The ROYAL COLLEGE of OPHTHALMOLOGISTS

Professional Standards for Refractive Surgery Standards Consultation August to October 2016: Responses and Comments

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18 Stephenson Way, London, NW1 2HD T. 020 7935 0702
contact@rcophth.ac.uk rcophth.ac.uk @RCOphth

Contents

1 Introduction

1.1 This consultation sought views on the document 'Professional Standards in Refractive Surgery' from health and care professionals, stakeholder organisations and the public. The document builds on the April 2016 guidance from the General Medical Council 'Guidance for doctors who offer cosmetic interventions', associated guidance issued simultaneously from the Royal College of Surgeons 'Professional standards for cosmetic practice' and the Keogh Report 'Review of the Regulation of Cosmetic Surgery Interventions' (Department of Health 2013). It incorporates elements from the responses to the Spring 2016 consultation on draft Standards for Patient Information and Consent and replaces that draft document.

Consultation period

24 August 2016 to 5 October 2016

Consultation document

Professional Standards for Refractive Surgery

About us

1.4 The Royal College of Ophthalmologists (RCOphth) is the only professional body for eye doctors, who are medically qualified and have undergone or are undergoing specialist training in the prevention, treatment and management of eye disease, including surgery. As an independent charity, we pride ourselves on providing impartial and clinically based evidence, putting patient care and safety at the heart of everything we do. Ophthalmologists are at the forefront of eye health services because of their extensive training and experience.

1.5 RCOphth received its Royal Charter in 1988 and has over 3,500 members in the UK and overseas. We are not a regulatory body, but we work collaboratively with government, health departments, charities and eye health organisations to develop recommendations and support improvements in the co-ordination and management of hospital eye care services both nationally and regionally.

www.rcophth.ac.uk

About this document

1.6 This document summarises the responses we received to the consultation.

1.7 It explains how we handled and analysed the responses and our comments, response and decisions.

2 List of respondents

Twenty responses were received via the comments form:

- 1 optometrist who has worked in the refractive surgery industry
- Companies involved in the delivery of refractive surgery: Advanced Vision Care, The Royal Liverpool University Hospital, Midland Eye, Optical Express Group
- The Medical Defence Union. Disclosure We are a non-profit making mutual organisation whose medical members include ophthalmic surgeons. Members pay us an annual subscription in return for access to the benefits of membership which include medico-legal advice, assistance and indemnity for clinical negligence claims.
- 8 Consultant Ophthalmologists
- The College of Optometrists
- The British Society for Refractive Surgery (BSRS) - The society receives sponsorship from industry for its annual meeting
- 1 Member of the public
- My Beautiful Eyes: Refractive Surgery Patient Group
- The United Kingdom and Ireland society of Cataract and Refractive Surgeons - Receive sponsorship from a number of pharmaceutical companies to support annual and satellite meeting similar to RCOphth
- The Optical Confederation - Our member organisations include those who provide, carry out and assist with refractive surgery procedures

3 Analysing the responses

3.1 Respondents were requested to use a standard Comments Form, responses sent in other formats or document types.

3.2 Comments received during our consultations are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the comments received, and are not endorsed by The Royal College of Ophthalmologists, its Trustees or committees.

3.3 For copyright reasons, The Royal College of Ophthalmologists is not able to publish attachments from respondents such as research articles, letters or leaflets.

3.4 The responses were collated in a formatted table and presenting the Working Group for consideration. Comments from the authors and the RSSWG were recorded and discussed by the Working Group at its meeting on 14 October 2016, and subsequent email discussions. Changes to the documents agreed with the Group and the College Board of Trustees.

3.5 We reserve the right to summarise and edit comments received during consultations, or not to publish them at all, if we consider the comments are too long, or publication would be unlawful or otherwise inappropriate.

4 Consultation comments and Working Group Responses

4.1 Comments are recorded in the order in which they were received.

A. Do these standards meet all requirements of refractive surgery in the context of UK medical practice and regulation?

If not, please explain what is missing and why it is important?

Comments received from	Comment(s)	Comments from the Refractive Surgery Standards Working Group (RSSWG)	Changes to the guidance document(s)
Optometrist	Section 5 standard 22 The use of stating 95% satisfactory should not be used as it is misleading and biased.	Comment refers to patient information – which includes references from multiple sources supporting satisfaction rates at 95% or better for contemporary refractive surgery https://www.rcophth.ac.uk/wp-content/uploads/2016/04/Patient-Information-References.pdf	No change
Advanced Vision Care	Comment 1 Section 2 Standard 2.1 Just being GMC Specialist does not make a surgeon competent to do Laser Refractive surgery as it is not in the curriculum of training. I have personally seen and trained NHS consultant surgeons and their	Although subspecialist fellowship level training is desirable and included in some UK corneal fellowships, there is no current system for accrediting ophthalmic subspecialist fellowship training in the UK. The entry level Cert LRS (2.2) will require a	No change

	knowledge for Laser Refractive surgery is minimal. Hence these surgeons should do 3-6months of fellowships in Laser Refractive surgery or work under supervision with CertLRS surgeon to do minimum of 20 cases before they are allowed to operate on their own	minimum level of experience https://www.rcophth.ac.uk/examinations/certificate-in-laser-refractive-surgery/	
Advanced Vision Care	Comment 2 Section 3 Standard 3.3 This might not always be possible as there is no constructive relationship with the NHS and private sector. Hence this should be changed to attend case seminars or video complications in National or International Refractive meetings	This falls under 'participating in professional networks' (3.3)	3.2 Take part in professional networks, national and international meetings to allow discussion of complex cases with colleagues and help ensure that their practice is well aligned with contemporary clinical evidence. (note 3.2 deleted – 3.3 becomes 3.2)
Advanced Vision Care	Comment 3 Section 4 Standard 4.3 We agree for separate instrumentation for each eye in bilateral surgery cases if it is cataract or any other intra ocular surgery. But there is no scientific evidence to have separate instrumentation for bilateral laser surgery cases as this has been performed worldwide with the same set of instruments	The PubMed search 'bilateral infection after LASIK' calls up 36 publications (accessed 9th Oct 2016)	No change
Advanced Vision Care	Comment 4 Section 5 Standard 16 This is confusing as there is different versions from GMC and the Royal College. If the screening, emergency and the Post-Operative care is done by a skilled refractive surgeon according to Royal College then the initial consultation and explanation of the consent can be done by a skilled medical professional (not by an optometrist). The decision for surgical intervention can be made in consultation with the operating surgeon.	Point 5.6 puts the GMC point 16 into context for refractive surgery.	No change

Advanced Vision Care	Comment 5 Section 5 Standard 5.6 & 5.9 Agreed that the consent with the Operating Surgeon should not be on the day of the surgery. But if the screen consultation, the surgical decision, explanation of the procedure with complications and the consent form and any other materials was given by a skilled Refractive Surgeon in consultation with the Operating Surgeon then it can only be necessary for the Operating Surgeon to see the patient the day before the surgery. This gives adequate cooling period for the patient to read the information and understand the consent form and any questions can be communicated to the skilled Refractive Surgeon and Operating Surgeon by email. But we agree the Operating Surgeon should see the patient before the surgery and that could be anything between one day to a week. If standard 5.9 is applied then the Operating Surgeon needs to see the patient at least a day before the surgery at minimum. As this two stage process (Initial Consultation) can be done by LRS Certified Refractive Surgeon.	See GMC point 16 – this precludes procedure choice and consent by one surgeon and performance by another (unless working under supervision).	No change
Advanced Vision Care	Comment 6 Section 5 Standard 5.10 If the consultation, information, consent form and surgical decision was given to the patient with consultation with the Operating Surgeon by Certified Laser Refractive Surgeon then there is no need for a minimum one week cooling off period, as there will be adequate time for the patient to understand the implications and also communicate with the Operating Surgeon. This is because if the Operating Surgeon is going to trust the skilled refractive surgeon, look at the pre op, emergency and post-operative care. This will allow an additional visit for	The one-week cooling-off period, derived after extensive discussion with stakeholders, is a compromise between the two-week cooling-off period stipulated by CSIC for cosmetic surgery and requests based on convenience and GMC point 25 for a shorter period from some refractive surgery providers. If there are good reasons in individual cases for operating after a shorter cooling-off period, these must be agreed with the patient and recorded in the medical record.	5.10 now reads: 5.10 Surgery should not take place on the day on which the procedure recommendation is made and the initial consent discussion with the operating surgeon takes place. A minimum cooling off period of one week is recommended between the procedure recommendation and surgery. In exceptional circumstances, where a one-week cooling off period is impractical, the reasons for this must be

	the patient to the clinic a week before surgery as the patients live far away to any Refractive Clinic. This regulation is not making it easy for the patient which it is supposed to be. GMC does not put any time restrictions for cooling off periods for any procedure but they insist there should be enough time given to the patient to reflect upon the surgical decision and the implications. Why then should Royal College put a minimum one week time frame?		agreed with the patient and documented in the medical record
Advanced Vision Care	Comment 7 Section 5 Standard 5.11 We feel this is outside the remit of Royal College as this does not deal with clinical decisions or patient's interest. The refund of consultation fees or deposits or when it should be done falls under financial conduct authority and there are already regulations. Royal College should not dedicate how one should run their financial aspects of their clinic as this is nothing to do with Clinical aspects of Refractive Surgery or patient care and safety.	5.11 is designed to deal explicitly with some common forms of pressure to proceed with surgery which have been prevalent in the sector. See also GMC points 26 et seq.	5.11 now reads: 5.11 There should be no pressure to proceed with surgery. Specifically, patients should not be offered time limited discounts, or a refund of the initial consultation fee if they choose to proceed. Any deposit for surgery should be fully refundable within a reasonable time period if patients choose not to proceed. Rates of conversion to surgery should not be used as a performance measure for surgeons, optometrists or other staff.
Royal Liverpool University Hospital	Comment 1 Section 1 Standard 1.2 The precise definition of 'Refractive Surgery' is missing. Does it, in addition to Excimer or other laser refractive surgery, include lens-based refractive surgery? If so, the statement that they are entirely elective and predominantly self-funded is incorrect. Does the new examination aim to encompass all these surgeries and surgeons who practise them?	The additional recommendations in the standards document apply to lens implantation techniques but not cataract surgery. We have tried to clarify this in the revised introduction paragraph 1.3	1.3 now reads: 1.3 This document builds on the April 2016 guidance from the GMC, associated guidance, issued simultaneously, from the Royal College of Surgeons Cosmetic Surgery Interspecialty Committee (CSIC), and the preceding 2013 Keogh Report. Our additional recommendations here apply to surgeons treating patients where the primary purpose of surgery is to reduce dependence on spectacles or contact lenses

			and the patient has a normal cornea and a normal lens in both eyes.
Royal Liverpool University Hospital	Comment 2 Section 2 Standard 2.2 Ophthalmologists on the specialist register are not required to hold specific qualifications in their sub-speciality whether it be vitreoretinal, strabismus, cornea etc. They are required through the appraisal and revalidation process to provide evidence that they deliver the required standard of care. The specialist register purposely excludes mention of sub-speciality qualifications. All NHS consultants are required through the appraisal and revalidation process to provide evidence that they practise within their competence and deliver the required standard of care. These standards do not allow for recognition of established laser refractive surgeons who meet all the requirements bar the CertLRS. Holding the CertLRS entry-level qualification in refractive surgery is incidental. Firstly the examination and its requirements have changed considerably since it was introduced prior to 2009. Hence holding the 2009 version is not the same as holding the 2016 or the new examination in 2017. Secondly, do those who hold the 2009 then need to sit the current examination given the changes or are they grandmother to grandfather -righted to the latest examination? Surgeons on the specialist register in Ophthalmology may have undertaken other forms of training or by way of publications in refractive surgery and these should be recognised as being equivalent to Cert LR.	Going forwards, new refractive surgeons will be required to hold the Cert LRS exam from 2018. This is because many important aspects of the knowledge base required to practice refractive surgery safely are not covered by the current OST curriculum. This contrasts with nearly all other ophthalmic subspecialties. However, after extensive debate within the RSSWG, the College Council and the Examinations Committee we recognise that an entry level examination should not be applied as a requirement for surgeons who are already on the specialist register and have evidence of an established refractive surgery practice in their last revalidation cycle (prior to 2018). We have amended the wording in 2.1 and 2.2 accordingly.	2.1 and 2.2 now read: 2.1 If in refractive surgery practice prior to 1 August 2018, refractive surgeons should either hold the CertLRS **or** be on the GMC Specialist Register in Ophthalmology, and should hold evidence in their last revalidation cycle of an established refractive surgery practice. 2.2 Refractive Surgeons who are not included in 2.1 (above), who are in, or commence, refractive surgery practice after 1 August 2018, should be on the GMC Specialist Register in Ophthalmology **and** hold the CertLRS entry level qualification.

	It is not clear what is meant by 'surgeons who perform refractive surgery **should** hold CertLRS entry-level qualification in refractive surgery'. If the GMC then stipulate that on the RCOphth recommendation (as per the consultation document) that surgeons should hold CertLRS entry-level qualification in refractive surgery it will significantly limit our practise.		
Royal Liverpool University Hospital	Comment 3 Section 2 Standard 2.4 In each revalidation cycle, undertake at least one patient feedback. Patient feedback is already obtained for all components of a doctors (in this case Ophthalmologists) practice as part of the appraisal and revalidation process. This therefore includes refractive surgery.	Wherever possible, as here, we have read directly across from April 2016 CSIC guidance.	No change
Royal Liverpool University Hospital	Comment 4 Section 3 Standard 3.1 Maintain an accurate portfolio of data. Again this is included in the appraisal process	3.1 refers to appraisal and draws attention to the Clinical Quality Indicators in Refractive Surgery document, and collection of standardised outcome data (as defined by a National Dataset).	No change
Royal Liverpool University Hospital	Comment 5 Section 3 Standard 3.4 Ensure that any implants, medicines and medical devices comply with guidelines of the MHRA. This is redundant. It is already a component of GCP	Wherever possible, as here, we have read directly across from April 2016 CSIC guidance. We have modified this paragraph in line with comments elsewhere to reflect the aim of drawing attention to the use of non-CE marked devices, custom devices and off label applications. A reference to the relevant MHRA guidance has also been added.	Sections 3.4 (now 3.3 – 3.2 deleted) now reads: 3.3 Ensure that the clinic or organisation in which they practise has policies in place to maintain compliance with MHRA guidelines on the use of implants, medicines and medical devices; the use of custom made or non-CE marked devices, and off-label use of medical devices.
Royal Liverpool University Hospital	Comment 6 Section 6 Standard 6.8 b,c,d,e.	Further work needs to take place with the College of Optometrists to define the	No change as a result of this comment.

	The operating surgeon must ensure that the optometrist or is appropriately trained in refractive surgery care. What are the requirements for the optometrist? Do they need for example to be on a register and or have passed an equivalent examination?	requirements for optometric training in refractive surgery co-management. Also see GMC paragraph 42 *42 You must make sure that anyone you delegate care to has the necessary knowledge, skills and training and is appropriately supervised*[8]	Section 6.8 has bene split into two sections for clarity.
Ophthalmologist	Comment 1 Section 4 Standard 4.3b Page 6, 4.3.b seems inadequate for bilateral intraocular surgery, where the global standard of care mandates not just different instruments, but different sterilisation cycles and fluids/solutions to come from different batch numbers: See http://isbcs.org/research-reviews/isbcs-general-principles-for-excellence-in-isbcs-2009/	See amended wording	Section 4.3b now reads: 4.3b Separate instrumentation for each eye in bilateral corneal surgery and, in addition, separate batches for fluids and separate sterilisation cycles for instruments used in each eye in bilateral intraocular surgery.
Ophthalmologist	Comment 1 Section 2 Standard 2.2 These standards do not allow for recognition of established laser refractive surgeons who already have met all the requirements bar the CertLRS. Surgeons on the specialist registrar in Ophthalmology may have taken additional training eg fellowship in refractive surgery in established training centres should be recognised as being equivalent of CertLRS. The format for CertLRS has changed significantly since its introduction prior to 2009. This mean that holding the CertLRS 2009 version is not the same as the holding the 2016/2017 CertLRS. Surely it means that those surgeons should be sitting the new version examination?	Going forwards, new refractive surgeons will be required to hold the Cert LRS exam from 2018. This is because many important aspects of the knowledge base required to practice refractive surgery safely are not covered by the current OST curriculum. This contrasts with nearly all other ophthalmic subspecialties. However, after extensive debate within the RSSWG, the College Council, and the Examinations Committee, we recognise that an entry level examination should not be applied as a requirement for surgeons who are already on the specialist register and have evidence of an established refractive surgery practice in their last revalidation	See above changes to section 2.1 and 2.2

	It is not clear what is meant by 'surgeons who perform refractive surgery **should** hold CertLRS entry-level qualification in refractive surgery' If the GMC then stipulate that on the RCOphth recommendation (as per the consultation document) that surgeons should hold CertLRS entry-level qualification in refractive surgery it will limit our practise. Ophthalmologists on the specialist register are not required to hold specific qualifications in their sub-speciality whether it be vitreoretinal, strabismus, cornea etc. They are required through the appraisal and revalidation process to provide evidence that they deliver the required standard of care.	cycle (prior to 2018). We have amended the wording in 2.1 and 2.2 accordingly.	
Ophthalmologist	Comment 2 Section 2 Standard 2.4 In each revalidation cycle, undertake at least one patient feedback Patient feedback is already obtained for all components of a doctors (in this case Ophthalmologists) practice as part of the appraisal and revalidation process. This therefore includes refractive surgery	Wherever possible, as here, we have read directly across from April 2016 CSIC guidance.	No change
Ophthalmologist	Comment 3 Section 3 Standard 3.1 Maintain an accurate portfolio of data This already happens in my appraisal.	3.1 refers to appraisal and draws attention to the Clinical Quality Indicators in Refractive Surgery document, and collection of standardised outcome data (as defined by a National Data Set).	No change
Ophthalmologist	Comment 4 Section 6 Standard 6.8 b,c,d,e. The operating surgeon must ensure that the optometrist or is appropriately trained in refractive surgery care. This is very unclear. What are the requirements for the optometrist? Do they need for example to be on	Further work needs to take place with the College of Optometrists to define the requirements for optometric training in refractive surgery co-management.	No change as a result of this comment

	a register and or have passed an equivalent examination?	Also see GMC paragraph 42 *42 You must make sure that anyone you delegate care to has the necessary knowledge, skills and training and is appropriately supervised*[8]	
Ophthalmologist	Comment 1 Section 2 GMC guidance 1: there is a huge variation in what people consider safe to treat with an excimer laser eg some treat high hyperopia with a laser whilst others feel that this should be performed intraocularly and hence may warrant referral to another individual. This is an area which is difficult to regulate but needs to be addressed	Whilst treatment decisions remain the responsibility of the operating surgeon, they must stay in step with contemporary evidence (see section 2 Knowledge, skills and performance)	No change
Midland Eye	Comment 1 Section 2 GMC guidance 1: there is a huge variation in what people consider safe to treat with an excimer laser eg some treat high hyperopia with a laser whilst others feel that this should be performed intraocularly and hence may warrant referral to another individual. This is an area which is difficult to regulate but needs to be addressed	Agreed	No change
Midland Eye	Comment 2 Section 2 Standard 2.1 Whilst I understand time to implementation, if this is what has been decided then there is going to be a huge rush to take the CertLRS before Jan 2018 to beat this requirement. Also as LRS is not taught as part of training curriculum, this is likely to be challenged (as it was last time this was proposed)	Going forwards, new refractive surgeons will be required to hold the Cert LRS exam from 2018. This is because many important aspects of the knowledge base required to practice refractive surgery safely are not covered by the current OST curriculum. This contrasts with nearly all other ophthalmic subspecialties.	See above changes to section 2.1 and 2.2

		However, after extensive debate within the RSSWG, the College Council, and the Examinations Committee, we recognise that an entry level examination should not be applied as a requirement for surgeons who are already on the specialist register and have evidence of an established refractive surgery practice in their last revalidation cycle (prior to 2018). We have amended the wording in 2.1 and 2.2 accordingly.	
Midland Eye	Comment 3 Section 2 Standard 2.3 In college guidance, refers to CPD credits whereas this document refers to hours. Should this be consistent?	An hour of CPD activity approximates to 1 CPD credit. Wherever possible, as here, we have read directly across from April 2016 CSIC guidance.	.3 now reads:2.3 They should ensure that their skills and knowledge are up to date by undertaking 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. This is consistent with the CPD programme of The Royal College of Ophthalmologists which started in 1996.
Midland Eye	Comment 4 Section 2 Standard 2.4 Does this mean one patient or one group of patients?	A group (the apostrophe is after the s). Wherever possible, as here, we have read directly across from April 2016 CSIC guidance.	No change
Midland Eye	Comment 5 Section 4 Standard 4.2b Is this really a College remit to impose?	Although the College can make recommendations, enforcement is a matter for the CQC. The CQC recently consulted on inspections for refractive laser surgery providers and it is hoped that these Standards will help inform their process.	No change

Midland Eye	Comment 6 Section 4 Standard 4.3b This is not the norm around the world and hence would be challenged if imposed	We are making recommendations for safe practice in the UK. This recommendation is based on limiting the risk of bilateral infection.	No change
Midland Eye	Comment 7 Section 5 Standard 5.1 Available where?	We are aiming to publish Standardised Patient Information, developed through public consultation in Spring 2016, on the College site in early 2017 and at NHS Choices and the Parliamentary Ombudsman sites shortly after (as recommended by the Keogh Report 2013).	No change
Midland Eye	Comment 8 Section 5 Standard 5.11 It is the norm for commercial clinics to offer discounts and time limited offers and if often their modus operandia. How will this be policed?	The College will publish standards but implementation will be a matter for individual providers and the relevant enforcement bodies including the GMC and the CQC.	Section 5.11 now reads: 5.11 There should be no pressure to proceed with surgery. Specifically, patients should not be offered time limited discounts, or a refund of the initial consultation fee if they choose to proceed. Any deposit for surgery should be fully refundable within a reasonable time period if patients choose not to proceed. Rates of conversion to surgery should not be used as a performance measure for surgeons, optometrists or other staff
Midland Eye	Comment 9 Section 6 Standard 6.7 I think this whole section needs to be spelt out in more detail.	See amendment – the principle here is that the role of allied health professionals in aftercare is restricted to screening for complications.	Section 6.7 now reads: 6.7 Review of complex cases should not be delegated until the treatment for any complications is complete, the risk of further complications has returned to baseline levels for the procedure, and routine care pathways can be resumed safely. 6.8 Complex cases are cases with preoperative risk factors for complications

			after surgery; or cases that, as a result of a complication during or after surgery, may require any addition to previously scheduled routine review or treatment. There should be clear arrangements for transfer to another provider where appropriate in the case of an emergency or where additional specialist treatment is required for the treatment of complications.
Midland Eye	Comment 10 Section 6 Standard 68e Optometrists don't have medical indemnity as such	They cannot take responsibility for review consultations without indemnity – either their own or cover from their employing provider.	No change
Midland Eye	Comment 11 Section 6 Standard 6.10 Should this include post laser biometry and IOP issues	Yes – but this is covered in the standardised patient information outputs.	No change
Ophthalmologist	There is no mention of intracorneal inlays	Covered in our Terms of Reference available at www.rcophth.ac.uk section 1, definition of refractive surgery. The additional requirements in the standards document are targeted at non-therapeutic applications of refractive surgery. We have clarified this in 1.3 of the introduction	See above change to section 1.3
Ophthalmologist	Comment 1 Section 2 Standard 2.2 The exam CertLRS, presumably for newcomers to this discipline rather than established practitioners, is in laser refractive surgery, however, refractive surgery has been defined by the College previously	The additional recommendations in the standards document apply to lens implantation techniques but not cataract surgery. We have tried to clarify this in the revised introduction paragraph 1.3	See above change to section 1.3

	as a wide range of procedures, including refractive lens exchange (RLE), phakic IOLs, etc. as well as laser. I imagine that the majority of surgeons carrying out refractive procedures in the UK do not perform laser, e.g. RLE being a very popular and successful procedure. It thus appears that newcomers to the discipline may be inadvertently forced to do an exam, along with attaining experience in treating patients with laser, when they have no intention of utilising these skills in the future.		
Ophthalmologist	Comment 2 Section 2 Standard 2.2 There are a considerable number of corneal laser surgeons who do not carry out other procedures such as RLE, with a far greater number of surgeons who perform RLE, but not laser. It seems incomprehensible to try and regulate these very different and successful groups with a 'one size fits all' approach, which does not address one of the commonest procedures (RLE).	See above change to section 1.3	See above change to section 1.3
Ophthalmologist	Comment 3 Section 2 Standard 2.2 Unless this is an error in the formulation of the guidelines, there will be those who believe that one of the subliminal goals of regulation is actually protectionism, allowing only corneal laser surgeons the right to carry out both laser and non-corneal procedures in a competitive market. This could likely very quickly divide the College, which would be unfortunate.	See above change to section 1.3	See above change to section 1.3
Ophthalmologist	Comment 4 Section 2 Standard 2.2	See above amendment to section 1.3– if you are performing RLE, you need, at minimum, a good knowledge of the relative risks and	See above change to section 1.3

	There are many RLE surgeons, with established and well-audited practices and excellent results, who do not carry our laser, but have established professional relationships with laser refractive surgeons for when laser top-up is required. In many cases, this is the best possible arrangement for patient safety, as a dedicated lens specialist – rather than a corneal specialist (who may only carry out a handful of lens cases and hence have questionable ability) – performs the RLE surgery, but the patient has the guarantee that if further surgery is required, a laser surgeon will perform the correction. In this context, the CertLRS is a completely unnecessary step, which would only serve to reduce standards in established practices and worsen patient care if future / existing lens specialists ceased providing the excellent levels of care that they currently do.	benefits of alternative procedures. This is not currently covered in the OST curriculum. Hence the requirement to take the Cert LRS exam.	
Ophthalmologist	Comment 5 Section 2 Standard 2.2 Refractive surgery in general – not laser refractive surgery – is an integral part of modern cataract surgery, which all holders of a CCT in Ophthalmology have proved their ability in. Examples include carrying out clear lens extraction for patients with postoperative anisometropia, something that all trainees will have performed by the end of their training, never mind established consultants, and all within the NHS setting in most cases; this is refractive surgery by definition. Other examples include the use of sulcus-fixated piggyback lenses, which in many cases are better techniques than laser (e.g. elderly corneal epithelium, patients with corneal ectasia etc.) The addition of the requirement of the CertLRS for new practitioners of established	See above change to section 1.3	See above change to section 1.3

	non-laser techniques seems to dumb down the training already undertaken, and which is already administered by the College.		
British Society for Refractive Surgeons	Comment 1 Section 2 Standard 2.2 The standard requiring CertLRS disregards the validity of the current UK medical practice and regulation (GMP appraisal) process that encompasses all areas of a doctors practice	The Cert LRS exam is complimentary to the appraisal process and in line with GMC points 1-3 & 6 No change to the requirements to section 2.1 and 2.2 however the wording has been amended to be clearer.	See above changes to sections 2.1 and 2.2
British Society for Refractive Surgeons	Comment 2 Section 5 Standard 5.11 Agree, however is it the College's remit to override the Consumer Rights Act regarding the 3 day refund?	This is not the intention of this section and the wording has been amended.	See above change to section 5.11
Member of the public	The proposed RCOphth standards leave me feeling enraged. The Working Goup must be completely clueless or corrupt, or both, because they are still churning out rubbish, about numbers of patients with complications and the severity of their problems. I am angry, because I have suffered for 9 years now, and have met many other victims who broke down as they explained what had been done to them, even years after the event. Many of our complications cannot be fixed, and it is as though the RCOphth refuses to accept that this is really happening to people. In my opinion the new standards are based on lies, and will DO LITTLE OR NOTHING TO STOP THE UNETHICAL TREATMENT OF PATIENTS, THE LIES, BULLYING AND CORRUPTION WITHIN THIS INDUSTRY.	Thank you for your comments. As these are not specific comments related to the content of the standards document we have not made any amendments to the Standards Document in response this comment.	No change

My Beautiful Eyes	Comment 1 Section 5 Standards 5.1 – 5.2 - 5.3 The claim of 95% success rate is ambiguous, without verifiable statistics that reflect the whole of the industry. If 95% satisfaction is claimed then it should not be 95% of patients in subset X or cohort Y, the statistics used must verifiably reflect the claim and not chosen selectively/cherry picked. Even if we were to accept 95%, then the implication is that 1 patient in 20 suffers an unsuccessful outcome. If this is the case then it is surely a major public health scandal and requires immediate attention from higher authorities than the RCO Not only the physical statistics but also the implicit meaning needs to be clarified as it is incomprehensible to the patient at the moment. Regardless of their veracity the presentation of statistics and methodology for collection does nothing to engender trust. What does 95% mean? Does it refer to 95% of patients worldwide, 95% of all refractive surgery patients, 95% of patients seen by a particular clinic or chain, does it include NHS patients, is this for cataracts, RLE or laser-based treatments, is this 95% constant for different lens types, both multifocal and mono-focal, different laser techniques, elective and cataract procedures? If this is the claim then it seems little short of miraculous (except for the detail that 1 in 20 patients are unsuccessful) and frankly more than a little ridiculous. Use of statistics like this stretch credulity to the limit, and demands specific qualification from the issuer – as would be the case in any other industry. Failure to qualify such claims	Please see patient information source publications. https://www.rcophth.ac.uk/wp-content/uploads/2016/04/Patient-Information-References.pdf Or is neither satisfied nor dissatisfied (neutral) about the result. A representative contemporary figure for LASIK is closer to 1 in 100 dissatisfaction (Sandoval et al 2016 – source references). We agree that this remains a source of concern and are working hard to set in place standards and processes that will help to reduce the number of dissatisfied patients further. We are also examining the feasibility of a national refractive surgery dataset designed to incorporate patient satisfaction input which is fed in independent of the provider. Refractive surgery is safe and effective for the vast majority of patients treated. The main alternative for many patients is contact lens wear. The risks of continued contact lens wear should be balanced against those for refractive surgery.	No change

	will without question result in multiple complaints to the Advertising Standards Authority amongst others.		
My Beautiful Eyes	Comment 2 Section 4 Standards 4.3 – 4.4 The Abbott paper suggests that there should be a limit on the number of operations a surgeon is allowed to perform in any given period. Abbott concludes that the higher volume of operations, the greater risk of damaged patients. This is hardly a revelation and statistically verifiable, if not entirely obvious. Higher patient lists inevitably result in higher numbers of damaged patients. Informed consent must not be delegated to non-surgical staff. At the very least GMC guidelines must be adhered to, consent should only be delegated to an individual who is capable of performing the same surgery and who is currently practising.	Low surgical numbers can also predispose to poor results. If supported, a national database in refractive surgery would help to ensure that surgeons with higher than expected complication rates are given appropriate remedial advice or stopped from operating. We are very clear (5.6) that the operating surgeon should not delegate responsibility for the consent process in refractive surgery	No change
My Beautiful Eyes	Comment 3 Section 7 Standards 7.1 - 7.2 Where are the statistics from patients themselves? For example, MBE has evidence that OE staff complete patient satisfaction reports themselves, and so their data cannot be relied upon. In addition, it is known that patients damaged by refractive surgery have been pressured into completing positive satisfaction reports before realising they had problems. It is also known that others who immediately knew they had problems gave positive feedback because they were scared the company would not continue to provide aftercare treatment. Further, patients who	See above – the aim for the national data set is to incorporate a patient portal, allowing patients to complete anonymised questionnaire data independent of the provider.	No change

	reported problems immediately were never asked for feedback. This highlights the requirement for collection of data to be independent of the provider.		
My Beautiful Eyes	Comment 3 Section10 Standards 10.1 – 10.2 We believe the cooling off period should be 14 days. We are aware that the RCOphth Lay Advisory Group supported this period and are surprised that the lay representative on the working group has not advocated this. It is imperative that the cooling-off period be adhered to. It is also imperative that there be a period of 14 days between counselling being provided and any commitment on the part of the patient being made. Deposits must not be taken prior to the conclusion of the cooling-off period. This would represent financial inducement and excerpt pressure on the patient. It would be advisable to seek legal counsel to ascertain whether agreements made under such pressure remain valid. We have evidence that since new guidance from the GMC was introduced on 1 June 2016, Optical Express continue to take deposits with a 7 day cooling off period from date of payment, but ensure prospective patients do not see a surgeon until 2-3 weeks later. When patients subsequently cancel after seeing the surgeon their deposits are withheld.	The one-week cooling-off period, derived after extensive discussion with stakeholders, is a compromise between the two-week cooling-off period stipulated by CSIC for cosmetic surgery and requests based on convenience and GMC point 25 for a shorter period from some refractive surgery providers. If there are good reasons in individual cases for operating after a shorter cooling-off period, these must be agreed with the patient and recorded in the medical record. See point 5.11 – any deposit for refractive surgery must be fully refundable within a reasonable timeframe.	Section 5.10 now reads: 5.10 Surgery should not take place on the day on which the procedure recommendation is made and the initial consent discussion with the operating surgeon takes place. A minimum cooling off period of one week is recommended between the procedure recommendation and surgery. In exceptional circumstances, where a one-week cooling off period is impractical, the reasons for this must be agreed with the patient and documented in the medical record.

Ophthalmologist	This is utter and complete nonsense and only serves to benefit those practitioners that already preform laser refractive surgery and who hold CertLRS. There is no transparency to this statement and only lends one to believe that this regulation was devised by someone who is more protective of their private practice and financial gain. There are many 'Cornea and Refractive' fellowship trained Consultants who have done their training in a recognised and reputable unit for cornea, cataract and refractive surgery, and who are usually more equipped to provide holistic refractive management options to patients compared to those that provide a sole laser based refractive service. Also, why should one have to have a CertLRS when they have had excellent fellowship training, just so that the college can make money to issue a piece of paper in order to allow a doctor to perform laser refractive surgery. It is equally patronising that a Consultant Ophthalmologist who routinely performs cataract surgery (the bread-and-butter of our profession) is unable to counsel a patient appropriately on premium intraocular lenses and has to be certified in order to do so. Many of us that perform anterior segment surgery have a lot of experience and competence in lens based refractive surgery, whether it be 'premium lenses' of various types in the private sector, or lenses available for refractive correction on the NHS. Does this then mean that one also requires this qualification to perform surgery on the NHS? If not,	Since there is currently no system for accreditation of fellowship level subspecialist training in the UK, we are unable (at this stage) to recommend that refractive surgeons are fellowship trained in ocular surface disease, cataract, corneal and refractive surgery. The additional recommendations in the standards document apply to lens implantation techniques but not cataract surgery. We have tried to clarify this in the revised introduction paragraph 1.3 Going forwards, new refractive surgeons will be required to hold the Cert LRS exam from 2018. This is because many important aspects of the knowledge base required to practice refractive surgery safely are not covered by the current OST curriculum. This contrasts with nearly all other ophthalmic subspecialties. However, after extensive debate within the RSSWG, the College Council, and the Examinations Committee, we recognise that an entry level examination should not be applied as a requirement for surgeons who are already on the specialist register and have evidence of an established refractive surgery practice in their last revalidation cycle (prior to 2018). We have amended the wording in 2.1 and 2.2 accordingly.	See above change to sections 1.3, 2.1 and 2.2

	then this is a double standard / creationism of a two-tier system of quality of service. This is a slippery slope. There are many other ocular surgical procedures that can affect a patients refractive outcome. Will we need to be certified to perform other specific surgical procedures – if not, then this is again a serves to look after the agenda of others that have a vested interest to introduce such a reactionary, ill-thought proposal, rather than for the vested interest of patients. Surely, if this is being considered for the best interest of the public, then other invasive ophthalmic surgical procedures, cosmetic or otherwise, require similar regulation. If the college go so far as saying that CertLRS is also required for patients that need laser refractive surgery on the NHS, then this will be to a significant detriment to our patients because many practitioners may have to stop providing this service, and many patients either will not receive treatment or have to travel large distances to receive treatment elsewhere. If doctors treating patients on the NHS are exempt from this regulation, then this would be equally unacceptable.		
Ophthalmologist	Comment 1 Section 1 Standard 1.2 The precise definition of 'Refractive Surgery' is lacking. Does it, in addition to Excimer or other laser refractive surgery, include lens-based refractive surgery? If so, the statement that they are entirely elective and predominantly self-funded is incorrect. The patient and the surgeon might be taking the opportunity afforded by the presence of cataract to	The additional recommendations in the standards document apply to lens implantation techniques but not cataract surgery. We have tried to clarify this in the revised introduction paragraph 1.3 The Cert LRS exam covers both lens based and laser refractive surgery techniques.	See above change to section 1.3

	also correct the patient's refractive error. This may include toric lens implantation which is offered in some centres on the NHS as the price of them has become comparable to monofocal lens implants. What about incisional (corneal) refractive surgery? We know that corneal collagen crosslinking and intrastromal corneal ring segments can and do have significant refractive effects. In fact cataract surgery with monofocal lens implant, e.g. monovision, itself could be considered refractive surgery. Does the new examination/certification aim to encompass all these surgeries and surgeons who perform them? In other words, who should hold CertLRS entry level qualification in refractive surgery? Even for Excimer refractive surgery, there are NHS centres that treat post-cataract or post-corneal graft surgery refractive errors for NHS patients and such procedures should not be dismissed as entirely elective, and they are not self-funded.		
Ophthalmologist	Comment 2 Section 2 Standard 2 Ophthalmologists on the specialist register are not required to hold specific qualifications in their sub-speciality. In fact the specialist register purposely excludes mention of sub-speciality qualifications. All NHS consultants are required through the appraisal and revalidation process to provide evidence that they practise within their competence and deliver the required standard of care. It is very unlikely that surgeons carrying out an intervention for the first time would do so without undergoing training or seeking opportunities for supervised practice. They would be doing so at their	Going forwards, new refractive surgeons will be required to hold the Cert LRS exam from 2018. This is because many important aspects of the knowledge base required to practice refractive surgery safely are not covered by the current OST curriculum. This contrasts with nearly all other ophthalmic subspecialties. However, after extensive debate within the RSSWG, the College Council, and the Examinations Committee, we recognise that an entry level examination should not be applied as a requirement for surgeons who are already on the specialist register and	See above changes to section 2.1 and 2.2

	career-threatening risk. Most or all surgeons would try to improve their skills one procedure at a time so that they could master it. Many or most would not contemplate performing the whole range/gamut of refractive procedures, although of course knowledge of them would be ideal and give the surgeon an overall view. With the many different procedures and many machines/laser platforms/devices/implants from different manufacturers, one can most effectively concentrate on that particular procedure/device for best outcomes. As a professional, a surgeon can be expected to have acquire a 'general overview' knowledge of all refractive surgery procedures and detailed testing of knowledge for each and all procedures/devices, would be poorly targeted. If it is indeed deemed necessary to test competence in both laser refractive surgery and lens-based refractive surgery, two separate exams/modules (detachable) would make more sense. Is the new planned examination entry-level? It would mean they would be for surgeons without prior refractive experience. They would not have a portfolio of cases to present, to be assessed. The current LRES exam requires submitting a portfolio and an assessment of cases etc. and so is aimed at surgeons who are already doing or already have performed laser refractive surgery. In other words, LRES certification is not required to start doing laser refractive surgery. Are two levels of certification envisaged? There are surgeons who undertake refractive procedures having had corneal/anterior segment and/or refractive fellowships. Some have published	have evidence of an established refractive surgery practice in their last revalidation cycle (prior to 2018). We have amended the wording in 2.1 and 2.2 accordingly.	

	papers in the subspeciality. Is any recognition of them planned		
Ophthalmologist	Comment 3 Section 8 Standards 8 b, c, d, e Should optometrists have passed an equivalent exam? If no such exams currently exists, should the College of Optometrists be encouraged to hold one?	Further work needs to take place with the College of Optometrists to define the requirements for optometric training in refractive surgery co-management. Also see GMC paragraph 42 *42 You must make sure that anyone you delegate care to has the necessary knowledge, skills and training and is appropriately supervised*[8]	Section 8 now reads: 8.1 Key stages of the patient journey in refractive surgery comprise: • Initial advice from clinic staff • Procedure choice and discussion with the operating surgeon • Surgery • Early and later stage review consultations A cohesive team based approach with clear lines of responsibility and each member of the team playing to their strengths is essential at every stage. 8.2 Although the performance of tests, screening consultations and routine postoperative review may be delegated to appropriately trained staff, the operating surgeon remains responsible for the entire patient journey until discharge from the provider after late stage review or transfer of care to another provider for emergency or additional specialist treatment. 8.3 Patients should be told at the outset whether it is the operating surgeon or another member of the team who will be providing their care

			at each of the main stages in their refractive surgery journey. The patient can then make an informed choice between refractive surgery providers.
Ophthalmologist	Comment 1 Section 2 The need for CERTLRS- this is unfair on many doctors who have the appropriate training and experience. It is viewed as an opportunity by the College to 'make money' and does really police the outcomes. It may more appropriate that each surgeon publishes an audit every 5 years in line with the GMC revalidation cycle. I know of some surgeons who have the CERTLRS but have poor understanding of patient needs and poor surgical skills. It should standard that doctors wanting to performing surgery should undergo fellowship / ASTO training in Corneal, Ocular surface and Refractive surgery	Since there is currently no system for accreditation of fellowship level subspecialist training in the UK, we are unable (at this stage) to recommend that refractive surgeons are fellowship trained in ocular surface disease, cataract, corneal and refractive surgery. Going forwards, new refractive surgeons will be required to hold the Cert LRS exam from 2018. This is because many important aspects of the knowledge base required to practice refractive surgery safely are not covered by the current OST curriculum. This contrasts with nearly all other ophthalmic subspecialties. However, after extensive debate within the RSSWG, the College Council, and the Examinations Committee, we recognise that an entry level examination should not be applied as a requirement for surgeons who are already on the specialist register and have evidence of an established refractive surgery practice in their last revalidation cycle (prior to 2018). We have amended the wording in 2.1 and 2.2 accordingly.	See above changes to section 2.1 and 2.2
Ophthalmologist	Comment 2 Section 5 Standard 5.11	See amendment	See above change to section 5.11

	Refund of initial consultation fee if patient chooses not to proceed- this is unclear. It will be misinterpreted that the patient will receive a refund if decide not to proceed.		
Ophthalmologist	Comment 3 Section 5 Standard 5.11 Refund in 3 working days – is impossible- Try tell that to Finance Dept of my Hospital Trust- who only do monthly batch runs!	See amendment	See above change to section 5.11
Ophthalmologist	Comment 4 Section 6 The onus is now on the doctor to provide total care- all high street provider owner will now pass the buck onto the surgeon. It should be that Provider of the facilities and doctor is responsible for care	See section 6 and section 8, also new paragraph 1.5 in the introduction. The operating surgeon remains responsible for patient care and should ensure that they only practice in an environment in which appropriate support, governance structures, and clear lines of responsibility are in place.	New section 1.5 reads: 1.5 Our additional recommendations take two forms: direct advice to surgeons, and advice that surgeons should ensure is upheld in relation to their practice. Direct advice to surgeons is prefaced by the heading *'In addition, surgeons who perform refractive surgery should.'* Advice that surgeons should ensure is upheld in relation to their practice is prefaced by the heading *'In addition, the following principles apply for refractive surgery.'*
Ophthalmologist	Comment 5 Section 6 In my experience- Patients often pitch up to their local emergency eye dept for routine care which has not been provided by an high street provider- this should be audited and data collected by the College- and owner of centres notified that this is happening.	An audit of NHS care after private refractive surgery would be valuable	No change
Optical Express Group	Comment 1 Section 1 Standard 1.2 It is not clear that the General Medical Council has advised that their 'Guidance for Doctors who offer	We have had specific advice from the GMC on this point: their April 2016 Guidance for Doctors Who Offer Cosmetic Interventions	No change

	Cosmetic Interventions' should also apply to refractive surgery. This is not stated in the GMC's guidance. The reference seems to come from an ambiguous quote attributed to Bruce Keogh, NHS England's Medical Director, in the press release, which refers to 'lifestyle procedures, including areas such as laser eye surgery.' The term "lifestyle" is nowhere defined and the quote makes no provision for Intra-ocular lens surgery. It should not be for the RCOphth to determine whether and to which procedures GMC guidance applies. The GMC is, in fact, very specific about what its guidance refers to. It states: "By cosmetic interventions we mean any intervention, procedure or treatment carried out with the primary objective of changing an aspect of a patient's physical appearance. This includes surgical and non-surgical procedures, both invasive and non-invasive." Refractive Surgery does not have the primary objective of changing an aspect of a patient's physical appearance. Indeed, that is no part of the purpose of any type of Refractive Surgery. While we support the principle of the GMC's guidance applying to refractive surgery, it is not for the RCOphth to so define. It would be constructive if the RCOphth were to seek explicit clarification from the GMC on the present situation of it not being clear whether and the extent to which the GMC guidance applies to all or any Refractive Surgery procedures. Clearly no guidance in this territory can be issued by RCOphth until this is made explicitly clear since clinicians must know, without ambiguity, which guidance applies to which procedures and, where relevant GMC	also applies to refractive surgery. See: http://www.gmc-uk.org/guidance/ethical_guidance/29160.asp (last accessed October 15th 2016) The parliamentary written answer below reinforces this point. **Mrs Theresa Villiers MP**: What steps he is taking to ensure high quality care is provided in the refractive eye surgery sector. [44573] **Mr Philip Dunne MP**: Providers of laser eye surgery are required to register with the Care Quality Commission (CQC), as this is a regulated activity. All providers of regulated activities under the Health and Social Care Act 2008 must be registered with the CQC and meet the fundamental standards of safety and quality. The CQC has a range of enforcement actions that it can take if providers do not meet the fundamental standards. CQC inspectors take into account best practice and recognised guidelines, when undertaking inspections of providers. The Department is consulting on extending the scope of CQC 's provider ratings to include providers of laser eye surgery. Ratings will give the public with clarity about how well these providers are performing above and beyond compliance with the requirements of the regulations.	

	guidance exists, any RCOphth guidance must be wholly consistent with that published by the GMC. As a general concern regarding the draft guidance it is redolent with proscribed matters e.g. not less than 7 days 'cooling off', no intermediate consultations by telephone, etc., where there is no evidence base for what is to be required. These are simply examples and many more could be given. Before a proscribed requirement is imposed on the clinical process it is essential that there be a clear evidential basis for what is to be insisted upon. Some of these requirements have appeared form nowhere without the slightest justification or evidential basis. This approach is wholly inappropriate. The whole document should be carefully examined for all such proscriptions and if the document does not provide a specific justification for the proscription backed up by a stated, referenced and publicly available evidential basis that the proscription would result in improved clinical outcomes, then each proscription should be deleted. The draft has all of the hallmarks of a document drawn up by a wholly unrepresentative group with no involvement in the process by the main suppliers to the public which carry out over 90% of the procedures. Guidelines should not be drawn up and imposed on the basis of the personal views of a few clinicians whose experience and methodology is removed from that of the overwhelming majority of the providers. The result is guidance which is hopelessly proscriptive, illogical, unsupported by evidence and skewed to a particular model of service provision utilised by a few independent providers. In part this will be explained by the	Doctors performing laser eye surgery in the United Kingdom must also be registered with the General Medical Council (GMC). All registered doctors are expected to be familiar with the GMC 's publication 'Good medical practice' and supporting guidance, which describes what is expected of them. This document makes clear that medical doctors must recognise and work within the limits of their competence. Following a review of the cosmetic industry in England by Professor Sir Bruce Keogh, the GMC has produced guidance for doctors that carry out cosmetic procedures and this also applies to refractive eye surgery. The new GMC guidance covers both surgical (such as laser eye surgery) and non-surgical procedures. In addition, as the professional body for setting the standards of practice for refractive procedures, the Royal College of Ophthalmologists are leading on work to improve the delivery, safety and standards for patient information for laser eye surgery. The GMC expect a doctor to be up to date with the latest medical guidance, including any new guidance published by the Royal College of Ophthalmologists on laser eye surgery.	

	failure of the process to adhere to NICE procedures and principles notwithstanding the original assertion that these would be complied with. The standards ought to reflect the practice of all clinicians engaged in this type of surgery and not just the few working in independent private practice who provide only a very small proportion of the procedures carried out in the UK in any defined time period. If the working party had included proportionate representation based on procedures carried out from across the UK providers then there was a reasonable prospect that a set of draft guidance might have resulted which would reflect the way in which surgeons actually deliver the exceptionally good clinical outcomes achieved by this type of surgery across the UK. Instead what has been delivered is draft guidance which, as a whole, is appropriate only for the very small proportion of providers represented on the working party. The guidance in its current form is not even-handed, but is geared towards independent practice and biased against the vast majority of refractive surgery practice in the UK, which takes place in a community setting. This is, at least in part, due to the inadequate process which has been followed in drafting these guidelines, which involved insufficient consultation and is primarily based on the unsubstantiated views of a small number of independent surgeons without reference to robust evidence. It is hoped that the RCOphth will take on board the response it receives in this instance. If the RCOphth is determined to proceed with this guidance in its present form, it should be made explicit in the guidance itself that it is only relevant	Two of four surgeons on the RSSWG panel are from multiple refractive surgery providers	

	to those engaged in independent private practice and applies only to surgery delivered by practitioners working in that sector. Assuming that it is explicitly confirmed in writing by the GMC that its guidance for cosmetic interventions applies to refractive surgery, notwithstanding the definition of cosmetic surgery, then the RCOphth guidance should state that for members working in this area of clinical practice who are not engaged in independent private practice they should not follow the RCOphth guidance but should rather rely exclusively on the GMC's guidance for cosmetic interventions.		
Optical Express Group	Comment 2 Section 1 Standard 1.2 The understanding that the GMC's guidance for cosmetic interventions should also apply to refractive surgery is based only on a single quoted comment made by Mr. Bruce Keogh. As he is NHS England's Medical Director, and has no role or authority in the devolved nations, anything said by him has no standing outside of England. It has not been explained how, even in England, his opinion on when GMC guidance should apply stands, since he has no role outside of the NHS in England and the vast majority of laser refractive procedures with which this guidance is concerned are not carried out within the NHS. The matter is too important to be left in this state of uncertainty.	See above	No comment
Optical Express Group	Comment 3 Section 2 Standard 2.1 and 2.2	Entry onto the GMC's Specialist Register can be obtained in several ways.	No change as a result of this comment

	The standards do not expressly state the RCOphth's guidance on an experienced Refractive Surgeon (from an EU country for example) who has General Medical Council registration and has re-located to the UK undertaking refractive surgery procedures. Is it the RCOphth's position that the Ophthalmic Surgeon after 1st January 2018 would have to work within the NHS to gain Specialist Registration status and complete the CertLRS before undertaking refractive surgery procedures in the UK? If that is its position then a full legal analysis is required on whether such restrictions on practice would be lawful in relation to both EU and non-EU citizens.	http://www.gmc-uk.org/doctors/SpecApps.asp The most common is by completing a GMC approved training programme in the UK and being recommended for a Certificate of Completion of Training (CCT). Other relevant mechanisms are listed on the GMC Website See information on Specialist and GP applications http://www.gmc-uk.org/doctors/24628.asp	
Optical Express Group	Comment 4 Section 4 Standard 4.1 The Care Quality Commission only has jurisdiction in England. The devolved nations in the UK – Scotland, Northern Ireland and Wales have other agencies with different jurisdictions. This should be reflected here.	See amendment	Section 4.1 has been amended to: 4.1 Refractive surgery must be carried out in premises registered with the Care Quality Commission (CQC) in England, or the equivalent regulator in Scotland, Wales and Northern Ireland.
Optical Express Group	Comment 5 Section 4 Standard 4.5 Incision point to the eye should be noted in addition to the points stated.	This would normally be documented in the operation record and is not directly relevant to a 'Safe Environment'	No change
Optical Express Group	Comment 6 Section 5 Standard 5.6 It was confirmed at the industry engagement day on 11th May (as stated in our last formal submission) that the RCOphth accepts that a suitably trained and experienced Optometrist can determine suitability for a refractive surgery procedure and make a preliminary recommendation on appropriate surgery to the patient, subject to the final recommendation	The wording (5.6) already includes: 'Although preparatory information may include written material, video material or advice from suitably trained non-medical staff, the consultation at which the procedure recommendation is made must be with the operating surgeon.'	No change

	to the patient being made by the Ophthalmic Surgeon. The Optometrist's role should be clearly stated in these terms to avoid any ambiguity and that, where an optometrist is involved he/she plays an important role in supporting the Ophthalmic Surgeon in the Informed Consent Process.	Allied health professionals can offer preliminary advice only. We have not, at any stage, accepted that decisions on procedure choice in refractive surgery can be delegated.	
Optical Express Group	Comment 7 Section 5 Standard 5.6 The requirement that all patients must have a face-to-face consultation with the surgeon, instead of a telephone conversation, prior to the day of surgery, is unnecessary and discriminatory and places an undue burden on those patients who may be disabled, elderly, in fulltime employment and/or have travel restrictions or significant travel distances. The problem is exacerbated in parts of the UK where the travelling distances are such as to make attending consultations a wholly unreasonable burden. Further, for all patients the additional cost of such face to face consultations in person is an unreasonable burden. It is acknowledged that a face to face consultation compliant with the draft guidance could take place by 'Skype' or 'Facetime' or the like but not all patients have access to such facilities or are comfortable with the technology. This is an area where it should be left to the clinician to decide if, in his or her judgement, the patient sufficiently appreciates the information communicated and the options available in a telephone or similar discussion. If the clinician decides that the patient does not do so then the clinician may require an in	The GMC underline in their April 2016 guidance that in some areas they are setting higher standards than in their wider guidance. This is in order to address specific safety and ethical concerns outlined in the Keogh Report (2013). Consultation with the surgeon before the day of surgery is a central point. This is based on the need for a shared understanding of the expectations and limitations for a procedure (GMC point 16). A consultation discussion is normally informed by a full ocular examination. Lines of responsibility are inevitably blurred if the surgeon gives advice by telephone or skype without examining the patient first. The pre-operative consultation with the surgeon must take place in person.	No change

person meeting at an intermediate stage as well as on the day of surgery.

The guidance should explicitly provide that between the initial examination and recommendation there should be at least one consultation with a surgeon on a day other than the day of surgery, that this consultation can be by electronic means, including telephone, and must be with a surgeon who would be qualified to undertake the surgery proposed in the initial recommendation. There is no clinical or other requirement, and none has been suggested or justified, as to why it should be the same surgeon as will undertake the surgery who must engage in this consultation. It is very common throughout clinical practice for different clinicians to undertake different parts of the informed consent process and for there to be a variety of modes of communication. Telephone discussion between clinicians and patients is now commonplace. For many patients, telephone discussion is at least as 'comfortable' in terms of the effectiveness of the communication as is a face to face discussion whether in person or by some form of face to face video.

This is but one example of the results of the wholly unrepresentative composition of the working party where what has been included in the draft are the historical practices of the few surgeons engaged in independent private practice where modern and effective modes of communication are not adopted.

The imposition of costly proscribed procedures which are burdensome on patients in terms of time, expense and inconvenience, and which for many will

	be a barrier to treatment, must be justified by clinical criteria. Laser Refractive Surgery and associated procedures have no peculiarities or complexities which justify unique barriers and hurdles to treatment. For the great bulk of patients an informed consent process which involves an initial consultation, detailed ocular examination, provision of detailed oral and written information consistent with the guidance, a separate discussion with a surgeon (whether electronically and/or in person) and final consent being given on the day of surgery following the operating surgeon verifying after examination the appropriateness of the proposed procedure(s) will be wholly effective in ensuring that fully informed consent is given in advance of surgery. This is not intended to be an exhaustive description of the process which has other detailed stages, videos, question sessions, reading and advice on forms and documents etc. It represents a significantly more thorough and comprehensive process of informed consent that is routinely the case for much more complex and invasive surgical procedures. If the GMC guidance is confirmed to be applicable then its approach in this territory is both preferred and more appropriate than the very detailed and proscriptive approach of the draft guidance, which in parts appears to remove form the clinician the critical role of determining what is the most effective means of ensuring that the patient is fully consented, on an informed basis, prior to having or deciding not to have the most appropriate treatment for that patient.		

Optical Express Group	Comment 8 Standard 5 Section 5.9 The patient should be provided with the Informed Consent document in advance of their first consultation with the Ophthalmic Surgeon.	This is covered in section 5.5	No change
Optical Express Group	Comment 9 Section 5 Standard 5.10 There is no justification for a cooling off period of one week. The recommendation should be reduced to 2 days to accommodate patients who provide their informed consent and need the procedure performed within a shorter time. There is no peculiarity of this type of surgery which places it in a category requiring a prescribed time period. Much more invasive forms of surgery proceed without such extensive time restrictions. This is not a territory for restrictions, in effect attempted regulation, on time periods. The surgeon should have the ability to decide if, in the circumstances, the patient has had adequate time to understand and consider the risks and benefits of the surgery so that he/she can give properly informed consent.	The one-week cooling-off period, derived after extensive discussion with stakeholders, is a compromise between the two-week cooling-off period stipulated by CSIC for cosmetic surgery and requests based on convenience and GMC point 25 for a shorter period from some refractive surgery providers. If there are good reasons in individual cases for operating after a shorter cooling-off period, these must be agreed with the patient and recorded in the medical record.	Section 5.10 now reads: 5.10 Surgery should not take place on the day on which the procedure recommendation is made and the initial consent discussion with the operating surgeon takes place. A minimum cooling off period of one week is recommended between the procedure recommendation and surgery. In exceptional circumstances, where a one week cooling off period is impractical, the reasons for this must be agreed with the patient and documented in the medical record.
Optical Express Group	Comment 10 Section 5 Standard 5.11 We believe the Working Group has misunderstood the intention and practice of discounts. Offers are not in any way intended to impose or pressure a procedure onto a patient when surgery is not appropriate or they have not provided their informed consent. Rather they are typically used, including in the NHS, to support workflow and enable services to be provided to the greatest number of patients in the most cost-efficient and effective way. The guidance provides no explanation	It is time-limited discounts rather than discounts per se that are at issue in terms of pressure to proceed. (Keogh recommendation 31)	Section 5.11 now reads: There should be no pressure to proceed with surgery. Specifically, patients should not be offered time limited discounts, or a refund of the initial consultation fee if they choose to proceed. Any deposit for surgery should be fully refundable within a reasonable time period if patients choose not to proceed. Rates of conversion to surgery should not be

	as to why patients should not benefit from economies which a provider may be able to make from organising its clinical processes in a particular way on a particular date. It is understood why those operating independent private practice clinics might not be able to offer such benefits to patients in light of their relatively small numbers of procedures on any one day but that is no reason to prevent patients with other types of provider from securing such price advantages. In the absence of any evidential or clinical justification for the blanket prohibition of offering discounts in any circumstances, one is forced to conclude that this has more to do with protecting the business practices of the small section of providers who are the authors of the draft than ensuring that guidance operates in the interests of patients. As regards the refund of deposits, the timing of this depends to some extent on the circumstances. For a patient who cancels a few days in advance and gives clear notice of not wishing to proceed through to a patient who gives no advance notice and who fails, without warning, to appear at a scheduled surgery day, the timing and circumstances of refunds will be different. Our T&Cs have been reviewed by consumer law experts and practitioners as well as by consumer groups and have been regarded as representing a fair balance between the interest of the patient and the need for us to operate efficiently and cost effectively. The timing of the return of deposits is wholly outwith the clinical remit of the RCOphth. Recommended change: delete all and substitute, "There should be no pressure to proceed with		used as a performance measure for surgeons, optometrists or other staff.

	surgery. Financial inducements should not put undue pressure on patients to make a decision without giving them the time to perform their own due diligence. Any deposit for surgery must be fully refundable within a reasonable time if patients choose not to proceed."		
Optical Express Group	Comment 11 Section 5 Standard 5.11 It is important to monitor the clinical performance and patient reported performance of eye care professionals to include Optometrists and Ophthalmic Surgeons. Organisations may differ in their approach to this.	Clinical performance of staff and patient satisfaction are distinct from the use of conversion rates as performance measures. Incentives relating to conversion rates can act as a form of pressure to proceed with surgery.	No change
Optical Express Group	Comment 12 Section 5 Standard 5.11 Unsure of the relevance of referring to Optometrists in this section without outlining their recommended role in the refractive surgery patient flow. The document should be clear as to the Optometrists role in the recommendation and consent process.	See response to comment 6 above	No change
Optical Express Group	Comment 13 Section 6 Standard 6.7 A definition of "complex cases" should be provided along with a timeline for how long the treating Ophthalmic Surgeon should assess complex cases for. This should be until a thorough management plan has been established and routine aftercare going forward is required.	See amendment – the principle here is that the role of allied health professionals in aftercare is restricted to screening for complications. For clarity, complex cases are cases with preoperative risk factors for complications after surgery; or cases that, as a result of a complication during or after surgery, may require any addition to previously scheduled routine review or treatment. There should be clear arrangements for transfer to another provider where appropriate in the	Section 6.7 and 6.8 now read: 6.7 Review of complex cases should not be delegated until the treatment for any complications is complete, the risk of further complications has returned to baseline levels for the procedure, and routine care pathways can be resumed safely. 6.8 Complex cases are cases with preoperative risk factors for complications after surgery; or cases that, as a result of a complication during or after surgery, may require any addition to previously scheduled

		case of an emergency or where additional specialist treatment is required for the treatment of complications. A new section 6.8 has been added	routine review or treatment. There should be clear arrangements for transfer to another provider where appropriate in the case of an emergency or where additional specialist treatment is required for the treatment of complications.
Optical Express Group	Comment 14 Section 6 Standard 6.8a The responsibility should directly relate to the provision of clinical management pertaining to the procedure performed and not necessarily all medical care.	See amendment	6.9 If early or later routine review appointments are delegated[9] to another member of the care team (ophthalmologist or optometrist) by the operating surgeon: a) The operating surgeon remains responsible for the care of the patient in relation to the procedure performed until discharge from the provider after late stage review. b) The operating surgeon should ensure that the optometrist or ophthalmologist reviewing the patient is appropriately trained in refractive surgery care. c) The operating surgeon should ensure that the optometrist or ophthalmologist is working from clear guidelines when defining whether he/she should refer back to the operating surgeon for guidance or additional review. d) Where possible, the ophthalmologist or optometrist caring for the patient after surgery should also have been involved in their pre-operative care. e) The ophthalmologist or optometrist caring for the patient after surgery should have adequate medical indemnity cover.

			f) The operating surgeon or an experienced refractive surgeon on-call should be available to deal with any additional interventions required or concerns raised. g) If the operating surgeon is unavailable post-operatively, he/she should transfer the patient's care to a named surgeon
Optical Express Group	Comment 15 Section 7 Standard 7.2 The terms and use of data associated with a national database need to be outlined in much greater detail in a separate document. What type of information is recorded, what are the controls for data integrity, who is responsible for the upkeep and analysis of the database and how is it to be published are some of the many questions and issues that need to be carefully addressed before requiring providers to contribute to a national database.	Agreed – these important questions will be considered in the development of additional a national data set for refractive surgery.	No change
Optical Express Group	Comment 16 Section 8 Standard 8.1 Does "referral" indicate the initial eye examination? The majority of patients are not referred from elsewhere.	Patients may be referred from a variety of sources with or without an examination, or self-referred.	No change
Optical Express Group	Comment 17 Section 8 Standard 8.1 There is no mention of the role of other eye care providers, specifically the capability of a trained optometrist to perform a consultation, make an initial surgery recommendation and initiate the informed consent process. This is a serious omission here and in other sections of the document.	See response to comment 6 above	No change

Optical Express Group	Comment 18 Section 8 Standard 8.1 Is a consultation with the Ophthalmic Surgeon recommended on the day of surgery itself? This is not expressed in the patient journey as outlined.	The patient should see the operating surgeon on the day the procedure choice is made, at least 1 week before the day of surgery. This is already clearly stated.	No change
Optical Express Group	Comment 19 Section 8 Standard 8.1 What is the role and responsibility of the Ophthalmic Surgeon	Responsibility for patient care and any delegation of patient care – this should already be clear from the April 2016 guidance for surgeons included here. Good Medical Practice Point 44	No change
Optical Express Group	Comment 20 Section 9 Standard 9.1-7 The Advertising and Marketing Section statements are beyond the scope of the RCOphth RSSWG. What level of external advice and guidance has been provided by advertising and marketing experts? The guidance on Advertising and Marketing should not go beyond the scope of the GMC Recommendations concerning Cosmetic Surgery.	The Keogh recommendations 29, 30 and 31 and GMC Guidance on Cosmetic surgery points 46-54 and Good Medical Practice 70 have been followed and principles applied. See specific amendments in response to comments 22 and 23 below.	No change
Optical Express Group	Comment 21 Section 9 Standard 9.3 Have the RCOphth RSSWG considered the legalities surrounding this statement in terms of patient data? What type of verification is required and who undertakes / oversees the verification process?	GMC Guidance on Cosmetic Procedures point 48. This applies to other medical procedures and similar legalities apply.	No change
Optical Express Group	Comment 22 Section 9 Standard 9.4 It is not for the RCOphth to prescribe forms of words – it is for the independent members meeting the terms of the guidance.	Other sectors including finance, tobacco and alcohol follow similar requirements for disclosure.	Section 9.4 amended to: 9.4 All advertisements for surgical procedures where possible should state the following: *"All eye surgical procedures carry a level of risk including not obtaining the desired outcome through to varying levels of*

			visual loss. Your eye surgeon will discuss the risks, benefits and alternatives of sight correction surgery, including those specific to your own circumstances, at the time of your preoperative consultation."
Optical Express Group	Comment 23 Section 9 Standard 9.6 This statement (as per our previous submission) is not in line with ASA / CAP codes. It conflicts with the codes of other organisations.	9.6 is guidance and makes clear that pricing should be discouraged. If pricing is used, then the CAP codes should be followed: 3.4 For marketing communications that quote prices for advertised products, material information [for the purposes of rule 3.3] includes: 3.4.1 the main characteristics of the product 3.4.2 the identity (for example, a trading name) and geographical address of the marketer and any other trader on whose behalf the marketer is acting **3.4.3 the price of the advertised product, including taxes, or, if the nature of the product is such that the price cannot be calculated in advance, the manner in which the price is calculated** 3.4.4 delivery charges **3.4.5 the arrangements for payment, delivery, performance or complaint handling, if those differ from the arrangements that consumers are likely to reasonably expect**	Section 9.6 has been amended to: 9.6 Advertising price is discouraged. In the event that price of surgery is advertised, all material information should be given which patients need in order to make an informed decision about the advertised price, such as eligibility criteria, specific details of the treatment being provided and, if there is a range of prices, patients should be made aware that actual pricing could vary significantly from the advertised price. Information should be given in a clear, unambiguous and intelligible manner.

		3.4.6 that consumers have the right to withdraw or cancel, if they have that right (see rule 3.55). Should the provider wish to advertise price, then the CAP rules should be followed so if advertised at “from £395 per eye” then precisely what is likely to eligible and delivered must be indicated on the advertisement, similar to car advertisements.	
Optical Express Group	Comment 24 Section 10 Standard 10.2 Surgeons at our organisation are not involved in any fee discussions with patients. This section is irrelevant for the majority of surgeons and indicates that these guidelines have been produced in order to support one form of provision at the expense of all others.	This is a narrow view. Many surgeons are involved at board level in refractive surgery providers and all surgeons share responsibility for the ethical standards or the organisations they work for. Surgeons should be aware of the content of discussions with their patients by those working on their behalf as their “agents”	Section 10.2 has been amended to 10.2 Surgeons performing refractive surgery should: a. Disclose any personal affiliation or other financial or commercial interest relating to their practice including: other private healthcare companies, laser manufacturers, implant manufacturers, pharmaceutical companies or instrument manufacturers. b. Obtain adequate professional indemnity insurance that covers the procedures they undertake.
Optical Express Group	Comment 25 Section 10 Standard 10.2b Does this mean that independent providers need to confirm to the patient they are seeing that they have a direct financial interest in the patient proceeding with services offered through their clinical care?	See response to comment 24 above	See above amendment to section 10.2

United Kingdom and Ireland Society of Cataract and Refractive Surgeons	Comment 1 Many of my colleagues and myself as well, fail to understand why UKISCRS and BSRS were not invited to select a delegate for the refractive surgery standards committee. By not doing this we/I do not feel the vast majority of refractive surgeons in the UK who are represented by these two bodies have been able to participate in this process. There is a strong feeling that this needs to be rapidly addressed and appointments to the committee even at this late stage arranged.	There was an open call for RSSWG panel members however no representation was made by the two organisations. Surgeons from a spectrum of UK providers are included on the panel. It is useful to receive comments from UKISCRS which are addressed below.	No change
United Kingdom and Ireland Society of Cataract and Refractive Surgeons	Comment 2 There is very strong feeling indeed that a recognised European/UK refractive/corneal fellowship, being more substantial than CertLRS, should be recognised as an alternative qualification to the CertLRS to allow refractive surgery practice in the UK. It is important that the general implementation of the ruling to undertake the CertLRS examination in order to offer refractive surgery should be only restricted to the people who have *not* undertaken corneal and refractive surgery fellowship or training.	Since there is currently no system for accreditation of fellowship level subspecialist training in the UK, we are unable (at this stage) to recommend that refractive surgeons are fellowship trained in ocular surface disease, cataract, corneal and refractive surgery.	No change
United Kingdom and Ireland Society of Cataract and Refractive Surgeons	Comment 3 Other refractive surgery qualifications and courses should also be considered in addition to the RCOphth CertLRS such as the Belfast course and Professor Alio's on line course both of which are excellent and actually much more comprehensive than the college examination. I know as I am an examiner for all three and many apologies but the CertLRS come in third…	There is currently no other qualification that has been assessed as equivalent to the CertLRS, which has undergone a review of 2017 https://www.rcophth.ac.uk/examinations/certificate-in-laser-refractive-surgery/ The College is aware of the new EBO exam. The view from the Examinations Committee is that it is too early to offer equivalence at this stage, but this could be reviewed in	No change

		future amendments to the Standards document.	
United Kingdom and Ireland Society of Cataract and Refractive Surgeons	Comment 4 Whilst, I recognise the excellent work that has been made with the introduction of the CertLRS, this exam needs to be extended to lenticular refractive surgery (see comment 3), especially given the increase in refractive lens exchange and the use of multifocal lenses in private practice, often by not anterior segment/corneal surgeons but by those who have no refractive surgery training and/or access to corneal laser technology such as VR surgeons	The Cert LRS exam will include lens based refractive surgery from 2017 https://www.rcophth.ac.uk/examinations/certificate-in-laser-refractive-surgery/	No change
United Kingdom and Ireland Society of Cataract and Refractive Surgeons	Comment 5 The refractive surgery examination is the most expensive examination which the college runs and this examination should not be a money making venture for the college (I know personally that the examiners only receive expenses) but should be tariffed in equivalence to other exams like the exit examination. The fees appear to be discriminatory.	The CertLRS fee is set in line with the small number of candidates that apply to sit it and does not make a profit for the College. The fee for the new format will be kept under review and reduced if feasible	No change
United Kingdom and Ireland Society of Cataract and Refractive Surgeons	Comment 6 The 'grandfather' recognition to established refractive surgeons needs spelt out in terms of experience, examiner status at national/international courses and examinations, research, previous training, teaching at national/international symposia.	Going forwards, new refractive surgeons will be required to hold the Cert LRS exam from 2018. This is because many important aspects of the knowledge base required to practice refractive surgery safely are not covered by the current OST curriculum. This contrasts with nearly all other ophthalmic subspecialties.	See above changes to sections 2.1 and 2.1

		However, after extensive debate within the RSSWG, the College Council, and the Examinations Committee, we recognise that an entry level examination should not be applied as a requirement for surgeons who are already on the specialist register and have evidence of an established refractive surgery practice in their last revalidation cycle (prior to 2018). We have amended the wording in 2.1 and 2.2 accordingly.	
United Kingdom and Ireland Society of Cataract and Refractive Surgeons	Comment 7 There is confusion as to why the college is involved in the financial process with regards to setting the 3 day time frame for refunds? There are surely legal requirement for these timings which are not under the control of the college.	See above change to section 5.11	See above change to section 5.11
United Kingdom and Ireland Society of Cataract and Refractive Surgeons	Comment 8 If a refractive surgery examination is made mandatory for individuals wanting to enter the refractive surgery practice then similar examination should be introduced for cosmetic oculo-plastic surgery, etc by the RCOphth. The college should not be biased for or against any sub-speciality.	Most other subspecialties are covered within current OST training. The intention is to bring refractive surgery into OST training in future. Until this happens, the Cert LRS exam will help to ensure that refractive surgeons enter the specialty with a uniform knowledge base.	No change
United Kingdom and Ireland Society of Cataract and Refractive Surgeons	Comment 9 The idea of national database is good but it is difficult to control the quality of data coming in and out so presumably will be standardized. There is a danger that it may generate false positive and negative results of newer refractive procedures as they are likely to be biased statically due to limited	The first step will be to agree a National Data Set according to current College Guidelines. Once this work is complete, an extension of the National Ophthalmic Database audit can be considered. If data is swept automatically from Electronic Healthcare Record (EHR)	No change

	sample sizes and limited surgeons offering it. This can then have a potential to prematurely kill or to encourage a new procedure/device, etc in the market. We assume that health economics/statistical expertise will be employed when setting up such a database.	systems, a highly relevant real-world picture of results in the UK should emerge. See GMC 7b	
United Kingdom and Ireland Society of Cataract and Refractive Surgeons	Comment 10 Page 6, 4.3.b seems inadequate for bilateral intraocular surgery, where the global standard of care mandates not just different instruments, but different sterilisation cycles and fluids/solutions to come from different batch numbers: See http://isbcs.org/research-reviews/isbcs-general-principles-for-excellence-in-isbcs-2009/	See amended wording	Section 4.3b has been amended to: 4.3b Separate instrumentation for each eye in bilateral corneal surgery and, in addition, separate batches for fluids and separate sterilisation cycles for instruments used in each eye in bilateral intraocular surgery.
Optical Confederation	Comment 1 Entire Document We have appreciated the College's efforts - belatedly - to engage with stakeholders and to have moved the standards on from earlier versions. The layout of the latest draft is significantly improved over the earlier version, and it has been an excellent idea to include the applicable sections of GMC guidance. This allows a clear differentiation between what is mandatory for surgeons and what is College advice (although, as we describe further in comment B2, some sections of GMC guidance have been transcribed into this draft in ways that are unhelpful – see comments A8, A9, B4 & C3). On the less positive side, in many areas this guidance strays beyond the GMC standards into areas where the College does not have competence, e.g.	The standards were formulated with input from across the refractive surgical spectrum in the UK and apply equally to surgeons taking a direct role in the management and governance of their clinics and surgeons who are employed with no direct management role. See new paragraph 1.5	New paragraph section 1.5 1.5 Our additional recommendations take two forms: direct advice to surgeons, and advice that surgeons should ensure is upheld in relation to their practice. Direct advice to surgeons is prefaced by the heading *'In addition, surgeons who perform refractive surgery should.'* Advice that surgeons should ensure is upheld in relation to their practice is prefaced by the heading *'In addition, the following principles apply for refractive surgery.'*

	optometry, business, finance and advertising. Moreover we still have concerns that the draft standards seem predicated on an old-fashioned model of individual doctors working in private independent practice (i.e. the Harley Street model as in paragraph 5.12, etc.). In fact surgeons are increasingly employed or engaged by companies, which actually offer the service and contract with patients, taking much of the administrative work off doctors' shoulders and leaving them to focus – as part of an integrated patient-focussed clinical team – on high-quality clinical work. The current standards do not seem to allow for this and thus would not be fit for purpose in 21st century models. For these reasons we do not believe the standards will achieve their desired aims.		
Optical Confederation	Comment 2 Entire Document It is regrettable to our mind that the College did not take the opportunity to work with partners across the whole refractive surgery sector from the outset and to develop pan-sector guidance appropriate for and relevant to all, for the benefit of patients. It is also regrettable that the College opted not to follow its NICE approved process in developing this guidance, as this could have prevented it falling into some of the more obvious pitfalls which will undermine its long term effectiveness and usefulness to the profession and the community ophthalmology sector. Nevertheless we will continue to work closely with the College and other sector partners to remedy these flaws, especially in respect of community refractive surgery models, which are likely to be increasingly the prevalent	This comment seems to be based upon a misapprehension of the nature of NICE accreditation. Of the College' publications, only two have been developed using NICE accreditation processes – the Cataract Surgery Commissioning Guide (2015) and the Glaucoma Commissioning Guide (2016). NICE accreditation is granted to an accredited processes used to produce a particular form of guidance – in this case, the College's Commissioning Ophthalmology Services Guides. It does not apply to all publications produced by the College. In order to achieve NICE accreditation for discrete types of guidance, the processes used to produce each type must be	No change

	mode of choice for patients and surgeons in the future.	submitted to NICE separately for assessment.	
Optical Confederation	Comment 3 Section 3 Standard 3.3 Whilst we agree that this should be best practice, the lack of strong links and collegiate working between the NHS and private sector in some cases acts as a barrier, and we suggest that the text promote alternative possibilities such as attending case seminars or video review sessions at national or international refractive surgery meetings.	Comes under 'professional networks' – wherever possible, we have read across directly from April 2016 CSIC guidance. But the wording here needs amendment to fit the refractive surgery context better.	Section 3.3 now reads (note 3.2 deleted – 3.3 becomes 3.2): 3.2 Take part in professional networks, national and international meetings to allow discussion of complex cases with colleagues and help ensure that their practice is well aligned with contemporary clinical evidence.
Optical Confederation	Comment 4 Section 4 Standard 4.3d We are not convinced this needs always to be nursing support and instead suggest "appropriate recovery support".	See above – this is a direct read across from April 2016 CSIC guidance and remains appropriate particularly in the operating theatre environment.	No change
Optical Confederation	Comment 5 Section 5 Standard 5.6 There needs to be some provision in this section to allow for one surgeon taking over from another (i.e. in case of sickness or force majeure) on the day of surgery when the performing surgeon will have to double-check the consent taken by a colleague on a different day, as is normal practice in other clinical teams. If a patient has made up their mind about surgery and made personal arrangements to attend on the day, it would be unprofessional not to proceed with the planned surgery if they wish and with their full knowledge that their surgeon is a different surgeon	This was discussed by the committee at the July meeting of the RSSWG. Refractive surgery is always elective. So there is no reason why surgery cannot be deferred in the event that the surgeon conducting the procedure consultation cannot perform the surgery as originally scheduled. The GMC underline in their April 2016 guidance that in some areas they are setting higher standards than in their wider guidance. This is in order to address specific safety and ethical concerns outlined in the Keogh Report (2013). Consultation with the	Section 5.6 amended to: 5.6 Responsibility for the consent process should not be delegated: the surgeon performing the procedure should be satisfied that the patient is happy to proceed with surgery, is aware of the risks, and has realistic expectations for the outcome. Although preparatory information may include written material, video material or advice from suitably trained non-medical staff, the consultation at which the procedure recommendation is made should be with the operating surgeon. This should be a face-to-face consultation (not

	from the one who carried out the original consultation and recommendation.	surgeon before the day of surgery is a central point. This is based on the need for a shared understanding of the expectations and limitations for a procedure (GMC point 16).	conducted by telephone) and should not occur on the day of surgery. At every stage, patients should be clearly informed about which staff they will meet and who they are receiving care from.
Optical Confederation	Comment 6 Section 5 Standard 5.6 This section fails to recognise that new models of care – in refractive surgery and elsewhere in the health care system – will increasingly involve remote access consultations, for example by telephone or video conference. These options are increasingly sought by patients to streamline the process for accessing the care they need. Reducing the number of face-to-face appointments that patients must attend is particularly important when they may need to travel and/or take time out from work or other responsibilities. It is therefore not appropriate in 21st century surgery to stipulate that consultations must always take place face-to-face.	A consultation discussion is normally informed by a full ocular examination. Lines of responsibility are inevitably blurred if the surgeon gives advice by telephone or skype without examining the patient first. So the pre-operative consultation with the surgeon must take place in person.	See above change to section 5.6
Optical Confederation	Comment 7 Section 5 Standard 5.10 We fully support the concept of a cooling off period, however, this needs to be patient-specific. We note that the GMC - rightly - does not specify the duration of the cooling off period. If this guidance does make a recommendation for the duration of the cooling-off period, “one week” is unclear and should instead be either “five working days” (our preference) or “seven calendar days”. Whilst a five- day cooling off period is workable, we nonetheless feel that the current draft is excessively prescriptive and paternalistic and impinges upon the clinical	The one-week cooling-off period, derived after extensive discussion with stakeholders, is a compromise between the two-week cooling-off period stipulated by CSIC for cosmetic surgery and requests based on convenience and GMC point 25 for a shorter period from some refractive surgery providers. If there are good reasons in individual cases for operating after a shorter cooling-off period, these must be agreed with the patient and recorded in the medical record.	See above change to section 5.10

	judgement of the operating surgeon and free patient choice.		
Optical Confederation	Comment 8 Section 5 Standard 5.22 We recognise that this section is taken from the GMC, however, this is a clear instance in which the GMC's guidance should not be included without appropriate interpretation as it is not applicable to increasingly prevalent community refractive surgery models in which care is delivered by clinical teams. In such cases it is the responsibility of the surgeon to ensure that the patient has been given clear and accurate information, not necessarily to do this themselves (they will not always be the best person to have this discussion with the patient). This standard needs also to include that information can be provided in advance in writing, in person or via a DVD/film.	See 5.6 - this allows for the role of allied health professionals, video and other aids in patient education. But responsibility for the consent process remains with the operating surgeon.	No change as a result of this comment
Optical Confederation	Comment 9 Section 5 Standard 5.28 Again, it is unhelpful to include GMC guidance without reference to the context in which an increasing amount of refractive surgery takes place. This standard assumes that the charges are set by the surgeon – this will not be the case for many. This section needs to make clear that this guidance applies only where the surgeon is personally the service provider. Where the surgeon is an employee or contracted to deliver the service, then charges are a matter for the provider and beyond the remit of the College and the scope of this guidance.	It does not assume that charges are set by the surgeon, but is reasonable to expect surgeons to have knowledge of the charges and to ensure that patients are not surprised by charges for treatment that are not explained at the outset. Models of care provision need to alter to fall in line with GMC guidance and cannot remain in status quo.	No change

Optical Confederation	Comment 10 Section 6 Standard 6.8 The text of this section should recognise that in an increasing number of cases these arrangements will be put in place by the service provider, where the operating surgeon is not personally the service provider. In such cases the text should clarify that operating surgeons should check/confirm that they are happy with these arrangements.	The responsibilities of the operating surgeon are already explicit throughout in section 6.	A new paragraph has been added: 1.5 Our additional recommendations take two forms: direct advice to surgeons, and advice that surgeons should ensure is upheld in relation to their practice. Direct advice to surgeons is prefaced by the heading *'In addition, surgeons who perform refractive surgery should.'* Advice that surgeons should ensure is upheld in relation to their practice is prefaced by the heading *'In addition, the following principles apply for refractive surgery.'*

B. Does the language and format of the document make it easily accessible and user-friendly?

Yes 11 No 4 Not Answered 5

Comments received from	Comment(s)	Comments from the Refractive Surgery Standards Working Group (RSSWG)	Changes to the guidance document(s)
Advanced Vision Care	Comment 1 Section 5 Standard 5.6, 5.9 and 5.10 The wording is not clear as to why the initial consultation should be done by the Operating Surgeon when the rest of the care can be delegated to a Skilled Refractive Surgeon. Agreed one week cooling off period from recommendation and surgery but the face to face consultation with the operating surgeon can be done a minimum one day before if there is adequate cooling period between the Initial consultation and surgery and if the patient was given access to the operating surgeon to ask any questions be email for documentation. This is not made clear either by the language or the content	The one-week cooling-off period, derived after extensive discussion with stakeholders, is a compromise between the two-week cooling-off period stipulated by CSIC for cosmetic surgery and requests based on convenience and GMC point 25 for a shorter period from some refractive surgery providers. If there are good reasons in individual cases for operating after a shorter cooling-off period, these must be agreed with the patient and recorded in the medical record.	5.6 No change 5.9 No change See above change to section 5.10

Medical Defence Union	Comment 2 Section 3 Standard 3.2 We understand GMC paragraph 7(b) to include audit, within the wider description of 'national programmes to monitor quality and outcomes'. It also refers specifically to the need to contribute to device registries. It is not clear what 3.2 is intended to add to or to clarify within the GMC guidance. If, for example, there are registries, other than device registries, to which ophthalmologists should be expected to contribute, it would be helpful to give some examples.	Agreed – 3.2 is a direct read across from April 2016 CSIC guidance in the same format. But 3.2 is indeed covered by GMC 7b, and is therefore redundant.	3.2 has been deleted
Medical Defence Union	Comment 3 Section 3 Standard 3.4 We do not think surgeons can be expected to be responsible for ensuring devices they use comply with MHRA guidelines because the guidelines are developed for the organisations in which these devices are used and cover a number of areas including for example acquisition, maintenance and repair which are likely to be outside the surgeon's competence. We suggest this part of the standard needs to be more specific. For example, it may be reasonable to expect surgeons to ensure their employing organisation, or the organisation in which they practise, has policies in place to ensure compliance with MHRA device guidelines. It may also be reasonable to expect surgeons to comply with any MHRA guidelines that are relevant clinically – for example in relation to training or competence. It would be helpful if the standard identified the parts of the MHRA guidelines that relate to ophthalmologists and that they should be expected to comply with.	Again, this is a direct read across from April 2016 CSIC guidance. Our particular aim here was to direct providers and surgeons to MHRA guidance on the use of any custom made or non-CE marked devices, and any off-label use of medical devices or medicinal products (see new reference 4: https://www.gov.uk/topic/medicines-medical-devices-blood/medical-devices-regulation-safety	3.4 (now 3.3) has been amended to: 3.3 Ensure that the clinic or organisation in which they practise has policies in place to maintain compliance with MHRA guidelines on the use of implants, medicines and medical devices; in particular the use of custom made or non-CE marked devices, and off-label use of medical devices [4].

Medical Defence Union	Comment 4 Section 4 Standard 4.4 The GMC cosmetic interventions guidance is quoted substantially after 4.4 and the standards document replaces the GMC phrase 'cosmetic interventions' with 'refractive surgical interventions', but only in the headings and not in the GMC text. It would be clearer to quote the GMC guidance fully and to preface the GMC quote with the instruction to read 'refractive surgical interventions' for each occasion the GMC guidance uses the term 'cosmetic interventions'.	Noted	'refractive surgical' now replaces 'cosmetic' in GMC paragraphs 15, 19 and 56.
Medical Defence Union	Comment 7 Section 5 Standard 5.10 While we believe the use of the phrase 'procedure recommendation' is appropriate in standard 5.6 (as the wider consent process is also covered and the procedure recommendation is only part of it), we do not think the phrase accurately reflects what the GMC expects to happen at 5.10 which must also reflect the fact there has been a full dialogue between the surgeon and patient so that the patient has all the information he/she needs in order to give consent. The phrase 'consent dialogue' or 'consent discussion' or something similar would provide a better indication of what needs to have taken place.	We have tried to build this into the re-worked para 5.10	See above change to section 5.10
Royal Liverpool University Hospital	Comment 1 Section 2 Not entirely. As already stated use of words such as 'should' are open to interpretation. This needs to be clarified and be clear as to whether it is 'must', 'mandatory', 'recommended' etc., is what is meant. This applies throughout the document. For example, what is meant by hold? Does this mean 'has passed one version of an examination'?	See 1.4 and pp2 'using this guidance' of the April 2016 GMC guidance in which the implications of the terms 'should' and 'must' is clearly explained. We are clear that the documents should be read in parallel.	The GMC, rather than the College, is the regulator. After legal advice on this point, almost all instances of 'must' in our additional recommendations have now been replaced by 'should'.

Royal Liverpool University Hospital	Comment 2 Section 2 Which version of the LRS?	There is no requirement for those already in possession of the CertLRS prior to the new format being introduced in 2017, to retake the CertLRS.	No change as a result of this comment
Royal Liverpool University Hospital	Comment 3 Section 4 Standard 4.4 refractive target Please can the authors specify what they mean by the 'refractive target' and how this is to be written e.g. target = -0.5/+0.50 x 80 or is it meant to be as a sphere or nearest spherical equivalent e.g. -0.25?	Amended for clarity.	Section 4.4 parts listed items 5 and 6 have been amended 5. (for implants) implant make, model and dioptric power and spherical equivalent refractive target 6. (for laser refractive surgery) the programmed treatment sphere, cylinder, axis and spherical equivalent refractive target
My Beautiful Eyes	The answer to the question depends on the user of the document. If the document is intended primarily as guidelines for surgeons then the document is a little troubling, as the tone, whilst accessible, seems to assume a somewhat junior level of experience. Although the tone is in line with publications from HMG, such publications are usually aimed at a wider demographic. User friendliness in documents aimed at a professional audience is not necessarily an advantage, as it tends to diminish the importance of the guidelines. Perhaps the tone should be more: '*sit down, shut up and pay attention?*' This is of course only a suggestion.		
Ophthalmologist	Comment 1 Section 2 Is the certification voluntary or compulsory? Or voluntary for now but moving towards compulsory later? What would be the time scale, if so? As far as I	The College is not a regulatory body so adherence to its recommendations in the Standards document are voluntary.	No change

	know, the American Board of Cosmetic Surgeons certification is still voluntary as is the CSIC certification. I don't know of any equivalent American or European refractive surgery exam and certification either, voluntary or compulsory. Subsequent to Refractive Surgery certification, will it need to be recertified at regular intervals? With existing hurdles to training in refractive surgery, would it not likely lead to concentration in a few centres (some NHS organizations but mostly oligopolistic commercial organizations) only, of refractive expertise?		
Ophthalmologist	Prices in the UK will increase if high street providers are to comply.	This may or may not be the case but this is not in the remit of the standards document.	No change
Optical Express Group	Comment 1 Section 5 Standard 5.1 By "standardised" information is it meant that the same information should be provided to each patient by a provider or that the same form of information should be provided to all providers to all patients?	Standardised patient information should be freely available (5.1). Provider specific information should build on this rather than contradict standardised procedure information as outlined in 5.3.	We have inserted 'standardised' in 5.3 for greater clarity on this point, see below.
Optical Express Group	Comment 2 Section 5 Standard 5.3 What is meant by Independent Audit? Is it meant that each provider has to have their data independently audited by a third party? What is the scope of the audit and how are the auditors to be verified? The use of the term audit is apt to confuse since it is an accounting term based on carefully defined rules and procedures.	The term 'clinical audit' is now widely used in medicine. We hope the spirit of 5.3 is clear: providers should not make claims for superior results that are not backed up by quality clinical outcome data. We have changed the wording in 5.3 to try and enhance precision of meaning. Our hope is the National Database will serve to provide 'independent audit' or independently	Section 5.3 amended to: 5.3 Provider-specific promotional and advertising materials are part of the consent process, and should not conflict with standardised patient information. Any claims for superior outcomes must be supported by independently verifiable or peer-reviewed clinical evidence.

		verifiable clinical evidence of the standard required.	
Optical Express Group	Comment 3 Section 5 Standard 5.4 Is it not expected that alternatives available at the said provider will not be informed of to the patient – for example do the RCO expect Optical Express to not inform patients on their spectacle or contact lens alternatives to refractive surgery that are available at OE? Furthermore where is the limit to be drawn on alternative procedures – SMILE / RK / CK / Corneal Inlays	If we have understood correctly here a) OE should indeed discuss the 'do nothing' option (stay in spectacles and contact lenses) as with consent for any medical intervention – this is already covered in standardised patient information. Current standardised patient information covers mainstream procedures in wide contemporary use that have an established clinical safety track record. These procedures should be covered in the discussion of alternatives whether or not they are available from the provider. See current wording 5.4 'together with standardised information on alternative treatment choices…'	No change
Optical Express Group	Comment 4 Section 5 Standard 5.5 This sentence is unclear in wording and intent. Suggest rewording to: "Written consent forms should be available to the patient throughout and should not differ in tone or content from the patient information for procedures."	The aim is to get away from the 'consent form as disclaimer' presented on the day of surgery. This approach has been used commonly in refractive surgery in the past. 5.5 is already clear on this and the intent is further emphasised in 5.9	No change
Optical Express Group	Comment 5 Section 5 Standard 5.7 The words "Information on" can be deleted from the first sentence.	Amended as suggested	5.7 The consent conversation should be 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.

Optical Confederation	Comment 1 Entire Document This document is far more accessible than previous drafts. However it is notable from the language that it is assumed that all doctors deliver this service in independent practice. This in turn makes the document less accessible and user-friendly for the increasing majority who work under different provider models, especially outside of hospital.	The standards are equally applicable to self-employed surgeons and surgeons employed by larger providers.	No change
Optical Confederation	Comment 2 Entire Document The format – following the GMC guidance – is helpful. However in places large sections have been included wholesale, with the implication that they apply in their entirety, without removing, editing or annotating parts that are irrelevant or inappropriate, for example many references to cosmetic surgery remain which in some instances is comparable, but not always. In many places these sections need to be tailored to be more appropriate for refractive surgery.	See similar comment from the MDU above – thank you for picking this up.	Remaining references to 'cosmetic surgery' (paragraph 15, 19, and 56) have been replaced with 'refractive surgery' as per the intention specified in the introduction 1.4
Optical Confederation	Comment 3 Entire Document The document repeatedly uses the phrase "if a patient requests an intervention you must/should". This assumes that in all cases the doctor will agree to proceed. In all cases this should be changed to "When agreeing to perform..."	We have not edited any of the GMC paragraphs other than the clarificatory substitution of 'refractive surgery' for 'cosmetic surgery' (see introduction 1.4). The terms 'must' and 'should' have a specific connotation in GMC guidance (see pp2 April 2016 GMC guidance).	No change
Optical Confederation	Comment 4 Section 5 Standard 5.15 This comment is a prime example of the issue we have already flagged up in comment B2 and elsewhere that it is unhelpful to include wholesale	See response to comment 2 above	See above

	segments of GMC guidance without contextualisation. Here it would be more appropriate to contextualise and remove the reference to cosmetic surgery so that the end of the sentence reads, “which we believe are relevant to doctors performing refractive surgery”.		
Optical Confederation	Comment 5 Section 8 Standard 8.1 This seems muddled and unclear with little resonance for patients or clinicians. Moreover, this section again assumes a model of doctors working in independent practice and fails to recognise the more typical patient journey experienced in community refractive surgery settings in several ways: a) Patients are not always referred for refractive surgery, many self-refer. b) An initial consultation may not be performed by the surgeon but rather delegated to a trained member of staff who can rule out unsuitable patients, provide information about different interventions and the risks associated with each option and, based on discussion with the patient, agree a preliminary choice of intervention. c) Where the initial consultation is not carried out by the surgeon, there will follow a final consultation with the surgeon to double check and confirm the above, at which point consent may be obtained. d) Prior to surgery on the day, a member of the provider team will confirm the patient’s understanding and their wish to proceed with the surgery.	Some of these points are valid but we do not accept that decisions on procedure choice or suitability for surgery can be delegated. See amended wording.	Section 8.1 amended to 8.1 Key stages of the patient journey in refractive surgery comprise: • Initial advice from clinic staff • Procedure choice and discussion with the operating surgeon • Surgery • Early and late stage review consultations A cohesive team based approach with clear lines of responsibility and each member of the team playing to their strengths is essential at every stage.

	On the day of surgery the operating surgeon will again confirm the patient's wishes, understanding of risk and consent to proceed.		

C. What is the likely impact on patient groups affected by the standards?

No changes were made to the document on the basis of the comments received on this section of the consultation. Comments received are noted below for clarification and transparency.

Comments received from	Comment(s)	Comments from the Refractive Surgery Standards Working Group (RSSWG)
Optometrist	Patients will be better informed	
Advanced Vision Care	Comment 1 Section 5 Standard 5.6, 5.9 and 5.10 If the Operating Surgeon is going to see the patient a week before the treatment then the patient needs to come twice to the clinic which will require additional costs to the patient as most of the them travel far away to any refractive clinic. They will be happy they are seen on Initial Consultation by a skilled Refractive Surgeon and a decision is made in consultation with the Operating Surgeon and they are adequate cooling period between consultation and the surgery. They will be happy if they are given Open access to the operating surgeon to ask any relevant questions and a face to face discussion the day before the treatment, not on the day of the treatment	Two visits may well be required. The alternative is for the surgeon to evaluate and counsel the patient at the initial consultation.
Advanced Vision Care	Comment 2 Section 9 Standard 9.2 Again, we want to point out that this is not a remit of Royal College as this is nothing to do with Clinical standards. Celebrity Endorsement or Celebrity pictures in the clinic is universal practice. This enhances confidence of the patients not only in the clinic but in the procedure itself. It has been standard practice for well-known Surgeons to speak and promote a particular technique or device or any machine in well-known national and international scientific meetings. Nobody is declaring what is involved in their endorsement. Some of the well-known surgeons use one particular lenses or laser by they never declare	A declaration of financial interests or a conflict of interest statement is now a requirement for presenters at most international meetings. Patients are vulnerable and in the age of celebrity culture, declaration of financial arrangements or potential conflicts is ethical and transparent.

	their paid consultants to a particular company either in their CV or in the website which is universal in most of the NHS consultants and hospitals	
Advanced Vision Care	Comment 3 Section 9 Standard 9.5 Strongly agree with point C 'buy one get one free' and time limited deals. Most of the clinical practices are built upon word of mouth and it has been a tradition in most of the medical practices to offer a discount or reduced price to the previous patients and friends and family. It is not a financial endorsement but appreciation of their good will and also most of the patients do expect that. Again, this is nothing to do with clinical guidelines but falls under financial regulatory authority. Royal College should not interfere in how one should run their clinic or business practice.	This follows Recommendation 20 to 31 of the Keogh report as well as points 47 to 54 of the GMC Guidance on Cosmetic surgery which also applies to refractive surgery.
Royal Liverpool University Hospital	If the requirements are mandated we will no longer be able to continue to provide a tertiary referral NHS and non-NHS service for patients requiring laser corrective surgery. For example, we provide a laser refractive service to NHS patients who have poor refractive outcomes following cataract or corneal transplantation. We will also no longer be able to provide a service to patients who wish to have laser refractive surgery.	See response to similar comments above. If the problem is taking the Cert LRS exam, this will no longer be a requirement for surgeons who are on the specialist register and have evidence of an established refractive surgery practice in the last revalidation cycle.
Ophthalmologist	Section 2.2 If the requirements are mandated I will no longer be able to provide a tertiary referral NHS and non-NHS service for patients requiring laser corrective surgery. For example, I provide a tertiary laser refractive service to NHS patients from the region (Macclesfield Hospital, Leighton Hospital, Warrington Hospital and Stepping Hill Hospital) who have refractive surprise following cataract surgery and poor refractive outcomes following corneal transplantation. I also no longer be able to provide a service to patients who wish to have laser refractive surgery.	See response to similar comments above
Ophthalmologist	Comment 1 Section 5 Standard 5.6 Patients will be pleased to meet and discuss options with their operating surgeon. This move will inspire confidence	

Ophthalmologist	Comment 2 Section 9 Standard 9.6 Patients will spend less time haggling and worrying about the final price. Add-on options and prices confuse and bewilder. The focus of the encounter with the refractive practice should be - the best possible visual outcome.	
Ophthalmologist	Comment 3 Section 5 Standard 5.11 Patients will be relieved	
Ophthalmologist	Comment 1 Section 2 Standard 2.2 There are many RLE surgeons, with established and well-audited practices and excellent results, who do not carry our laser, but have established professional relationships with laser refractive surgeons for when laser top-up is required. In many cases, this is the best possible arrangement for patient safety, as a dedicated lens specialist – rather than a corneal specialist (who may only carry out a handful of lens cases and hence have questionable ability) – performs the RLE surgery, but the patient has the guarantee that if further surgery is required, a laser surgeon will perform the correction. In this context, the CertLRS is a completely unnecessary step, which would only serve to reduce standards in established practices and worsen patient care if future / existing lens specialists ceased providing the excellent levels of care that they currently do.	See response to similar comments in relation to the Cert LRS exam above
Ophthalmologist	Comment 2 Section 2 Standard 2.2 There is currently a wide choice for patients choosing to undergo RLE surgery, which would diminish with the introduction of a CertLRS examination for new surgeons, as not all would want to practise laser eye surgery – an alternative being local professional relationships, as above. This could lead to higher prices for patients, possibly with reduced quality, if lens surgery specialists are prevented from carrying out RLE and other procedures. This could also lead to accusations of protectionism by some regarding the standards.	See response to similar comments in relation to the Cert LRS exam above

Ophthalmologist	Comment 3 Section 2 Standard 2.2 National standards in RLE and other surgery may fall. Within larger commercial organisations, surgeons who are specialised in providing corneal laser surgery – and hence obtain the CertLRS – may be required to provide lens surgery, in lieu of specialist lens surgeons. Holding the CertLRS should not be taken to mean that the corneal laser surgeon is safe to perform RLE – there are many corneal laser surgeons who do not carry out intraocular work.	See response to similar comments in relation to the Cert LRS exam above
Ophthalmologist	Comment 4 Section 2 Standard 2.2 Taken to extremes, refractive surgery for conditions such as postoperative anisometropia and refractive surprise, currently performed by very competent lens and cataract specialists, may not be provided without having the CertLRS. This could lead to lengthy delays and disrupted relationships between patients and clinicians, which serves no purpose, except protectionism.	See response to similar comments in relation to the Cert LRS exam above
British Society for Refractive Surgeons	Reduced choice of surgeons for patients	An alternative view is that the implementation of the standards will result in better information for patients to inform decision making. Surgeons who do not yet meet the requirements in section 2.1 and 2.2 have the option of conforming to the standards.
British Society for Refractive Surgeons	Reduced competition with possible increase in price	This may be the case but this is not in the remit of the standards document.
My Beautiful Eyes	The question of patient groups per se does not appear to be addressed within the standards, so we assume this refers to consequential impact). The standards lack teeth. Although well meaning they are diluted and ineffectual by virtue of not outlining consequences for breach of guidelines. For example, on page 14 the GMC is quoted: '*55 You must be open and honest with your patients about any financial or commercial interests*	The role of the Royal College is to set professional standards, but enforcement is a matter for the regulators including the GMC, the CQC, and the ASA.

	that could be seen to affect the way you prescribe for, advise, treat, refer or commission services for them.' Although this is a GMC recommendation the instruction is itself open to interpretation and abuse. Phrases such as '*could be seen*' imply misunderstanding, as opposed to wrongdoing. In this context the threat of sanction or legal action should be raised if the guidelines are to be taken seriously. The lack of consequence means that certain providers will undoubtedly simply ignore the guidelines. This is a set of standards that have failure already built-in. In this sense, the impact on patient groups will be negative. The lack of consequence for ignoring the guidelines will undoubtedly encourage certain surgeons and providers to ignore the guidelines. In this regard the standards are also self-defeating.	
Ophthalmologist	Comment 1 Section 2 Standard 2.2 If the requirements are mandated, it could discourage some centres to provide or develop a tertiary referral NHS service e.g. for NHS patients who have poor refractive outcomes following cataract or corneal transplantation. Currently these centres also provide a service to non-NHS patients who wish the have laser refractive surgery.	See response to similar comments above
Ophthalmologist	High street providers will get in untrained doctors from abroad who are registered with the GMC to do it for a short period as they will not pay the surgeon the appropriate rate to do the job properly.	See 2.1 and 2.2
Optical Express Group	Comment 1 Section 5 Standard 5.11 Ruling out certain schemes which allow providers to offer treatment more affordably will reduce patients' access to care. Denying suitable patients safe, high-quality treatment cannot be in their best interest, yet is precisely what the effect of these proposals will be.	It is time-limited discounts rather than discounts per se that are at issue in terms of pressure to proceed.

Optical Express Group	Comment 2 Section 5-6 Standard 5.1 – 6.10 These guidelines' promotion of an independent surgeon-focussed model ahead of other models of delivery, will significantly increase the cost of providing the procedure for patients. Denying suitable patients safe, high-quality treatment.	The standards are equally applicable to self-employed surgeons and surgeons employed by larger providers.
Optical Express Group	Comment 3 Section 5-6 Standard 5.1 – 6.10 These regulations will drive up the cost of surgery without improving safety. Many patients would either have to pay for the burden of unjustified and needless regulations or not have surgery. Another option that patients may consider, and one of the many unintended consequences of the draft guidelines, would be to travel abroad to undergo a less expensive procedure, in a country where there may be no assurance on the quality of care they receive. The public's interests could not possibly be best served by forcing these options onto patients. This is diametrically opposed to the RCOphth's purpose to champion safe surgery and improve the lives of patients.	The apparent lack of any willingness to take clear messages from the GMC (April 2016) and Keogh (2013) on board here is disappointing. Transferring the time required for a clear consent conversation with the operating surgeon from the day of surgery to a prior appointment should have no special cost implications. Improved standards will provide prospective patients with more confidence in surgery within the UK.
Optical Confederation	Comment 1 Entire Document The standards as drafted do not appear to have considered that many patients may want and benefit from refractive surgery under an equally safe but more affordable community "team" model. We are further concerned that because the standards fail to take account of, or understand, the realities of community ophthalmology they could inhibit the delivery and development of this service. As a consequence, if complied with, these draft standards could disenfranchise cohorts of patients from accessing safe, affordable refractive surgery in the community – reducing the already low levels of people who could benefit from accessing refractive surgery and further widening health inequalities. At worst this guidance could be deemed anti-competitive because it appears to favour an old-fashioned model	See response to the same point from OE above. It is not clear that the standards will directly result in any cost increase. The goal of these standards is to improve patient care in alignment with Keogh, CSIC and GMC recommendations.

	and does not provide for new models of provision developed to make refractive surgery safely available to all at reasonable cost.	
Optical Confederation	Comment 2 Section 3 Standard 3.1 We fully support the development of quality standards and PROMs, but it is hard to sign up to them as a requirement without having seen them first. It is to be hoped therefore that, in future, community optometrists and providers – through the Optical Confederation – will be involved in this work from the outset and not just consulted post-hoc which, as predicted, has regrettably led to problems with this current draft. Engagement with a range of providers is particularly pertinent to the development of PROMs for the refractive surgery sector given that, as we pointed out in response to the first consultation, the standard of patient engagement in this exercise from the outset does not inspires confidence.	The need for PROMs alongside objective clinical outcome measures is widely accepted and emphasised in GMC para. 5. Any new PROMs will be developed using a standard methodology with appropriate scientific support, user and patient input.
Optical Confederation	Comment 3 Section 5 Standard 5.19 Again, refractive surgery is not cosmetic surgery and so quoting the GMC text is unhelpful. We would suggest the following preferable form of words: *When you discuss interventions and options with a patient, you must consider their vulnerabilities and psychological needs. You must satisfy yourself that the patient's desire for refractive surgery is made by their own choice and volition.*	See above – the intention is not to deviate from the GMC text other than to replace 'cosmetic surgery' with 'refractive surgery' (see introduction 1.4) The GMC are clear (May 2018 – see link above) that their April 2016 guidance applies to refractive surgery. 1. *Section 5 GMC point 19 When you discuss interventions and options with a patient, you must consider their vulnerabilities and psychological needs. You must satisfy yourself that the patient's request for the refractive surgical intervention is voluntary.*

D. What is the likely impact on doctors affected by the standards?

Comments received from	Comment(s)	Comments from the Refractive Surgery Standards Working Group (RSSWG)	Changes to the guidance document(s)
Advanced Vision Care	Comment 1 Section 5 Standard 5.6, 5.9 & 5.10 If the Operating Surgeon is going to see the patient a week before the treatment then the patient needs to come twice to the clinic which will require additional costs to the patient as most of the them travel far away to any refractive clinic. They will be happy they are seen on Initial Consultation by a skilled Refractive Surgeon and a decision is made in consultation with the Operating Surgeon and they are adequate cooling period between consultation and the surgery. They will be happy if they are given Open access to the operating surgeon to ask any relevant questions and a face to face discussion the day before the treatment, not only on the day of the treatment	See GMC point 16 Procedure choice and the associated consent discussion is the responsibility of the operating surgeon. See also responses above in relation to the one week cooling off period. Any deviation from this should be exceptional and not part of an established practice pattern.	No change
Advanced Vision Care	Comment 2 Section 2 Standard 2.1 Just being GMC Specialist does not make a surgeon compete tent to do Laser Refractive surgery as it is not in the curriculum of training. I have personally seen and trained NHS consultant surgeons and their knowledge for Laser Refractive surgery is minimal. Hence these surgeons should do 3-6months of fellowships in Laser Refractive surgery or work under supervision with CertLRS surgeon to do minimum of	Although subspecialist fellowship level training is desirable and included in some UK corneal fellowships, there is no current system for accrediting ophthalmic subspecialist fellowship training in the UK. The entry level CertLRS will require a level of experience as part of the eligibility criteria https://www.rcophth.ac.uk/examinations/certificate-in-laser-refractive-surgery	No change as a result of this comment.

	20 cases before they are allowed to operate on their own		
Advanced Vision Care	Comment 3 Section 10 Standard 10.1 NHS Trust do co management for glaucoma and cataract with Optometrists and GPs. They don't explain the financial arrangements to the patient. Hence the same principles should be applied with the Refractive Surgery. This is not a referral fee but the fee paid for, for their chair time for the clinical work done by the Optometrists or any other provider. We don't understand the relevance why the co management fee should be charged directly to the management. Again, why is the Royal College interfering with business and financial aspects of running the business?	See GMC para 55 section 10 Honesty in Financial Dealings. The GMC are clear in that, in some areas, their April 2016 guidance which is applicable to refractive surgery sets a higher standard than is applied elsewhere. This is in order to address specific safety issues and ethical concerns particular to the sector. 10.1 is designed to ensure that doctors, optometrists and other health professionals are free from any financial conflict when directing referrals in refractive surgery, and that any transactional relationship between professionals in relation to aftercare is transparent. To put it another way, referrals should always be made in the patients' best interest. The College of Optometrists has produced Guidance for professional practice http://guidance.college-optometrists.org/home/, and also the GOC has its own Standards for Practice (their equivalent of GMP). This makes similar points about financial incentives for referral.	No change as a result of this comment.
Royal Liverpool University Hospital	Sections 2-7 None of the surgeons in our organisation (Royal Liverpool University Hospital) hold or have not sat the LRES examination. We have been undertaking Laser and other refractive surgical procedures on behalf of The Royal Liverpool University Hospital for the past 20years. There was not adequate provision of information regarding the	See similar comments on the Cert LRS exam above and revised 2.1 and 2.2 clarifying the recommendations on the evidence for knowledge, skills and evidence for surgeons who perform refractive surgery.	See changes to sections 2.1 and 2.2 as noted above

	LRES, the changing format of the examination and the repercussions of not having the LRES until this consultation. For example, applications for the current examination in October 2016, closed on the 22nd of August 2016 and the requirements to even enter the examination are substantial including the cost. In particular, many of those surgeons who hold the LRES, sat a much simpler version of the current examination on or before 2009 without similar requirements or cost. As with any change of practise and requirements, e.g. GMC licencing, an encompassing consultation with explanation and adequate time to respond is required. By requiring surgeons to hold the LRES will limit our practise and for practical purposes will potentially mean closing the service at the Royal Liverpool University Hospital. No other ophthalmic subspecialty requires an extra exam for a CST holder NHS consultant to practise his or her subspecialty All of us in the NHS undergo annual appraisal and regular revalidation. A system to monitor that one practises within one's competence is in place. What are their plans for surgeons who have obtained the LRES? Re-certification every 3 or 5 years? It would appear that an examination industry is being unnecessarily created and inhibiting new entries to the subspecialty, especially given the significant financial and training hurdles, which already exist. Going ahead with these requirements will lead to considerable difficulty for many UK surgeons There should be first an assessment and consultation as to		

	the need for an examination and how established surgeons can be accommodated and an accepted process for the latter. This should take place first and before the RCOphth goes out to consultation with the recommendation that refractive surgeons should be on the specialist register in the future.		
Ophthalmologist	Doctors will become aware of optometrists pretending to be ophthalmologists and the risks of delegating consent and post-operative complication management! Some doctors will have to spend significantly more time with their patients rather than just doing the surgical act. This is a good thing and should reduce the numbers of unsuitable patients receiving refractive surgery.	Noted	No changes as a result of this comment
Ophthalmologist	None of the surgeons in our organisation (Optegra Manchester Eye Hospital) or the local eye units with refractive surgery service (Liverpool University Hospital or Manchester Eye Hospital) hold or have not sat the LRES examination. There was not adequate provision of information regarding the LRES, the changing format of the examination and the repercussions of not having the LRES until this consultation. For example, applications for the current examination in October, closed on the 22nd of August and the requirements to even enter the examination are substantial including the cost. In particular, many of those surgeons who hold the LRES, sat a much simpler version of the current examination on or before 2009 without similar requirements or cost. As with any change of practise and requirements, e.g. GMC licencing, an encompassing consultation with explanation and adequate time to respond is required. By requiring	See similar comments on the Cert LRS exam above and revised 2.1 and 2.2	See changes to sections 2.1 and 2.2 as noted above

	surgeons to hold the LRES will limit our practise and for practical purposes will potentially mean closing the many of the centres offering refractive service in the Northwest. No other ophthalmic subspecialty requires an extra exam for a CST holder NHS consultant to practise his or her subspecialty All of us in the NHS undergo annual appraisal and regular revalidation. A system to monitor that one practises within one's competence is in place. What are their plans for surgeons who have obtained the LRES? Re-certification every 3 or 5 years? It would appear that an examination industry is being unnecessarily created and inhibiting new entries to the subspecialty, especially given the significant financial and training hurdles, which already exist. Going ahead with these requirements will lead to considerable difficulty for many UK surgeons. There should be first an assessment and consultation as to the need for an examination and how established surgeons can be accommodated and an accepted process for the latter. This should take place first and before the RCOphth goes out to consultation with the recommendation that refractive surgeons should be on the specialist register in the future.		
Ophthalmologist	Comment 1 Section 3 Standard 3.2 To make this a requirement when not a requirement for cataract surgery to submit to national audits is not fair and will be seen as such	3.2 deleted (redundant after GMC point 7b in the same section)	3.2 deleted

Ophthalmologist	Comment 2 Section 3 Standard 3.3 This is not clear as to which meetings this refers to and why is the case when not requirement for cataract surgery	See amended text	(note 3.2 no deleted – 3.3 becomes 3.2) Section 3.2 amended to 3.2 Take part in professional networks, national and international meetings to allow discussion of complex cases with colleagues and help ensure that their practice is well aligned with contemporary clinical evidence.
Ophthalmologist	Comment 1 Section 5 Standard 5.10 Patients occasionally insist on next available date that may be less than a week away. I always give consent forms to take away which gives them the time for a considered decision.	Wherever possible, the one-week cooling off period should apply. See amended text	See changes to section 5.10 as noted above.
Ophthalmologist	Comment 2 Section 7 Standard 7.2 Visual acuity measurements must be standardised for any national database	This will be an important component in defining the outcomes to be collected (see guidance on National Data Set development at https://www.rcophth.ac.uk/standards-publications-research/clinical-data-sets/	No changes as a result of this comment.
Ophthalmologist	Comment 3 Section 6 Standard 6.7 Optimistic this document will encourage partnership between the NHS and the private sector	Noted	
Ophthalmologist	Comment 1 Section 2 Standard 2.2 The LRS cert is not the only method of learning refractive surgery. There are other respected courses such as The Ulster MSC, The Refractive course at ESCRS, and numerous Refractive fellowships. Also there are good surgeons with wide experience who will be driven out of the industry and should be	See similar comments on the Cert LRS exam above and revised 2.1 and 2.2	See changes to sections 2.1 and 2.2 as noted above

	given "Grandfather rights". This looks like profiteering by the RCO and should be avoided by using the term "or equivalent"		
Ophthalmologist	Comment 1 Section 2 Standard 2 There is no mention in the standards regarding provision – effectively grandfathers' or acquired rights - for established refractive surgeons, be they laser specialists or RLE specialists, who do not hold the CertLRS. In particular, for those specialists who do not perform laser eye surgery (particularly where they have an established or potential professional relationship with a laser refractive surgeon) there seems absolutely no logic or merit in working towards a laser surgery certificate, lest to protect their business interests. Specifically, 2.2 states 'should' hold the CertLRS, rather than 'must', but a clause detailing that *newcomers* to **laser** refractive surgery should hold the certificate would be welcome, with established laser practitioners being exempt, provided they can demonstrate that they are providing a safe service; non-laser surgeons should not be required to hold a laser certificate at all, as per the other points made in my response. I suspect that, in the absence of provision for established practitioners, there may be significant appetite amongst many for a legal challenge to these standards.	See similar comments on the Cert LRS exam above and revised 2.1 and 2.2	See changes to sections 2.1 and 2.2 as noted above
Ophthalmologist	Comment 2 Section 2 Standard 2 These standards have provoked considerable debate amongst established surgeons, many of whom are cynical regarding the true purpose of these	Agreed, this is the purpose of the consultation exercise and subsequent amendments to the Standards document.	No changes as a result of this comment

	standards. The College certainly has a duty to help protect the public, but must be mindful of trying to produce guidance that does not alienate established providers of good quality refractive services.		
British Society for Refractive Surgeons	Comment 1 Section 1 The standards lack clarity on the definition of refractive surgery e.g. does it include RLE? cataract with multifocal/accommodating/multifocal-toric/toric IOLs? Laser lens and cataract surgery?		
British Society for Refractive Surgeons	Comment 1 Section 1 The standards lack clarity on the definition of refractive surgery e.g. does it include RLE? cataract with multifocal/accommodating/multifocal-toric/toric IOLs? Laser lens and cataract surgery?	See modified 1.3.	See changes to section 1.3 noted above
British Society for Refractive Surgeons	Comment 2 Section 2 Standard 2.2 There is no recognition for surgeons with clinical experience and those who have been through fellowship training in refractive surgery.	See similar comments on the Cert LRS exam above and revised 2.1 and 2.2	See changes to sections 2.1 and 2.2 as noted above
British Society for Refractive Surgeons	Comment 3 Section 2 Standard 2.2 The CertLRS is currently a laser refractive surgery examination. If this is to change, there should be clear documentation of its requirements before a proposal is made to make it a mandatory requirement. Also, a mandatory examination should be enforced prospectively (for surgeons wishing to start practicing refractive surgery)	See similar comments on the Cert LRS exam above and revised 2.1 and 2.2	See changes to sections 2.1 and 2.2 as noted above

British Society for Refractive Surgeons	Comment 4 Section 2 Standard 2.2 An on-going competency based online assessment (e.g. every 5 years) which requires knowledge of safe refractive practice is likely to be more effective than an arbitrary one off examination. This format would save money, time, remove examiner bias and is widely accepted in many fields including mandatory safety courses.Also, competency judgment should be outcome based rather than volume based. This would not disadvantage low volume surgeons.	This suggestion was debated at some length by the RSSWG, the College Council and with representatives of the examinations committee. It was felt that the viva component of the examination was essential, since the Cert LRS is there to fill the gaps left by OST training, and the Fellowship examinations include this component. The CertLRS will be continuously reviewed to ensure reliably of each component or amended if this is shown to be lacking.	No changes as a result of this comment
My Beautiful Eyes	We are of the opinion that because of the lack of consequence for ignoring the standards, these standards will actively encourage certain surgeons to behave badly. We do not currently have comments with respect to doctors.	The role of the Royal College is to set professional standards, but enforcement is a matter for the regulators including the GMC, the CQC, and the ASA.	No changes as a result of this comment
Ophthalmologist	Comment 1 section 2 Standards 2.2 This is utter and complete nonsense and only serves to benefit those practitioners that already preform laser refractive surgery and who hold CertLRS. There is no transparency to this statement and only lends one to believe that this regulation was devised by someone who is more protective of their private practice and financial gain. There are many 'Cornea and Refractive' fellowship trained Consultants who have done their training in a recognised and reputable unit for cornea, cataract and refractive surgery, and who are usually more equipped to provide holistic refractive management	See similar comments on the Cert LRS exam above and revised 2.1 and 2.2	See changes to sections 2.1 and 2.2 as noted above

	options to patients compared to those that provide a sole laser based refractive service. Also, why should one have to have a CertLRS when they have had excellent fellowship training, just so that the college can make money to issue a piece of paper in order to allow a doctor to perform laser refractive surgery. It is equally patronising that a Consultant Ophthalmologist who routinely performs cataract surgery (the bread-and-butter of our profession) is unable to counsel a patient appropriately on premium intraocular lenses and has to be certified in order to do so. Many of us that perform anterior segment surgery have a lot of experience and competence in lens based refractive surgery, whether it be 'premium lenses' of various types in the private sector, or lenses available for refractive correction on the NHS. Does this then mean that one also requires this qualification to perform surgery on the NHS? If not, then this is a double standard / creationism of a two-tier system of quality of service. This is a slippery slope. There are many other ocular surgical procedures that can affect a patients refractive outcome. Will we need to be certified to perform other specific surgical procedures – if not, then this is again a serves to look after the agenda of others that have a vested interest to introduce such a reactionary, ill-thought proposal, rather than for the vested interest of patients. Surely, if this is being considered for the best interest of the public, then other invasive		

	ophthalmic surgical procedures, cosmetic or otherwise, require similar regulation. If the college go so far as saying that CertLRS is also required for patients that need laser refractive surgery on the NHS, then this will be to a significant detriment to our patients because many practitioners may have to stop providing this service, and many patients either will not receive treatment or have to travel large distances to receive treatment elsewhere. If doctors treating patients on the NHS are exempt from this regulation, then this would be equally unacceptable.		
Ophthalmologist	Comment 1 Section 2 Standard 2 A compulsory and recurring certification requirement could discourage trainees from coming into the sub-speciality.	Noted	No changes as a result of this comment
Optical Express Group	Comment 1 Section 2 Standard 2.1 and 2.2 Will the RCOphth be offering more sittings throughout each given year, particularly in 2017 for Ophthalmic Surgeons to undertake the CertLRS examination? It seems sensible based upon the standard for there to be several sittings in 2017 and then more than one sitting each year thereafter.	The cut off has been extended to 2018 to give at least 2 opportunities for established refractive surgeons who are not on the specialist register to sit the exam.	The cut off has been extended to 2018 to give at least 2 opportunities for established refractive surgeons who are not on the specialist register to sit the exam.
Optical Express Group	Comment 2 Section 3 Standard 3.3 We are of the view that the first sentence should read “Participate in case reviews.” We are unsure of the need for “in morbidity and mortality meetings.”	Agreed, see modified text	Section 3.2 amended to (note 3.2 no deleted – 3.3 becomes 3.2): 3.2 Take part in professional networks, national and international meetings to allow discussion of complex cases with colleagues and help ensure that their practice is well aligned with contemporary clinical evidence.

Optical Express Group	Comment 3 Section 5 and 6Standard 5.1 – 6.10 These guidelines dictate one particular model of care, which may be suitable in some settings but inappropriate in others. The guidelines should support surgeons in making appropriate clinical decisions to suit the setting and the needs of the patient. These guidelines would significantly restrict the surgeon's ability to make independent clinical decisions.	The guidelines are designed to help surgeons have sufficient time with the patient to ensure that they are making appropriate clinical decisions.	No change
Optical Express Group	Comment 4 Section 5 and 6 Standard 5.1 – 6.10 These guidelines give pre-eminence to surgeons, undermining the importance of teams of healthcare providers working together in refractive surgery delivery. Appropriately trained optometrists are essential to the refractive surgery team in community practice. Under the supervision of the operating surgeon, optometrists provide important pre- and post-operative patient care. The current drafts ignore the role of the optometrist, undermining the profession and having an adverse effect on the wider refractive surgery team and patient care - needlessly increasing surgeon workload.	See section 8 Working with colleagues	No change
Optical Express Group	Comment 5 Section 5 Standard 5.11 Ruling out certain schemes which allow providers to offer treatment more affordably will reduce doctors' ability to manage their workflows.	The problem with time-limited discounts is that they act as a form of pressure to proceed with surgery – see 5.11	No change
Optical Express Group	Comment 6 Section 8 Standard 8.1 The Optometrist will conduct the overwhelming majority of eye examinations in the UK and be the	Many patients self refer	No change

	clinician in the majority of cases that "refers" the patient to the Ophthalmic Surgeon.		
Optical Express Group	Comment 7 Section 10 Standard 10.2 Surgeons at our organisation are not involved in any fee discussions with patients. This section is irrelevant for the majority of surgeons and indicates that these guidelines have been produced in order to support one form of provision at the expense of all others.	Amended	10.2 Surgeons performing refractive surgery should: a. Disclose any personal affiliation or other financial or commercial interest relating to their practice including: other private healthcare companies, laser manufacturers, implant manufacturers, pharmaceutical companies or instrument manufacturers. b. Obtain adequate professional indemnity insurance that covers the procedures they undertake
Optical Confederation	Comment 1 Entire Document The standards assume a model of practice that is not relevant for many doctors and this will become increasingly the case. The standards in some cases seek to impose responsibilities that are not appropriate to modern practices, for example because they do not recognise that the surgeon will in many instances be employed or engaged by a service provider. In such cases the College guidance will put surgeons under duties with which, by definition, they cannot comply, and which will bring both the guidance and College itself into disrepute. The GMC in its guidance has wisely avoided such pit-falls by being clear on principles but leaving detail to the context and judgement of doctors.	The standards were formulated with input from across the refractive surgical spectrum in the UK and apply equally to surgeons taking a direct role in the management and governance of their clinics and surgeons who are employed with no direct management role. See new paragraph 1.5 clarifying the surgeon's responsibilities.	Section 1.5 amended to: 1.5 Our additional recommendations take two forms: direct advice to surgeons, and advice that surgeons should ensure is upheld in relation to their practice. Direct advice to surgeons is prefaced by the heading *'In addition, surgeons who perform refractive surgery should.'* Advice that surgeons should ensure is upheld in relation to their practice is prefaced by the heading *'In addition, the following principles apply for refractive surgery.'*

Optical Confederation	Comment 2 Section 6 Standard 6.1 It should be recognised that many service providers will provide information about the procedure to the patient in a standard format. It will therefore be sufficient for operating surgeons to check/confirm that they are satisfied with these arrangements	The current wording of 6.1 allows for pre-treatment instructions standardised by procedure.	No changes as a result of this comment
Optical Confederation	Comment 3 Section 8 Standard 8.2 The operating surgeon remains responsible for the clinical outcome of the surgery and patient episode but can only be responsible for the entire patient journey where they are personally providing the whole end-to-end service.	See 6.7 and 6.8 and additional clarification in the amended wording of 8.2.	Section 8.2 amended to: 8.2 Although the performance of tests, screening consultations and routine postoperative review may be delegated to appropriately trained staff, the operating surgeon remains responsible for the entire patient journey until discharge from the provider after late stage review or transfer of care to another provider for emergency or additional specialist treatment.

E. What is the likely impact on other groups affected by the standards?

No changes were made to the document on the basis of the comments received on this section of the consultation. Comments received are noted below for clarification and transparency.

Comments received from	Comment(s)	Comments from the Refractive Surgery Standards Working Group (RSSWG)
Royal Liverpool University Hospital	We will no longer be able to provide a tertiary referral NHS service for patients requiring laser corrective surgery. For example, we provide a laser refractive service to NHS patients who have poor refractive outcomes following for example, cataract or corneal transplantation.	See similar comments on the Cert LRS exam above and revised 2.1 and 2.2
Ophthalmologist	Optometrists in some high street clinics are likely to revert to measuring refractive error and stop believing they have the medical	Further work needs to take place with the College of Optometrists to define the requirements for optometric training in refractive surgery co-management.

	training required for managing refractive surgery patients pre and post-operatively.	
Ophthalmologist	I will no longer be able to provide a tertiary referral NHS and non-NHS service for patients requiring laser corrective surgery. For example, I provide a tertiary laser refractive service to NHS patients from the region (Macclesfield Hospital, Leighton Hospital, Warrington Hospital and Stepping Hill Hospital) who have refractive surprise following cataract surgery and poor refractive outcomes following corneal transplantation.	
Ophthalmologist	Comment 1 Section 6 Standard 6.8 Optometrists will have to ensure they have indemnity cover – good recommendation	Noted
Ophthalmologist	Comment 2 Section 9 Standard 9.5 It is good to discourage irresponsible advertising. Levels the playing field	Noted
British Society for Refractive Surgeons	How would this impact on other aspects of ophthalmic surgery practice e.g. oculoplastic surgeons (performing blepharoplasties, botox, fillers, etc) and anterior segment surgeons (cosmetic removal of pterygia etc)	See April 2016 CSIC guidance covering cosmetic surgery
My Beautiful Eyes	We believe these standards will only serve to diminish the reputations of independent surgeons who operate at the high-end of the industry, will encourage larger, less reputable organisations to continue to provide unpredictably varying qualities of health-care, and fail to prevent ever increasing numbers of patients being both damaged and convinced of the benefits of inappropriate surgery.	Noted

Optical Express Group	Section 5 Standard 5.1-5.13 As stated in our previous response, a significant conflict will also be created among patients that have a cataract. There is no clinical difference between certain types of refractive surgery and cataract surgery performed on the NHS. It is unclear what the effect of this guidance on the NHS and cataract patients.	The important distinction here is that the 'do nothing' option is generally not valid in cataract surgery – since cataracts only get worse; whereas refractive surgery is performed in patients who have good vision in glasses or contact lenses. But we accept that the margins are blurred at the interface between cataract surgery and refractive lens exchange.
Optical Confederation	Comment 1 Entire Document The scope of the standards in some cases goes beyond the remit or competence of the College. For instance team working within the new providers is the way forward and the guidance does not address this, nor recognise new models of delivery, in any helpful way.	See sections 6 and 8
Optical Confederation	Comment 2 Entire Document Optometrists, nurses and others who are essential members of the community ophthalmology team are not governed by the GMC or the College but by their own regulators and professional bodies. In places the guidance attempts to set standards for other professions where it does not, in our view, have locus.	See section 8 and in particular GMC para 42 and 43. Clear lines of responsibility, appropriate governance structures and good supervision are essential in teamwork. Ensuring that these elements are in place is part of the surgeon's duty of care.
Optical Confederation	Comment 3 Section 2 Standard 2.1 and 2.2 We believe the requirements here are too restrictive and not all surgeons will be on the GMC Specialist Register and/or hold the CertLRS entry level qualification. Whilst the long-term aim is appreciated, we would expect there to be some 'grandfathering' or other transitional arrangement (for which there are several good precedents) to enable safe, experienced refractive surgeons and College members to continue to provide their services to the public.	See similar comments on the Cert LRS exam above and revised 2.1 and 2.2
Optical Confederation	Comment 4 Section 5 Standard 5.11 The College has, in our view, no locus or expertise to determine how community ophthalmology providers manage their business, and	See responses above with reference to time-limited discounts. From the patient perspective, these inevitably act as a pressure to proceed. The

	cannot specify that time limited incentives, discounts, etc. cannot be used in order to efficiently manage workflow, keep down costs for patients and preserve the viability of provision. We suggest this paragraph should read: *There should be no pressure to proceed with surgery at any stage. However this does not rule out incentives such as time limited discounts, or a refund of the initial consultation fee if patients choose to proceed, to encourage suitable patients to consider refractive surgery or service providers to manage their work flows most efficiently.*	same applies to inducements to undergo surgery by refunds of consultation fees.
Optical Confederation	Comment 5 Section 5 Standard 5.12 We are not convinced of the case for saying that deposits must be fully refundable. This runs counter to practice for other health services (private and NHS, elective or not) for which a patient must pay – for example it is normal to be charged for a dental appointment even if the patient decides not to attend.	See GMC paragraph 26. Non-refundable deposits run counter to this and again, from the patient perspective, can act as a pressure to proceed.
Optical Confederation	Comment 6 Section 5 Standard 5.13 The College has no locus in determining how community ophthalmology providers manage their business and cannot advise that conversion rates cannot be used as a performance measures for optometrists, nurses and other staff, unless those staff are directly employed by a surgeon. We suggest the text be amended to read, "should not be used as a performance measure for surgeons, or any staff employed by them".	Again, consider the patients' best interests. There should be no pressure on any staff, employed by the surgeon or not, to give anything other than balanced advice to patients regarding the risks and benefits of surgery.
Optical Confederation	Comment 7 Section 9 Standard 9.0 Whilst it may be considered unethical for surgeons themselves directly to offer promotional incentives, service providers may offer the option of surgery as prizes to suitable, willing and informed patients. The College has no locus to rule on the legitimate practices of businesses	The GMC exerts control over its members. Surgeons working in an environment where these practices or competitions and prizes are used as inducements are ultimately responsible if they operate on patients who have been subjected to this type of tactic. They could potentially be disciplined by the GMC and will have to consider whether this a risk they

	nor to impose its views on others in these areas, which are already controlled by other forms of regulation.	wish to undertake. The RCOphth has provided standards that are in alignment with those of the GMC, CSIS and Keogh.
Optical Confederation	Comment 8 Section 9 Standard 9.2 Again, the College has no locus to rule on the legitimate practices of businesses nor to impose its opinions on legitimate business practices unrelated to clinical standards. For example celebrity endorsements can help to raise awareness of and build patient confidence in refractive surgery, which is a valuable but under-utilised intervention. So long as any financial relationship is adequately declared there is no reason to discourage this routine business practice. An appropriate celebrity endorsement (unless they have not actually had successful refractive surgery) is no more inappropriate than a Royal Warrant or a brass plate.	See above response
Optical Confederation	Comment 9 Section 9 Standard 9.6 It is not clear why, in these days of transparency, the College is opposed to advertising by doctors or providers. This should of course be in line with CAP guidance, BIS Pricing Practices Guides and Advertising Standards Agency rules where the UK business norm is 10%, not 50%, of patients. The College cannot possibly have competence or expertise to overrule these national authorities.	The College is not in opposition to advertising as long as it follows the principles outlined by the GMC, CSIC, Keogh and of course the ASA and CAP. Any pricing indicated in an advertisement needs to adhere to CAP guidance where what is being advertised is indicated within the advertisement: 3.4 For marketing communications that quote prices for advertised products, material information [for the purposes of rule 3.3] includes: 3.4.1 the main characteristics of the product 3.4.2 the identity (for example, a trading name) and geographical address of the marketer and any other trader on whose behalf the marketer is acting **3.4.3 the price of the advertised product, including taxes, or, if the nature of the product is such that the price cannot be calculated in advance, the manner in which the price is calculated** 3.4.4 delivery charges

		3.4.5 the arrangements for payment, delivery, performance or complaint handling, if those differ from the arrangements that consumers are likely to reasonably expect 3.4.6 that consumers have the right to withdraw or cancel, if they have that right (see rule 3.55)
Optical Confederation	Comment 10 Section 10 Standard 10.1 By its own definition the College is the professional body for eye doctors and its advice should confine itself to doctors. GMC and College advice does not extend to community optometrists and other eye care professionals. The words “and relevant similar guidance” need to be inserted here.	The College of Optometrists has produced Guidance for professional practice http://guidance.college-optometrists.org/home/, and also the GOC has its own Standards for Practice (their equivalent of GMP). Optometrists have to abide by the GOC's standards, and the College Guidance is there to help them.
Optical Confederation	Comment 11 Section 10 Standard 10.1b and 10.2 It would be most unusual practice for a surgeon to make clear to patients how much they pay other members of the team and we can see no reason for this. Moreover, a surgeon would not know about the remuneration of other staff if they were not the employer, nor would it be appropriate for them to have this information. The patient pays a fee for a service and needs of course to know what that services includes but not how all elements of the service are costed, paid or charged for.	This is a read across from CSIC guidance and relates primarily to payments or incentives for referrals but is probably redundant after 10.1 and GMC 55 and 56

F. Do the standards achieve their intended aim(s)

Yes 7 No 6 Not Answered 7

Comments received from	Comment(s)	Comments from the Refractive Surgery Standards Working Group (RSSWG)	Changes to the guidance document(s)
Advanced Vision Care	Comment 1 Section 5 Standard 5.6, 5.9 & 5.10 If you want to provide quality of care for patients' safety then the whole patient journey or the Initial Consultation and at least the initial minimum of two post ops should be done by a skilled Refractive Surgeon or a Medical professional (not by a non-medical person). The skilled Refractive Surgeon or Medical professional should do all these in consultation with the Operating Surgeon. Only part of the patient journey with regard to the Post-Operative care should be delegated to non-medical professionals or optometrists. It seems that some of the regulations are intended to curb the practice of high street clinics. But merely seeing the operating surgeon, one week before the surgery but the rest of the pre op and post op care is done by Optometrists does not aim to give the intended standard of care.	See 6.8 for the relevant caveats on any delegation of postoperative review and GMC paragraph 42	No changes as a result of this comment
Advanced Vision Care	Comment 2 Section 9 Standard 9.2, 9.5 The Royal College has gone beyond their limits in these sections. We agree with some of the practices of financial inducements but it is not for the Royal College to dictate how the clinic should be run with regards to the business or financial arrangements as it has got nothing to do with providing high quality clinical standards.	The College has no desire to inform providers how they run their financial arrangements. The standards are in alignment with the recommendations of Keogh and CSIC as well as the standards from the GMC that already apply. GMC standards have been in place since June 1st 2016.	No changes as a result of this comment

Advanced Vision Care	Comment 3 Section 5 Standard 5.6, 5.9 & 5.105 The intended aim to provide high standards and good quality care can be achieved only if the initial part of the patient journey is done by the skilled refractive surgeon with LRS certification or any medical profession in consultation with the operating surgeon. The initial consultation with operating surgeon is not essential but the patients should have open access to the operating surgeons and patients should be seen a minimum a day before the surgery not only on the day of the surgery. We also agree there should be a minimum cooling period of one week between the initial consultation and the surgery. Also, the surgery should never be done on the same day as the consultation. This is what we recommend.	See GMC point 16 Procedure choice and the associated consent discussion is the responsibility of the operating surgeon.	No changes as a result of this comment
Royal Liverpool University Hospital	They discriminate against surgeons and their patients	Noted	No changes as a result of this comment
Ophthalmologist	No, for the reasons mentioned above. They discriminate against many established surgeons already practicing at a very high standards of refractive surgery and their colleagues and their patients.	See similar comments on the Cert LRS exam above and revised 2.1 and 2.2	No changes as a result of this comment
Ophthalmologist	Comprehensive and detailed recommendations!	Noted	No changes as a result of this comment
Ophthalmologist	Comment 1 Section 2 Standard 2.2 The exam CertLRS, presumably for newcomers to this discipline rather than established practitioners, is in laser refractive surgery, however, refractive surgery has been defined by the College previously as a wide range of procedures, including refractive	See similar comments on the Cert LRS exam above and revised 2.1 and 2.2	See amendments to sections 2.1 and 2.2 noted above.

	lens exchange (RLE), phakic IOLs, etc. as well as laser. I imagine that the majority of surgeons carrying out refractive procedures in the UK do not perform laser, e.g. RLE being a very popular and successful procedure. It thus appears that newcomers to the discipline may be inadvertently forced to do an exam, along with attaining experience in treating patients with laser, when they have no intention of utilising these skills in the future. As a result, patients will necessarily be exposed to treatment by surgeons with no intention of carrying out laser in the future (there being a requirement of the CertLRS to have exposure to the technique as part of the 50 cases within the audit), the net result being a low level of harm to patients (as it is likely that more experienced surgeons would have a greater chance of a good result). In addition, considerable unnecessary energy will be invested by surgeons.		
Ophthalmologist	Comment 2 Section 2 Standard 2.2 There are a considerable number of corneal laser surgeons who do not carry out other procedures such as RLE, with a far greater number of surgeons who perform RLE, but not laser. It seems incomprehensible to try and regulate these very different and successful groups with a 'one size fits all' approach, which does not address one of the commonest procedures (RLE).	See similar comments on the Cert LRS exam above and revised 2.1 and 2.2	See amendments to sections 2.1 and 2.2 noted above.
Ophthalmologist	Comment 3 Section 2 Standard 2.2 There are many RLE surgeons, with established and well-audited practices and excellent results, who do	See similar comments on the Cert LRS exam above and revised 2.1 and 2.2	See amendments to sections 2.1 and 2.2 noted above.

	not carry our laser, but have established professional relationships with laser refractive surgeons for when laser top-up is required. In many cases, this is the best possible arrangement for patient safety, as a dedicated lens specialist – rather than a corneal specialist (who may only carry out a handful of lens cases and hence have questionable ability) – performs the RLE surgery, but the patient has the guarantee that if further surgery is required, a laser surgeon will perform the correction. In this context, the CertLRS is a completely unnecessary step, which would only serve to reduce standards in established practices and worsen patient care if future / existing lens specialists ceased providing the excellent levels of care that they currently do.		
Ophthalmologist	Comment 4 Section 2 Standard 2.2 Refractive surgery in general – not laser refractive surgery – is an integral part of modern cataract surgery, which all holders of a CCT in Ophthalmology have proved their ability in. Examples include carrying out clear lens extraction for patients with postoperative anisometropia, something that all trainees will have performed by the end of their training, never mind established consultants, and all within the NHS setting in most cases; this is refractive surgery by definition. Other examples include the use of sulcus-fixated piggyback lenses, which in many cases are better techniques than laser (e.g. elderly corneal epithelium, patients with corneal ectasia etc.) The addition of the requirement of the CertLRS for new practitioners of established non-laser techniques seems to dumb down the	See similar comments on the Cert LRS exam above and revised 2.1 and 2.2	See amendments to sections 2.1 and 2.2 noted above.

	training already undertaken, and which is already administered by the College.		
Ophthalmologist	Comment 5 Section 2 Standard 2.2 National standards in RLE and other surgery may fall. Within larger commercial organisations, surgeons who are specialised in providing corneal laser surgery – and hence obtain the CertLRS – may be required to provide lens surgery, in lieu of specialist lens surgeons. Holding the CertLRS should not be taken to mean that the corneal laser surgeon is safe to perform RLE – there are many corneal laser surgeons who do not carry out intraocular work.	See similar comments on the Cert LRS exam above and revised 2.1 and 2.2	See amendments to sections 2.1 and 2.2 noted above.
British Society for Refractive Surgeons	In principle the standards do achieve their intended aims but can be improved in their implementation as suggested in the previous sections.	See above	No changes as a result of this comment
British Society for Refractive Surgeons	Those involved in setting core competencies and/or the assessment system should be practising refractive surgeons. This would ensure wider acceptance and enhance the credibility.	Agreed – refractive surgeons will be involved with the examinations committee in formulating updates to core competencies and the Cert LRS exam.	No changes as a result of this comment
College of Optometrists	Comment 1 Section 6 Standard 6.8e We would suggest adding 'or other healthcare professional' after 'optometrist'.	The delegation of postoperative review to allied healthcare professionals other than optometrists was not considered. To the best of our knowledge, any delegation of postoperative eye-care in refractive surgery in the UK is exclusively to either ophthalmologists or optometrists. But we will consider this in future amendments to the standards if there is a change in practice patterns.	No changes as a result of this comment

College of Optometrists	Comment 2 Section 8 Standard 8.1 We would like to suggest adding 'or self-referral' after 'referral', as patients may approach providers directly.	See comments above and amended wording designed to take this in.	Section 8.1 has been amended to: 8.1 Key stages of the patient journey in refractive surgery comprise: • Initial advice from clinic staff • Procedure choice and discussion with the operating surgeon • Surgery • Early and late stage review consultations A cohesive team based approach with clear lines of responsibility and each member of the team playing to their strengths is essential at every stage.
College of Optometrists	Comment 3 Section 10 Standard 10.1 GMC advice can only apply to doctors. It is not appropriate to try to extend this to other professions, such as optometrists, as they have their own regulatory and professional guidance.	The College of Optometrists has produced Guidance for professional practice http://guidance.college-optometrists.org/home/, and also the GOC has its own Standards for Practice which clearly state that optometrists should not accept fees for referral. We accept that GMC advice can only apply to doctors and, for clarity on this point, have amended the wording in 10.1 and added 1.5 to the introduction to make it clear that our advice applies to surgeons and their practice.	Section 1.5 has been added for clarification: 1.5 Our additional recommendations take two forms: direct advice to surgeons, and advice that surgeons should ensure is upheld in relation to their practice. Direct advice to surgeons is prefaced by the heading *'In addition, surgeons who perform refractive surgery should.'* Advice that surgeons should ensure is upheld in relation to their practice is prefaced by the heading *'In addition, the following principles apply for refractive surgery.'* Section 10.1 has been amended to: 10.1 To help avoid any financial conflict where referral recommendations are made, surgeons should ensure that they or their

			employing refractive surgery provider only accept referrals where: a. Any fee for services provided in relation to making a referral to a refractive surgery provider has been charged directly to the patient. b. Any contractual relationship with a refractive surgery provider, including fees paid by the provider for co-management or continuing care after discharge, has been made clear to patients prior to referral.
College of Optometrists	Comment 4 Section 10 Standard 10.1a It is our understanding that optometrists (or others) must not be paid for simply making a referral. They can, however, be paid for providing a service prior to referral. We think the paragraph as it stands does not make this distinction clear. We would suggest rewording it to say: 10.1a Healthcare professionals must not be paid for simply making a referral to a refractive surgery provider. 10.1b Healthcare professionals may receive fees for services provided in relation to making a referral to a refractive surgery provider. Such services may include taking measurements and/or discussing the options with the patients. Any such fee must be made clear to the patient. 10.1c Any contractual relationship with a refractive surgery provider, including fees paid by the provider	This point was debated at length by the RSSWG with input from a representative of the College of Optometrists. Briefly, in refractive surgery, there is no standard tariff for services provided in relation to making referrals. The problem with reimbursement from providers is that it can create a market in which healthcare professionals are incentivised to refer to the highest bidder and this may constitute bribery. Payment from the patient for services provided in relation to referral is the most practical alternative.	See above changes to sections 10.1 and 10.2

	for co-management or continuing care must be made clear to patients prior to referral. We have removed the wording around patients paying for services prior to referral, as if the healthcare professional was not paid by the clinic they would be at liberty to charge the patient and this would not be an ethical matter.		
My Beautiful Eyes	As has been already stated by multiple industry groups, the standards fail on many points. MBE has every expectation of its comments being side-lined by commercial interests, but if we were to make a wish list of 5 points we would change in order to improve the guidelines it would be these: 2,5,6,7,8,9,10 Proposed changes to RCO guidelines 1: Unambiguous, verifiable statistics that reflect the whole of the industry and which are not chosen selectively. If 95% satisfaction is claimed then it should not be 95% of patients in subset X or cohort Y, the statistics used must verifiably reflect the claim. 2: Informed consent must not be delegated to non-surgical staff. At the very least GMC guidelines must be adhered to, consent may only be delegated to an individual who is capable of performing the same surgery and who is currently practicing. 3: Cooling-off periods must be adhered to and there must be at least 14 days between counselling being	Your comments and suggestions are appreciated. The following points hopefully address these adequately are far as is practical: We are hoping that a National Database project, in which patient satisfaction information is gathered independent of providers, will improve the evidence base on patient satisfaction for refractive surgery procedures, but the 95% satisfaction rating is conservative and based on multiple studies. See section 5, GMC para 16, and 5.6 The one-week cooling-off period, derived after extensive discussion with stakeholders, is a compromise between the two-week cooling-off period stipulated by CSIC for cosmetic surgery and requests based on convenience and GMC point 25 for a shorter period from some refractive surgery providers. If there are good reasons in individual cases for operating after a shorter cooling-off period, these must be agreed with the patient and recorded in the medical record.	No changes as a result of this comment

	provided by the surgeon and any commitment by the patient. 4: Deposits must not be taken prior to the conclusion of the cooling-off period as this represents financial inducement or pressure. 5: A compulsory checklist should be provided to patients at the start of the process and must be completed by both patient and surgeon prior to surgery. Failure to have sign-off of all steps from both patient and surgeon prior to surgery should be sufficient to prevent surgery from going ahead. The voluntary nature of the standards remains troubling to MBE. Whilst we are aware the RCO has no ability to impose sanctions, it should at least be able to identify instances of contraventions, write to the surgeons/organisations involved **and then publish the details of these contraventions in the public domain.** In that way at the very least the public would have the opportunity to remain informed as to the reliability or otherwise of surgeons and refractive surgery companies	See amended wording of 5.11. Any deposit must be refundable within a reasonable timeframe so as not to act as a pressure to proceed. This, in essnce, is the consent record. See also comments above in relation to the respective roles of the College (setting standards) and the regulators (enforcement).	
My Beautiful Eyes	We are not happy with the fact that, if not for an anonymous email sent to me the night before close of registration for the 18 May meeting, there would have been no patients/public present - this includes industry stooge Alan Tinger The RCOphth and entire refractive surgery industry are fully aware that MBE is the only patient group of its kind and therefore the most obvious to contact	Noted	No changes as a result of this comment

	with details of any event of interest to refractive surgery patients. We have also learned that the BCLA were not at any point invited to contribute to the draft consultation, in fact they had no knowledge of the RSSWG until I spoke with CEO Cheryl Donnelly earlier today. This causes us further concern as we believe comments from BCLA members are essential given the numbers of damaged patients visiting scleral lenses providers for help. With the above points in mind we are asking for a second consultation. We therefore ask that you add this addendum to our Professional Standards in Refractive Surgery: MBE Response.		
Ophthalmologist	Comment 1 Section 2 Standard 2.2 The standards/guideline are in general helpful. An unfocussed and overbroad definition of refractive surgery and the compulsory direction the exam/certification will likely take could have uncertain and undesirable consequences.	See modified paragraph 1.3	Section 1.3 now reads: 1.3 This document builds on the April 2016 guidance from the GMC, associated guidance, issued simultaneously, from the Royal College of Surgeons Cosmetic Surgery Interspecialty Committee (CSIC)2, and the preceding 2013 Keogh Report3. Our additional recommendations here apply to surgeons treating patients where the primary purpose of surgery is to reduce dependence on spectacles or contact lenses and the patient has a normal cornea and a normal lens in both eyes.
Optical Express Group	Comment 1 Standard 5 Section 5.1-5.13	See above	No change as a result of this comment

	As stated in our previous formal response, it is often not clear as to the purpose or intended aim of many of the recommendations, especially concerning the consent process. Often recommendations do not appear to promote patient safety or access of care, but instead appear to be intended to endorse one model of care over another with no justification.		
Optical Express Group	Comment 2 Section 9 Standard 9.6 No evidential basis whatsoever has been provided to support the inclusion of the >50% proportion in relation to 'from price advertising' in the sector. Furthermore this is an area which falls far outside the expertise and area of operation of the RCO, and it is not clear what the RCO's intended aim is in this regard. Since it is already regulated by public sector bodies with all relevant expertise and authority why is it that it is considered that 'the RCO knows best' and it intends to impose through purported guidance a rule for which it provides no justification We have undertaken a detailed review of the regulatory guidance and other materials to confirm that the '10% rule of thumb' remains as valid now as was the case 10 years ago when it was first considered by the ASA in the context of laser refractive surgery. . Your attention is first of all drawn to the **Updated CAP Executive Guidance** of 18 December 2015 headed "Prices: General". As well as addressing other issues, this document specifically addresses the issue of "from" prices under reference to two ASA rulings. The guidance makes it explicit that the minimum 10% figure	9.6 has been modified after consultation with CAP and legal advice.	Section 9.6 now reads: 9.6 Advertising price is discouraged. In the event that price of surgery is advertised, all material information should be given which patients need in order to make an informed decision about the advertised price, such as eligibility criteria, specific details of the treatment being provided and, if there is a range of prices, patients should be made aware that actual pricing could vary significantly from the advertised price. Information should be given in a clear, unambiguous and intelligible manner.

remains the percentage of the market at which products or services should usually be available at the "from" price point quoted in advertising.

It is noted that in the **Utilities Price Claims Advertising Guidance (Non-Broadcast)** the minimum 10% figure is specifically referred to as continuing to apply. At page 4 it states:

"*If the claim indicates that few will benefit, "up to" and "from" may be used. If "up to" or "from" are used, at least 10% of consumers should be able to save the stated amount*".

The CAP **Lowest Price Claims and Price Promises** does not indicate that any departure from the 10% guide is contemplated.

The current **Pricing Practices Guide** published by BIS in November 2010 remain in force, although it is due to be replaced with new **Pricing Practices Guidance**, the most up to date draft being October 2015. Neither of these documents indicates any departure from the minimum 10% availability where "from" pricing is used.

It is important to stress that there is no indication that the use of "from" pricing is in any way discouraged or is under consideration for prohibition. The requirement is that the basis upon which the price is expressed to be "from" must be stated and the guide for the minimum percentage availability remains unaltered at 10%.

Previous Rulings

This 10% minimum percentage of the market for products and services has been the subject of

	consideration and confirmation in numerous rulings by the ASA. As examples, reference is made to: **Thomson Travel Group t/a Thomson -** 9 May 2001 – ASA Ref: 29763; **Hilton International Hotels (UK) Ltd** – 23 October 2013 – ASA Ref: A13-235257; **Heart of Midlothian plc** – 8 August 2012 – ASA Ref: A12-192085; **Deutsche Lufthansa AG** – 12 March 2014 – ASA Ref: A13-250488; and **Iceland Tours Ltd** – 24 July 2013 – ASA Ref: A13225627. **Optical Express** - A07-29925/NB In the summer of 2016 the ASA decided, without issuing a formal ruling, in a complaint made regarding Optical Express that it had no case to answer where the complainer took issue with 'from' a specified price advertising and the ASA applied the 'more than 10%' rule of thumb. It should be stressed that these are only a selection of exemplar rulings and that in every case the relevant percentage of the market for goods and services is a minimum of 10% of the potential customer base, for the particular service or product, who realistically have the service and product available to them at the stated price. The final one of these rulings expressly approved the "minimum 10%" of the market as being appropriate in the Laser refractive surgery sector of health care."		

Optical Confederation	Comment 1 Entire Document Regrettably no – unless the aim is to prevent safe and ethical community provider models operating and delivering refractive surgery at affordable prices to the general public – which we do not believe can be the case in the case of a charitable body operating for the public good like the College. We believe a major opportunity has been missed to develop genuinely inclusive and high-quality sector-wide guidance with which all providers and professions engaged in refractive surgery could comply. To this end it would have been more helpful if the College had been inclusive from the outset, called for evidence which would have been willingly made available and followed the NICE protocol which has delivered high quality guidance for the College in other areas, i.e. cataracts and glaucoma. Whilst we acknowledge that this set of draft standards is improved from those consulted on earlier in the year, we are still concerned that they appear to have been drafted primarily with doctors who work in independent practice in mind. They do not take account of the different models of practice which have developed in the community in response to need, and indeed patient preference, and put surgeons in positions with which they cannot possibly comply. As this is the model most likely to expand in coming years – of ophthalmic surgeons working alongside and as part of a community team, with the surgeon employed or engaged by independent providers who do much of the administrative work and patient work up for them	Please see the Terms of Reference for the RSSWG at https://www.rcophth.ac.uk/wp-content/uploads/2016/03/ToR-Refractive-Surgery-Standards-Working-Group-V1.4.pdf The standards were developed through public consultation and consultation with industry stakeholders.	No change as a result of this comment

	pre- and post-consent – we do not believe the standards will achieve their desired aims.		
Optical Confederation	Comment 2 Section 5 Standard 5.5 We agree that the tone and content of consent forms should be consistent. However it is not clear why the College would wish to stipulate that they must be “appended to patient information”? Different provider models will operate different procedures in the interest – and at times at the request – of the patient, e.g. in cases where information is provided in alternative, accessible or digital formats. We therefore recommend removing the second sentence of this section.	This is designed to eradicate the practice of giving patients a sugar coated promotional lead in to the procedure and then providing them with a jargon heavy, multi-clause consent form reading like a disclaimer prior to surgery. 5.5 should work for any written patient information format.	No change as a result of this comment

27 March 2017