegates early or later routine review appointments to another member of the care team such as an ophthalmologist or optometrist, how does the service make sure the RCOphth professional standards are met?
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Report sub-heading: Meeting people’s individual needs

<ul style="list-style-type: none"> • R1.4 How does the service identify and meet the information and communication needs of people with a disability or sensory loss. How does it record, highlight and share this information with others when required, and gain people’s consent to do so? • R2.1 How are services delivered, made accessible and coordinated to take account of the needs of different people, including those with protected characteristics under the Equality Act and those in vulnerable circumstances? • R2.2 How are services delivered and co-ordinated to be accessible and responsive to people with complex needs?¹ • R2.3 How are people, supported during referral, transfer between services and discharge? • R2.4 Are reasonable adjustments made so 	<ul style="list-style-type: none"> • NICE QS15 statement 4 People using adult NHS services experience care and treatment that is tailored to their needs and preferences. • RCOphth Eye Care for Adults with Learning Disabilities. September 2015 • Accessible Information Standard (<i>From 31 July 2016, all organisations that provide NHS care or adult social care are legally required to follow the Accessible Information Standard</i>) 	<ul style="list-style-type: none"> • Are appropriate arrangements put into place to take account of individual needs of people being discharged who have complex health and social care needs that require special considerations? • Does the provider comply with Accessible Information Standard by identifying, recording, flagging, sharing and meeting the information and communication needs of people with a disability / sensory loss? • Are there arrangements in place for people who need translation services? • Are there suitable arrangements in place for people with a learning disability in line with RCOphth information?
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¹. For example, people living with dementia or people with a learning disability or autism.

<p>that people with a disability can access and use services on an equal basis to others?</p> <ul style="list-style-type: none"> • R2.5 Do key staff work across services to coordinate people's involvement with families and carers, particularly for those with multiple long-term conditions? 		<ul style="list-style-type: none"> • How well does the service care for people with other complex needs, e.g. deaf/blind/wheelchair access?
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Key line of enquiry: R3

R3. Can people access care and treatment in a timely way?

Prompts	Professional standard	Sector specific guidance
<ul style="list-style-type: none"> • Report sub-heading: Access and flow 		
<ul style="list-style-type: none"> • R3.1 Do people have timely access to initial assessment, test results, diagnosis, or treatment? • R3.2 Can people access care and treatment at a time to suit them? • R3.3 What action is taken to minimise the length of time people have to wait for care, treatment, or advice? • R3.4 Do people with the most urgent needs have their care and treatment prioritised? • R3.5 Are appointment systems easy to use and do they support people to access appointments? • R3.6 Are appointments care and treatment only cancelled or delayed when absolutely necessary? Are delays or cancellations 	<p>RCOphth Professional standards for refractive surgery April 2017</p>	<ul style="list-style-type: none"> • How does the service manage the provision of un-planned surgery, such as unexpected return to theatre, particularly at night, weekends and public holidays? • Are appropriate cooling off periods taken account of as set out in the RCOphth professional standards?

<p>explained to people, and are people supported to access care and treatment again as soon as possible?</p> <ul style="list-style-type: none"> • R3.7 Do services run on time, and are people kept informed about any disruption? • R3.8 How is technology used to support timely access to care and treatment? Is the technology (including telephone systems and online/digital services) easy to use? 		
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Key line of enquiry: R4

R4. How are people’s concerns and complaints listened and responded to and used to improve the quality of care?

Prompts	Professional standard	Sector specific guidance
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Report sub-heading: **Learning from complaints and concerns**

<ul style="list-style-type: none"> • R4.1 How well do people who use the service know how to make a complaint or raise concerns and how comfortable do they feel doing so in their own way? How are people encouraged to make a complaint, and how confident are they to speak up? • R4.2 How easy is it for people to use the system to make a complaint or raise concerns? Are people treated compassionately and given the help and support, through use of accessible information or protection measures if they need to make a complaint? • R4.3 How effectively are complaints handled, including to ensure openness and 	<ul style="list-style-type: none"> • <u>RCS Good Surgical Practice 2014</u>. In particular section 3 • <u>ISCAS: Patient complaints adjudication service for independent healthcare</u> • The <u>NHS constitution</u> gives people the right to <ul style="list-style-type: none"> ○ Have complaints dealt with efficiently and be investigated. ○ Know the outcome of the investigation. ○ Take their complaint to an 	<ul style="list-style-type: none"> • Where the internal complaints process has been exhausted, what arrangements are in place for the independent review of complaints where the patient is receiving non-NHS funded care (e.g. is the service a member of the Independent Services Complaint Advisory Services (ISCAS) and if not, does the provider have an alternative arrangement?). This includes NHS Private Patient Units, whose patients do not have access to the PHSO if their care is not NHS funded.
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<p>transparency, confidentially, regular updates for the complainant, a timely response and explanation of the outcome, and a formal record?</p> <ul style="list-style-type: none"> • R4.4 How are people who raise concerns or complaints protected from discrimination, harassment or disadvantage? • R4.5 To what extent are concerns and complaints used as an opportunity to learn and drive improvement? 	<p>independent Parliamentary and Health Service Ombudsman.</p> <ul style="list-style-type: none"> ○ Receive compensation if they have been harmed. 	
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Well-led

By well-led, we mean that the leadership, management and governance of the organisation assures the delivery of high-quality person-centred care, supports learning and innovation, and promotes an open and fair culture.

Key line of enquiry: **W1**

W1. Is there the leadership capacity and capability to deliver high-quality, sustainable care?

Prompts	Professional standard	Sector specific guidance
Report sub-heading: Leadership		
<ul style="list-style-type: none"> • W1.1 Do leaders have the skills, knowledge, experience and integrity that they need – both when they are appointed and on an ongoing basis? • W1.2 Do leaders understand the challenges to quality and sustainability, and can they identify 	<ul style="list-style-type: none"> • CMA Order: https://assets.digital.cabinet-office.gov.uk/media/542c1543e5274a1314000c56/Non-Divestment_Order_amended.pdf • GMC guidance about the CMA Order 	<ul style="list-style-type: none"> • How does the provider ensure that they comply with the Competitions and Marketing Authority (CMA) Order that came into force in April 2015 about the prohibition of inducing a referring clinician to refer private patients to, or treat private patients at, the facilities?

<p>the actions needed to address them?</p> <ul style="list-style-type: none"> W1.3 Are leaders visible and approachable? W1.4 Are there clear priorities for ensuring sustainable, compassionate, inclusive and effective leadership, and is there a leadership strategy or development programme, which includes succession planning? 	<p>http://www.gmc-uk.org/guidance/news_consultation/26575.asp</p> <ul style="list-style-type: none"> National Safety Standards for Invasive Procedures (NatSSIPs) Version 1 September 2015. <i>Private hospitals that do not provide NHS-funded care can still create LocSSIPs that are compliant with the NatSSIPs. Refer to FAQs on Publications Gateway Reference: 04043</i> Fit and Proper Persons Guidance 	<ul style="list-style-type: none"> How do leaders ensure that employees who are involved in the performance of invasive procedures are given adequate time and support to be educated in good safety practice, to train together as teams and to understand the human factors that underpin the delivery of ever safer patient care?
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Key line of enquiry: **W2**

W2. Is there a clear vision and credible strategy to deliver high-quality sustainable care to people who use services, and robust plans to deliver?

Prompts	Professional standard	Sector specific guidance
Report sub-heading: Vision and strategy		
<ul style="list-style-type: none"> W2.1 Is there a clear vision and a set of values, with quality and sustainability as the top priorities? W2.2 Is there a robust, realistic strategy for achieving the priorities and delivering good quality sustainable care? W2.3 Have the vision, values and strategy been developed using a structured planning process in collaboration with staff, people who use services, and external partners? 	<ul style="list-style-type: none"> RCOphth professional standards for refractive surgery published April 2017 GMC Guidance for doctors who offer cosmetic interventions. April 2016 – came into force 1 June 2016 	<ul style="list-style-type: none"> How has the leadership demonstrated that it has taken account of the RCOphth Professional standards for refractive surgery that were published in April 2017? How has the service ensured themselves that doctors carrying out surgery have taken into account the GMC guidance for doctors who offer cosmetic interventions that came into

<ul style="list-style-type: none"> W2.4 Do staff know and understand what the vision, values and strategy are, and their role in achieving them? W2.5 Is the strategy aligned to local plans in the wider health and social care economy, and how have services been planned to meet the needs of the relevant population? W2.6 Is progress against delivery of the strategy and local plans monitored and reviewed, and is there evidence to show this? 		force on 1 June 2016?
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Key line of enquiry: W3

W3. Is there a culture of high-quality, sustainable care?

Generic prompts	Professional Standard	Sector specific guidance
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Report sub-heading: **Culture**

<ul style="list-style-type: none"> W3.1 Do staff feel supported, respected and valued? W3.2 Is the culture centred on the needs and experience of people who use services? W3.3 Do staff feel positive and proud to work in the organisation? W3.4 Is action taken to address behaviour and performance that is inconsistent with the vision and values, regardless of seniority? W3.5 Does the culture encourage, openness and honesty at all levels within the organisation, including with people who use services, in response to incidents? Do leaders 	<ul style="list-style-type: none"> NMC Openness and honesty when things go wrong: the professional duty of candour NRLS - Being Open Communicating patient safety incidents with patients, their families and carers Duty of Candour – CQC guidance RCOphth Refractive Surgery Advertising and Marketing Standards April 2017 https://www.rcophth.ac.uk/patients/refra 	<ul style="list-style-type: none"> Does the service ensure that practitioners, and the service carry out marketing that is honest and responsible and that complies with the guidance contained within the Committee on Advertising Practice’s (CAP)? And the RCOphth standards published April 2017? Is there a system in place to ensure people using the service are provided with a statement that includes terms and conditions of the services being provided to the person and the amount and method
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<p>and staff understand the importance of staff being able to raise concerns without fear of retribution, and is appropriate learning and action taken as a result of concerns raised?</p> <ul style="list-style-type: none"> • W3.6 Are there mechanisms for providing all staff at every level with the development they need, including high-quality appraisal and career development conversations? • W3.7 Is there a strong emphasis on the safety and well-being of staff? • W3.8 Are equality and diversity promoted within and beyond the organisation? Do all staff, including those with particular protected characteristics under the Equality Act, feel they are treated equitably? • W3.9 Are there cooperative, supportive and appreciative relationships among staff? Do staff and teams work collaboratively, share responsibility and resolve conflict quickly and constructively? 	<p>ctive-surgery/</p> <ul style="list-style-type: none"> • CAP: Laser eye surgery • CAP: Healthcare: Overview • CAP: Cosmetic Interventions: Social Responsibility • GMC & NMC 'Openness and honesty when things go wrong: the professional duty of candour' • NRLS 'Being Open Communicating patient safety incidents with patients, their families and carers' • https://www.england.nhs.uk/about/equality/equality-hub/equality-standard/ 	<p>of payment of fees?</p> <ul style="list-style-type: none"> • How has the provider met the requirements related to Duty of Candour? (for example, training, support for staff, audits and monitoring) • Where the provider has an NHS Standard Contract to provide treatment: <ul style="list-style-type: none"> ○ What work is being undertaken to address workforce equality at a provider level? ○ How have you implemented any organisation-wide strategy or priorities on workforce race equality in your location? ○ How are you ensuring at a location level that there is an inclusive workplace for staff, which welcomes diversity? ○ What work has been undertaken to ensure that staff from different equality groups feel able to speak up about their experiences at work – either as an employee or in relation to patient care? ○ Are there mechanisms for providing all staff at every level with the development they need, including high-quality appraisal and career
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development conversations?

Key line of enquiry: **W4**

W4. Are there clear responsibilities, roles and systems of accountability to support good governance and management?

Generic prompts	Professional Standard	Sector specific guidance
Report sub-heading: Governance		
<ul style="list-style-type: none"> W4.1 Are there effective structures, processes and systems of accountability to support the delivery of the strategy and good quality, sustainable services? Are these regularly reviewed and improved? W4.2 Do all levels of governance and management function effectively and interact with each other appropriately? W4.3 Are staff at all levels clear about their roles and do they understand what they are accountable for, and to whom? W4.4 Are arrangements with partners and third-party providers governed and managed effectively to encourage appropriate interaction and promote coordinated, person-centred care? 	<ul style="list-style-type: none"> The Health Care and Associated Professions (Indemnity Arrangements) Order 2014 RCOphth Professional standard for refractive surgery April 2017 NICE QS61 Statement 2: Organisations that provide healthcare have a strategy for continuous improvement in infection prevention and control, including accountable leadership, multi-agency working and the use of surveillance systems. National Safety Standards for Invasive Procedures (NatSSIPs) Version 1 September 2015. <i>Private hospitals that do not provide NHS-funded care can still create LocSSIPs that are compliant with the NatSSIPs. Refer to FAQs on Publications Gateway Reference: 04043</i> 	<ul style="list-style-type: none"> Is there a clinical governance group responsible for reviewing surgical ophthalmic procedures? How does the Registered Manager ensure that all surgery carried out is monitored and reviewed? How does the Registered Manager ensure that consultant surgeons inviting NHS staff or others into theatres are appropriately granted either practising privileges or other checks as required by Schedule 3 of the Health and Social Care Act 2008 (Regulated Activity) Regulations 2014? How does the hospital manager ensure that surgeons have an appropriate level of valid professional indemnity insurance in place? i.e. Arrangements to ensure those staff working under practising privileges

		<p>hold appropriate indemnity insurance in accordance with <u>The Health Care and Associated Professions (Indemnity Arrangements) Order 2014</u></p> <ul style="list-style-type: none"> • How does the provider make sure medical practitioners inform their appraiser of this in their annual appraisal and maintain accurate information about their personal performance in line with national guidance on appraisal for doctors? • Are roles and responsibilities of the Medical Advisory Committee or equivalent local medial governance arrangements set out and available? • Is there a system is in place to ensure that governance arrangements take account of and are aligned with recommendation published with National Safety Standards for Invasive Procedures?
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Key line of enquiry: **W5**

W5. Are there clear and effective processes for managing risks, issues and performance?

Generic prompts	Professional Standard	Sector specific guidance
Report sub-heading: Managing risks, issues and performance		
<ul style="list-style-type: none"> • W5.1 Are there comprehensive assurance 	<ul style="list-style-type: none"> • Refer to section 4.2 of RCOphth 	<ul style="list-style-type: none"> • Does the service have tested back-

systems, and are performance issues escalated appropriately through clear structures and processes? Are these regularly reviewed and improved?

- W5.2 Are there processes to manage current and future performance? Are these regularly reviewed and improved?
- W5.3 Is there a systematic programme of clinical and internal audit to monitor quality, operational and financial processes, and systems to identify where action should be taken?
- W5.4 Are there robust arrangements for identifying, recording and managing risks, issues and mitigating actions? Is there alignment between the recorded risks and what staff say is 'on their worry list'?
- W5.5 Are potential risks taken into account when planning services, for example seasonal or other expected or unexpected fluctuations in demand, or disruption to staffing or facilities?
- W5.6 When considering developments to services or efficiency changes, how is the impact on quality and sustainability assessed and monitored? Are there examples of where financial pressures have compromised care?

[professional standards for refractive surgery published April 2017](#); this guidance sets out that 'Uninterruptable power supplies should be in place for all refractive surgical lasers'

- [NICE QS61 Statement 2](#): Organisations that provide healthcare have a strategy for continuous improvement in infection prevention and control, including accountable leadership, multi-agency working and the use of surveillance systems.

up emergency generators in place in case of failure of essential services?

- Does such a back-up generator (or the laser itself) ensure that should the power fail mid-treatment that the treatment is not compromised

Key line of enquiry: **W6**

W6. Is appropriate and accurate information being effectively processed, challenged and acted upon?

Generic prompts	Professional Standard	Sector specific guidance
Report sub-heading: Managing information		
<ul style="list-style-type: none"> • W6.1 Is there a holistic understanding of performance, which sufficiently covers and integrates people’s views with information on quality, operations and finances? Is information used to measure for improvement, not just assurance? • W6.2 Do quality and sustainability both receive sufficient coverage in relevant meetings at all levels? Do all staff have sufficient access to information, and do they challenge it appropriately? • W6.3 Are there clear and robust service performance measures, which are reported and monitored? • W6.4 Are there effective arrangements to ensure that the information used to monitor, manage and report on quality and performance is accurate, valid, reliable, timely and relevant? What action is taken when issues are identified? • W6.5 Are information technology systems used effectively to monitor and improve the quality of care? • W6.6 Are there effective arrangements to ensure that data or notifications are submitted to external bodies as required? • W6.7 Are there robust arrangements (including internal and external validation) to 	<ul style="list-style-type: none"> • <u>RCS: Good Surgical Practice 2014. Point 3.4</u> • <u>GMC Good medical practice: communication, partnership and teamwork</u> 	<ul style="list-style-type: none"> • How does the service ensure that the surgeon and anaesthetist always receive appropriate information about the patients and surgery being undertaken at any time? • Do GPs/optometrists have direct access? Can they speak to a surgical consultant or staff for advice on the phone?

ensure the availability, integrity and confidentiality of identifiable data, records and data management systems, in line with data security standards? Are lessons learned when there are data security breaches?

Key line of enquiry: **W7**

Are the people who use services, the public, staff and external partners engaged and involved to support high-quality sustainable services?

Generic prompts

Professional Standard

Sector specific guidance

Report sub-heading: **Engagement**

- W7.1 Are people’s views and experiences gathered and acted on to shape and improve the services and culture? Does this include people in a range of equality groups?
- W7.2 Are people who use services, those close to them and their representatives actively engaged and involved in decision-making to shape services and culture? Does this include people in a range of equality groups?
- W7.3 Are staff actively engaged so that their views are reflected in the planning and delivery of services and in shaping the culture? Does this include those with a protected characteristic?
- W7.4 Are there positive and collaborative relationships with external partners to build a shared understanding of challenges within the system and the needs of the relevant

<p>population, and to deliver services to meet those needs?</p> <ul style="list-style-type: none"> W7.5 Is there transparency and openness with all stakeholders about performance? 		
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Key line of enquiry: W8

W8. Are there robust systems and processes for learning, continuous improvement and innovation?

Prompts	Professional standard	Sector specific guidance
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Report sub-heading: Learning, continuous improvement and innovation

<ul style="list-style-type: none"> W8.1 In what ways do leaders and staff strive for continuous learning, improvement and innovation? Does this include participating in appropriate research projects and recognised accreditation schemes? W8.2 Are there standardised improvement tools and methods, and do staff have the skills to use them? W8.3 How effective is participation in and learning from internal and external reviews, including those related to mortality or the death of a person using the service? Is learning shared effectively and used to make improvements? W8.4 Do all staff regularly take time out to work together to resolve problems and to review individual and team objectives, processes and performance? Does this lead to improvements and innovation? W8.5 Are there systems to support 		
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improvement and innovation work, including objectives and rewards for staff, data systems, and processes for evaluating and sharing the results of improvement work?		
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