



*The* ROYAL COLLEGE of  
OPHTHALMOLOGISTS

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# Refractive Surgery Standards Consultation April to June 2016: Responses and Comments

August 2016

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# 1 Introduction

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## About the consultation

1.1 The Royal College of Ophthalmologists consulted on the following standards documents and patient information documents between 27 April 2016 to 8 June 2016:

- [Standards for Patient Information and Consent](#)
- [Advertising and Marketing Standards](#)
- Procedure specific information for patients; [Patient Information Refractive Lens Exchange](#), [Patient Information Phakic Intraocular Lens Implantation](#), [Patient Information Laser Vision Correction](#), [Patient Information References](#).

1.2 We informed a range of stakeholders about the consultation including College Members, professional bodies, and employers of refractive surgeons. The consultation was advertised on the College website and we also issued a notification to the UK and Ireland Society of Cataract and Refractive Surgeons. <https://www.rcophth.ac.uk/2016/05/consultation-open-for-improving-standards-for-refractive-surgery-in-the-uk/>

1.3 The College also held two engagement sessions; one for industry representatives (11 May 2016) and one for the public (18 May 2016) as part of the consultation exercise.

1.4 We would like to thank all those who took the time to respond to the consultation document and attend the engagement sessions.

## About us

1.5 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.

1.6 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](http://www.rcophth.ac.uk)

## About this document

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

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

## 2. Analysing the responses

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### Method of recording and analysis

2.1 Respondents were instructed to send their comments directly via email to a member of College staff. No specific structure of format was designated for the return of comments. The College specifically asked for comments on:

- the comprehensiveness and applicability of the documents
- the content and content and clarity of the documents and their suitability for different environments
- whether the advice looks straightforward and is usable by service providers and service users
- the interpretation of the evidence available to support its recommendations
- the likely impact on patient groups affected by the standards
- the likely impact / ability of service providers to implement the recommendations
- do the standards achieve their intended aim(s)

2.2 Most respondents did not set out their comments in a formal structure that directly addressed these aspects.

2.3 The College held two engagement sessions; one for industry representatives (11 May 2016) and one for the public (18 May 2016) as part of the consultation exercise. Feedback from the industry and public engagement sessions is summarised and included in the response to the consultation.

2.5 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 agreed at its meeting on 13 July and changes to the documents agreed.

Comments received from (organisation/surgeon/public/optometrist)	Document title	Comment	Comments from the Refractive Surgery Standards Working Group	Changes to the document
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2.6 A table of responses provided below. All respondents were asked for permission to publish their responses, if permission was not received the response has not been published.

### **Written responses to the consultation**

2.7 18 written comments were received as part of the consultation process.

2.8 Comments were received from: practicing surgeons, practicing optometrists, members of the public, the College's Lay Advisory Group, the College of Optometrists, the Optical Consumer Complaint Service, The Royal College of Surgeons, the Optical Confederation and a provider organisation.

- Optometrists 5.5% (one response)
- Consultant Ophthalmologist 16.5% (three responses)
- Patient/member of the public 16.5% (three responses)
- RCOphth Lay Advisory Group 33.5% (six responses)
- Professional body 22.5 % (four responses)
- Provider organisation 5.5% (one response)

### **Refractive Surgery Standards Industry Engagement Session 11 May 2016**

2.9 There were 27 industry/provider delegates. Representatives from the Care Quality Commission, the General Medical Council and the Cosmetic Surgery Interspecialty Committee of the Royal College of Surgeons were also present.

### **Refractive Surgery Standards Public Engagement Session 18 May 2016**

2.10 14 members of the public had registered an interest in attending the session however only eight attended on the day.

### **Summary**

2.11 As a result of the consultation feedback, the Working Group has decided to prepare an overarching document that sets builds on General Medical Council advice for cosmetic and lifestyle procedures<sup>3</sup>. This will replace the consultation document 'Standards for Patient Information and Consent' but will take account of comments from the consultation. The Royal College of Ophthalmologists will run a further consultation on this document 'Professional Standards in Refractive Surgery'.

2.12 A number of changes have been made to the patient information documents.

### 3. Consultation comments and Working Group Responses

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

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

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

Comments received from	Document title (if specified)	Comment(s)	Comments from the Refractive Surgery Standards Working Group (RSSWG)	Changes to the guidance document(s)
Optometrist		<p>As an optometrist who worked in refractive surgery for 2 years and has over 30 years' experience in optics.</p> <p>I would make the following comments on the proposed standards.</p> <p>1. The use of the term "over 95%" satisfied is misleading as it is too subjective and undefined. It does not explain why 5% are not.</p>	<p>1. 95% is derived from validated questionnaire data referenced (e.g. Solomon KD et al Ophthalmology 2009<sup>1</sup>). But the essential aim is indeed to target the up to 5% of patients who are not either satisfied or very satisfied with their outcome</p>	

		<p>2." Side effects" implies temporary mild symptoms. This is untrue and is a minimising term. Better would be "serious and sometimes permanent life-changing side effects".</p> <p>3. The surgeon must not be under any pressure financial or time.</p> <p>4 The optometrist must also behave in a professional manner and not be subject to financial pressure to recommend a procedure.</p>	<p>2. Side effects are, by definition, self-limiting in the vast majority of cases. The current wording reflects the evidence base.</p> <p>3.&amp; 4. Agreed absolutely – hopefully this is clear from the standards outputs.</p>	
Consultant Ophthalmologist	General comment and Patient Information Refractive Lens Exchange	<p>The Refractive Surgery Standards Working Group should be congratulated for their initial efforts in producing these important documents for consultation. I am grateful to the College for the opportunity to comment on these documents. My overwhelming impression is that these are excellent, however, I would like to make the following suggestions for the Patient Information Refractive Lens Exchange document:</p>		

	<p>3.4 In these modern times, the CMA would probably not approve of the second sentence. While it is fair to say that most do charge for subsequent YAG capsulotomy, stating that “An additional fee is <i>normally</i> charged for YAG...” could be construed as protecting an income stream; suggest simply change to “additional fee may be charged....”</p> <p>7.2 While fortunately exceptionally rare, the <i>worst</i> scenario would be loss of the eye itself, not complete loss of vision in the affected eye.</p> <p>7.5 - Laser vision correction to fine tune the focus is only <i>sometimes</i> - not often - required to fine tune the focus. Furthermore, there may be occasions when an alternative technique such as a sulcus-fixated lens is required instead. Suggest change to “Limitations on the accuracy of these techniques mean that fine-tuning of the focus after RLE can sometimes be required with an additional procedure, such as laser vision surgery, or other techniques.”</p>	<p>This point was debated by the RSSWG. Loss of an eye can result from any eye surgery complicated by infection or contact lens related infection. Other respondents have pointed to the need for balance in including reference to serious but highly unlikely complications in close proximity to more likely, less serious, downside risks. The feeling of the RSSWG after due consideration was that the altered wording was fair. Whilst we are not explicit about the (minimal) risk of losing the eye, the wording “complete loss of</p>	<p>Change accepted</p> <p>“This may mean vision worse than the driving standard or, in some cases, complete loss of vision in the affected eye.”</p>
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		<p>8.3 The peripheral vision negative dysphotopsia symptoms mentioned for monofocals can also occur in multifocals, although obviously MFs tend to produce more obvious central problems in those liable to problems. Suggest remove the word 'monofocal' from the second sentence of 8.3</p> <p>8.4 Last sentence. IOL exchange - "swapping" the multifocal for a monofocal implies this procedure is a doddle, rather like changing an inner tube! I would suggest changing to: "...IOL exchange, a potentially complicated procedure swapping the multifocal IOL for a monofocal IOL...".</p> <p>I also wonder whether there should be a sentence or two on the potential for late movement of a multifocal IOL and hence dysphotopsia symptoms and potential surgery; this is particularly important with the MPlus-type</p>	<p>vision" should make the downsides clear.</p> <p>Adjustments required are usually small order and easily addressed with laser correction. Gross errors are infrequent and covered by paragraph 1 in this section</p> <p>A valid point but there is very little in the current literature on this.</p>	<p>Change 'sometimes' accepted.</p> <p>Change accepted</p> <p>Change accepted</p>
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		<p>design lens, where long-term centration is crucial for it to work well.</p> <p>Thank you again for your efforts. I would be more than happy to be involved in helping in the work of this Working Group, although I should state at the outset that I am not corneal-trained; it may of course be useful to have such a perspective, as it will be vital for the College to engage with all ophthalmologists performing refractive surgery, not just the corneal cognoscenti..!</p>		
Patient/ Member of the public	Patient information with respect to refractive surgery	<ol style="list-style-type: none"> <li>1. The distinction between cataract surgery (necessary) and refractive lens exchange (elective) and which the patient is being treated for should be made clear.</li> <li>2. The distinction between monofocal (straightforward) lenses and multi-focal (complex) lenses should be made clear.</li> <li>3. It should be made clear that the process of 'neuroadaptation' to Multi-Focal Intra-Ocular Lens</li> </ol>	<p>Paragraph 2 is already clear on this.</p> <p>See paragraph 3 and the following</p> <p>See under side effects 'approximately 1% of patients</p>	

	<p>replacements is not fully understood by the scientific community, as it is a part of the neurological vision system, which in itself is not yet fully understood by the scientific community. The consequence of this is that it is impossible to predict whether a given patient will respond well or badly to MF IOL's.</p> <p>4. Consent documents should not be dual purpose (i.e. documents for necessary cataract surgery and elective RLE should not be combined and should not be identical documents, especially with regards to sign-off).</p> <p>5. With respect to patient information: terms such as 'starbursts' and 'halos' are open to interpretation. For example, 'starbursts' experienced by Rigid Gas Permeable contact lens users are significantly different to 'starbursts' as experienced by MF IOL users. Visual examples of these should be presented, using straightforward comparisons produced in industry-</p>	<p>cannot adapt, and will elect to undergo IOL exchange'.</p> <p>The indication for surgery is obviously different but the operation and side effects are identical.</p> <p>The draft information documents here are a starting point. The aim is to add appropriate illustrations once the text is agreed.</p>	
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		<p>standard image editing tools such as Photoshop.</p> <p>6. Greater emphasis should be given to other undesirable characteristics of MF IOL's, such as lack of contrast and poor intermediate distance vision.</p> <p>7. MF IOL's have widely varying characteristics; one brand or model may have markedly different characteristics to another (e.g. bi-focal versus tri-focal). This should be made clear to the patient.</p> <p>8. The specific characteristics of the particular lens the surgeon intends to implant should be explained in detail by the surgeon to the patient, the reason for this choice should be made clear, and the benefits and disadvantages of this lens choice should be made clear. In addition, this material should be provided both verbally to the patient and in writing for the patient to take away and consider. This information</p>	<p>Intermediate vision is good with contemporary (trifocal) designs or micromonovision. Contrast losses are also small and well tolerated.</p> <p>See 'IOL alternatives' under 'What are the alternatives'.</p> <p>See intro 'If you are suitable for RLE, your surgeon will discuss which IOL type is the best option for you.'</p> <p>Also see standards document – we are clear in this that promotional material should not differ in tone or content from consent information.</p>	
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should not take the form of a glossy brochure or a sales document.

9. It should be made clear to the patient that any form of lens exchange will result in a quality of vision, which is inferior to the average quality of vision in the population at large. Lens exchange should only be contemplated when the patients vision has deteriorated to a point at which it can be improved by lens exchange. Visual acuity (such as Snellen eye-chart metrics) should not be quoted in isolation, effects on quality of vision should always be made in conjunction with these claims.

10. Refractive Lens Exchange should never be offered for purely cosmetic reasons unless there are overwhelming medical / psychological reasons for so doing.

11. Statistics must be fully qualified. A claim, such as 'approximately 95% are satisfied' for example, is not a qualified statistic. The sample size,

This is incorrect, modern IOLs (including multifocals) provide contrast sensitivity that is similar to or better than age matched patients who have not had surgery (see review de Vries & Nuijts 2013<sup>2</sup> – source references). We are not arguing for restricting the evaluation of visual function to Snellen acuity.

Please refer to the source references document [Patient Information References](#).

the date, the specific product under discussion (i.e. mono-focal versus multi-focal lenses), the organisation or research group conducting the research and the specific question asked should be made available to the patient.

12. Both surgeon and patient should sign a checklist detailing every step in both the consultation process and the examination process. This should be sufficiently clear and robust to not be open to interpretation. It should begin with: I am aware and I understand that my surgery is for 'x' (i.e. RLE or cataracts) and that this is (either) elective or necessary. There should be a list of documents presented to the patient, an indication of who presented them and when, and what visual support material was given to the patient. If this is not conducted in meticulous detail and counter-signed at every stage then surgery should not go ahead. This document should include the conclusion of the examination, details of counselling, material supplied to the patient,

We have attempted to address some of these concerns in a unified professional standards document that builds on GMC advice<sup>3</sup>. The consent process should be clearly documented but we are seeking to move away from the 'consent form as disclaimer' approach.

		<p>explanation of the characteristics of lenses to be implanted, detailed statistical validation of the efficacy of the procedure, and an appraisal by the surgeon as to whether the patient will be better off or less well off as a consequence of eye surgery. Cosmetic improvement is not a valid benefit unless supported by a consultation with an appropriately qualified third party.</p>		
Member of the RCOphth Lay Advisory Group	Patient information documents	<p>2:3. It would indeed be interesting to back up this figure with evidence. What does "satisfied" mean? There's a big gap between adequate and delighted. Are there figures to show how long after the surgery the sense of "satisfaction" lasts? Life changing doesn't necessarily mean for the better!</p> <p>7:1. Does this mean all forms of eye surgery, or just refractive eye surgery? Should it say here that problems can occur in eg less than 5%, or whatever the risk is now? Is it correct to think that the risk is greater in a healthy eye than in a</p>	<p>Please refer to the <a href="#">Patient Information References</a>.. We acknowledge that more work needs to be done with patient reported outcome measures of vision quality, satisfaction with surgery, and other quality of life measures but some good evidence (cited) already exists.</p> <p>See above.</p>	

		<p>patient where there is a clinical reason for surgery?</p> <p>7:2. Corneal transplantation is a complicated procedure, and probably always "life changing"!</p> <p>7:3. It's probably a typo at the end of the paragraph, "Risks of contact lens wear..."</p> <p>8:3. I think it would be useful to spell out the symptoms of dry eye. It sounds here like a minor irritation, but it can cause distress and some people find the need to use artificial tears very inconvenient.</p>	<p>The figure 1/3000 per year is correct.</p> <p>Symptoms are usually minor and temporary. Untreatable, lasting problems resulting from surgery are rare. Although new eye discomfort symptoms occur in some patients after surgery, the majority (including ex-contact lens wearers) are more comfortable.</p>	
Consultant Ophthalmologist	General Comment/ Patient information	<p>Many thanks. I have looked at these many times now. I don't have particular comments except that phakic IOLs should not be normalised. It remains controversial and should be viewed as a stop gap for pre-presbyopic patients who are outside the range for laser refractive surgery. Complications such as glaucoma, inflammation, retinal</p>	<p>See supporting literature. Intraocular Collamer Lenses in particular have a very strong safety and efficacy record.</p>	

		<p>detachment, cataract formation can occur.</p> <p>If there are specific points you wish my opinion on, I shall be pleased to answer</p>		
Member of the RCOphth Lay Advisory Group	General Comment	<p>As June is almost upon us, I have at last got round to reading the attached consultation documents; they are most interesting and, for me, educational.</p> <p>Having also read other LAG responses I find I am in agreement with their comments and have nothing further to add.</p>		
Patient/ Member of the public	General Comment	<p>As a laser eye surgery victim, I am very concerned by the new refractive surgery standards, as I cannot see how they will protect the public.</p> <p>I can see no warning of the constant pain that a potential patient could be left with for the rest of their life, and the terrible psychological damage, that no amount of counselling etc. can cure, such as depression and in some cases</p>	<p>This level of negative impact is rare but very distressing. There is often (but not always) effective treatment for complications resulting from surgery and improving access is a priority.</p> <p>One of the important dimensions of our work in the RSSWG later this year will be to look at ways of enhancing support for patients with problems after surgery.</p>	

suicide. I did not think that surgery would leave me with terrible RSSS, including PTSD, nor did I imagine that I would suffer unbearable physical pain for the rest of my life....at least I had some idea that my eyesight might not be perfect (it's dreadful), but I think that people need to be warned of these other risks, as many victims suffer similar types of problems to mine. People need to know that they may have to get out of bed every night for the rest of their lives, just to nurse their eyes, and they may not be able to drive at night etc. Their lives could be ruined, they may not be able to work. The emotional harm is very great.

Percentages and statistics are worrying, they can be presented anyway, in order to mislead. Almost all laser treated eyes, lose some contrast sensitivity, and in some cases the loss is great, yet no one ever mentions this, and they don't explain that it makes colours fade. I see less colour now, and I self harm because of the grief it causes me. I

		<p>am horrified, that the public are not warned that they will (most likely) lose a little of their colour perception at the very least. Honesty is vital, but this industry is so corrupt.</p> <p>I believe that this industry is so horribly corrupt, that these new measures will do little if nothing to help. Authorities that I once thought were there to protect the public, will continue to pass the buck of responsibility and turn a blind eye, doing far too little, too late, to protect the public.</p> <p>Thank you for reading my concerns, and although I am sure that it's not what you were hoping for, I hope that it will be helpful.</p>		
Member of the RCOphth Lay Advisory Group	General Comment/ Patient information	<p>The RS standards documents read very well indeed and I am especially pleased to see the following: <i>“You may not be aware of a problem that requires treatment in the healing phase. So make sure you attend your review appointments even if your eyes feel good. “</i></p>		

Both for PIOLI and RLE Patient info, I would prefer some statement to be included so that patients are very clear about **driving** . e.g. as an addition to: 10.6 “You can wash and shower normally from day one after surgery. Most surgeons recommend no swimming for a week and no contact sports for a month. Non contact sports such as gym and jogging can be resumed from day one after surgery”.

Also, I should much prefer the sentence (e.g. in 1.7) “Qualifications and experience should not be exaggerated or misleading “ to become “Qualifications and experience should **be truthful and** should not be exaggerated or misleading “.

Finally, a comment from the heart. These documents are a very very far cry from the one side of A4 paper that I received before my cataract operations.

So much of the information contained within them would have

“Your surgeon will advise you when it is safe to start driving again. Typically, this is within a few days of surgery.”

See GMC guidance<sup>3</sup>: *46 You must always be honest and never misleading about your skills, experience, qualifications, professional status and current role.*

		<p>been both helpful and encouraging to me.</p> <p>It would be simply great if they could become very widely known in the profession and used and adapted for other patients.</p>		
Patient/member of the public	General comment	<p>I'll keep this short! Suffering every day as a result of PRK surgery. The clinic never explained just how painful dry eye can be. They never explained what Mgd or corneal erosions are. I'm suffering with both. They also don't advertise how many of their patients are not happy. They say good vision is a success, I have perfect vision as a result of the surgery but I certainly wouldn't say my outcome is a success. I'd rather have glasses and less perfect vision and live a normal life again. I regret the surgery so much and I don't believe I was correctly monitored before being allowed to go ahead with it. I also think clinics who allow opticians to consult with the patients should be banned. I saw the surgeon himself once. An optician approved me, the surgeon did the surgery and even after a lot of issues</p>	<p>One of the key changes introduced by the GMC<sup>3</sup> is that surgeons will have to review patients at a pre-surgery consultation. We are emphasising in our Professional Standards in Refractive Surgery document the need for a clear line of communication between the patient and the operating surgeon at every stage in the journey between the initial consultation and discharge with a stable outcome.</p>	

		and complications, I've only seen opticians after. Opticians are not doctors and are not qualified to deal with the complications I've had.		
College of Optometrists	General comments	<p>Thank you for giving us the opportunity to comment on the draft documents produced by the Royal College of Ophthalmologists' Refractive Surgery Group. We will take the documents in turn:</p> <p><b>Overall</b> We note the GMC has recently stated that <i>laser and refractive eye surgery share many similarities with cosmetic surgery and we would consider these to be covered within the scope of [the cosmetic interventions] guidance.</i> We are disappointed that this was not made clear in the actual GMC guidance when it was published. We would concur with the Group's original decision that it is functional surgery, which is different, and some forms of it are similar in nature to cataract surgery.</p>	<p>See recent further GMC guidance – it is now very clear that the guidance for cosmetic surgery will embrace elective, self-pay, lifestyle procedures including refractive surgery.</p> <p><a href="http://www.gmc-uk.org/guidance/ethical_guidance/29160.asp">http://www.gmc-uk.org/guidance/ethical_guidance/29160.asp</a></p>	

College of Optometrists	Standards for patient information and consent for refractive surgery	Para 4.2: We should like to see the phrase ‘advice from non medical staff’ expanded. We accept that the GMC principles that apply to cosmetic surgery should also apply to refractive surgery. We do not believe, however, that the Royal College of Ophthalmologists should go beyond those principles. In particular, while we agree that the surgeon will take consent, we believe that the optometrist can play a significant role at earlier stages, making the surgeon’s task easier. We should like this section to be expanded to say that the optometrist could interpret the results of the tests and explain these, and the different procedures, to the patient. He or she could also explain which procedure was most likely to be appropriate and why, and answer any questions the patient might have so that the patient was better prepared for the discussion with the surgeon.	We are already clear that ‘preparatory information may include written material, video material or advice from suitably trained non-medical staff’  Suitable training in refractive surgery care for non-medical staff requires further definition.	
College of Optometrists	Advertising and marketing standards for	Para 1.6: We accept that it is important that the patient is not misled by the way that pricing is set	This clause refers to “bait and switch” advertising. Prices are advertised in order to entice	

	refractive surgery	<p>out but we believe that it is helpful for patients to have an understanding of the likely price range before they approach a provider.</p> <p>Para 4.6: Is the College in a position to prohibit deals? Paragraph 4.10 states that the Royal College has no role or remit in terms of enforcement. If the prohibition comes from elsewhere, it might be clearer to say xxx prohibits the following...</p>	<p>patients only to be upsold. This is misleading practice. A range of pricing would be useful but this is not in alignment with advice and guidance of the Committee of Advertising Practice<sup>4</sup>.</p>	
College of Optometrists	<p>Patient information</p> <p>These comments are based on the PIOL information document but relate to all documents.</p>	<p><i>Structure</i></p> <p>The structure is confusing for those who have no knowledge of the procedures. Points are not set out logically. For example, para 5.1 sets out the alternative procedures but para 5.5 suggests the only alternative is staying in spectacles or contact lenses. This is not the case.</p> <p>Risks are mentioned in 5.8 but the actual section on risks is later in the document.</p> <p>In the 'what are the risks' section – presumably the risks of PIOL – there</p>	<p>Structure is derived from market research on what information patients need commissioned by the Royal College of Surgeons<sup>5</sup>. See comments from RCS below.</p> <p>Continuing in contact lenses is the main alternative for many patients considering refractive surgery. Risks of contact lens wear are therefore summarised briefly alongside risks of surgery. The need for this balanced</p>	



out the comparative risk factors and odds ratios helpful.

There is not always enough information, for example in paras 2.2 and 2.4, there is not much information on what this means for the patient. It might be helpful for them to have some examples, say for paragraph 2.2 – this means that you might need glasses for reading or eating, particularly in low light if you have reached the age where you might already have to do this.

#### *Style*

Para 2.1 of *Standards for patient information and consent for refractive surgery* states that providers should write patient information in plain English. These documents do not conform to the principles of plain English <http://www.plainenglish.co.uk/> and should be re-written in line with those principles.

The document is not addressed to the reader and the sentences and paragraphs are over long.

readers, and we have aimed to strike a balance between detail and information overload. Other feedback has been generally positive in this regard.

Feedback from elsewhere has been very positive. Illustrations and videos will be added once the text is finalised to help make the information as accessible as possible.

PIOLs can be removed if they are causing problems – see text.

Again, a question of brevity vs clarity. See respondent's own advice above. The smartphone caveat is more relevant to the cataract age group.

		<p>Terms such as ‘corneal waterlogging’ and ‘light scatter’ are not familiar to all lay people. ‘Clips on to iris’ (para 1.4) might imply that you could remove the PIOL. Instructions such as ‘Set up a smartphone reminder’ are not helpful to those unfamiliar with smartphones and this might be better used as an example: ‘Set up a reminder system, for example on your smartphone,’</p> <p><i>Links</i></p> <p>It would be helpful to add links to references to information on the other procedures, where these are mentioned, or to other paragraphs where information is linked. Patients might not know where to look when references to ‘as explained above’ occur, for example in paragraph 9.2.</p> <p>We should be happy to ask our public patient reference group to comment on these documents if that is helpful.</p>	<p>We will hope to add text hyperlinks in transition to the web format.</p> <p>The documents have been developed with feedback from the College lay advisory group and public consultation. We will set in place a mechanism for periodic revision but we are not planning any further consultation before the first release of the finalised documents.</p>	
College of Optometrists	Review of the evidence base	No comments.		

Member of the RCOphth Lay Advisory Group	Advertising and Marketing Standards	No comment – seems useful and effective		
Member of the RCOphth Lay Advisory Group	Standards for Patient Information and Consent	<p>There is no mention of the need for patient information to be produced in VI accessible format and font size. Should conform to RNIB standards <a href="http://www.psncorp.com/Downloads/RNIB_Clear_Print_Guidelines.pdf">http://www.psncorp.com/Downloads/RNIB Clear Print Guidelines.pdf</a></p> <p>I realize that most people coming for laser refractive surgery will have reading vision with glasses but I still think it is good practice for any eye clinic to produce their information in accessible formats</p> <p>The authors should consider whether there is a need to cover a patient who presents with a carer/relative and whether all patients will be completely competent to absorb information and make decisions for themselves.</p> <p>The discharge information material must also be in VI accessible font size and format</p>	<p>I am afraid this link is not working we think the reference is <a href="http://www.rnib.org.uk/information-everyday-living-reading/large-and-giant-print">http://www.rnib.org.uk/information-everyday-living-reading/large-and-giant-print</a></p> <p>Adults presenting for refractive surgery rarely have problems with capacity for consent – rare situations in which they do are covered in GMC guidance to be included in a revised standards document ‘Professional Standards for Refractive Surgery’.</p> <p>Covered under ‘realistic expectations for the outcome’</p>	

		The standard assumes that there will be no need for glasses after the procedure. Is this the case? If not the information discussion should include the concept that glasses may be needed in some circumstances. In fact, I see that this is mentioned in the individual PILs but should also be mentioned in the standard		
Member of the RCOphth Lay Advisory Group	Laser Vision Correction	No comment – looks comprehensive		
Member of the RCOphth Lay Advisory Group	Phakic IOL Implementation	No comment		
Member of the RCOphth Lay Advisory Group	Refractive Lens Exchange	No comment		
Optical Consumer Complaints Service	General Comments	Nockolds Solicitors deliver the complaints mediation service for optical consumer complaints relating to optical practices and professionals across the UK.  The service is funded by the General Optical Council but operates as an independent organisation. Our remit		

is primarily aimed at the optometric sector however it does include matters relating to refractive surgery where the procedure is performed under the auspices of a GOC registered body corporate.

This response to the Consultation is therefore provided from the independent perspective of complaints resolution and is based on the insights we have gleaned by handling consumer related concerns relating to refractive surgery since 2014.

We understand the thinking behind the College's recommendations and also note the published positions of the GMC. With those in mind we make the following suggestions based on the small number of complaints we receive about community refractive surgery, which are referred to the Optical Consumer Complaints Service for successful mediation. The OCCS appreciates that patients and circumstances are referred to the service where patient dissatisfaction cannot be resolved by the supplier.

OCCS interaction in this area does not therefore reflect the views of patients who are entirely satisfied with the refractive surgery. In our response, the OCCS seeks to highlight the nature of the concerns raised by patients in their complaints relating to refractive surgery in the community. Whilst we cannot confirm with statistical analysis, the OCCS are confident that dissatisfied consumers represent only a small minority. They do however provide some insight on challenges for clinicians and refractive surgery suppliers, and where complaints can arise. The OCCS response to that consultation is therefore based on the insight gained during complaints mediation.

Taking into account the responses of all involved in this sector of health care, the OCCS are hopeful that final guidance will seek to enhance the patient experience and satisfaction by supporting standards of practice for all clinicians and patient understanding and outcomes.

We have a number of suggestions that we believe the Royal College will find useful.

**1. Stability of prescription definition.**

Whilst we agree with your definition (<0.50DS change in previous two years) we believe to would be helpful to add some guidance when the patient is a myope in their early twenties. In these situations it would be useful to know if there is any evidence of increased regression and whether a more robust protocol or definition of prescription stability is required.

**2. Period of time during which a free retreat or enhancement should be included.**

A number of refractive surgery patients will regress following treatment and thus require a retreat or enhancement procedure. We believe most providers will include in their T&Cs a period during which these interventions are provided free of charge. Given the variance in

1. This is the group that is most likely to have a further drift towards myopia. There is no good data on proportions, but most surgeons emphasise to patients in this age group that there is a higher risk of a late myopic shift. A more robust protocol would be difficult, since limits of measurement repeatability mean that variations of up to 0.5D occur between tests. We cover this briefly in the final para of the introduction to the laser vision correction information.

2. Noted – see para 2 under ‘How much does laser vision correction cost’ 2 years is the generally accepted period during which retreatments are provided free of charge. This is based on the time to stability in long-term follow-up after LVC for high myopia.

		<p>how long it can take for a prescription to stabilise post operatively we feel this period should be a minimum of two years. Again it would be useful to know what data exist for postoperative stability however we feel that a two year period potentially balances the clinical outcome and the commercial requirement not to have open ended commitments to retreats.</p> <p><b>3. Presbyopic outcomes &amp; expectations.</b></p> <p>The complexities of managing postoperative vision for presbyopic refractive surgery patients is particularly challenging and any improvements in how the sector can better prepare and manage the expectations of this particular group would be very welcome. Similarly the need to explain the loss of spectacle magnification for hypermetropic spectacle wearers would be beneficial.</p>	<p>3. Noted – loss of magnification from hyperopic spectacles is not a common cause for complaint and usually more than offset by freedom from edge distortion, field restrictions and heavy spectacles. We hope this is covered under ‘relatively little compromise optically.’ Para 3, Who is suitable.</p>	
Optical Consumer	Standards for Patient	The provision of generic (or provider specific) data tables mapping preoperative prescription to	We would like to see data on refractive surgery collected and reported on at a national level	

Complaints Service	Information and Consent	<p>postoperative BCVA could be useful in managing expectations. For example XX% of patients with between 4 &amp; 6 dioptries of myopia secure 6/6 vision unaided post treatment.</p> <p>Once again we welcome the intention to improve information and care for patients through appropriate clinical team work. If we can be of any further help please feel free to contact us at <a href="mailto:enquiries@opticalcomplaints.co.uk">enquiries@opticalcomplaints.co.uk</a> or by calling 0844 800 5071</p>	<p>with the aim of deriving and presenting accurate contemporary outcome figures in an accurate, balanced and digestible form.</p> <p>Mechanisms for achieving this need to be further explored.</p>	
Optical Consumer Complaints Service	Advertising and Marketing Standards	<p>Section 1.4</p> <p>Whilst supporting the thinking behind this section would it be possible to increase clarity i.e be more specific about the reference to 'where possible' as this may be too ambiguous to achieve its aim.</p> <p>Sections 1.6 &amp; 1.8</p> <p>We support these two requirements, however it is not clear from the proposal how this will be validated and this will be essential to</p>	<p>In 1.4 The inclusion of "where possible" was following initial consultation where the practicality of including the phrase was brought to our attention e.g. Google ads do not provide an opportunity as ad sizes are limited in terms of characters. Defining specific exceptions is not practical.</p> <p>Validation will have to be following a complaint and would be by an independent</p>	

		<p>ensure compliance in these two important areas.</p> <p>Section 3.3</p> <p>This section states there is no specific code for refractive surgery advertising. Would it be possible for the sector to create such a code?</p>	<p>responsible authority such as the ASA or in the case of 1.8 GMC.</p> <p>In terms of section 3.3, it is hoped that this document will be adopted as the basis for a code for refractive surgery advertising.</p>	
Royal College of Surgeons of England	<p>Patient Information: phakic intraocular lens (PIOL) implantation/ Patient Information: refractive lens exchange</p>	<p><b>The layout of the guidance</b></p> <p>From our research with patients prior to writing our patient information, we know patients prefer it if information is not too clinical and is presented in a way that is appealing to them.</p> <p>One way to achieve this might be to remove the clinical numbered bullet points and to use headings and short paragraphs so patients can easily find the information they want to read. If this information is going to be on your website, the headings could then be visible and then patients can click on the headings they want to read and the answer can be revealed. This will reduce the amount of text visible when they</p>	<p>We used numbered bullet points in document development to help comment and editing.</p> <p>We will look at using headings as links to the relevant text as suggested when we format the documents for web publication</p> <p>Subsection titles are in an interrogative format – so we are already some way down this track.</p>	<p>Useful advice - we will look at this in the transition to web format</p> <p>Numbered bullet points to be removed for final outputs.</p>

first look at the page and it will be more manageable for the reader.

Another way to achieve this would be to use a questions and answers format in some parts of the text, to divide the text and to draw the reader in more.

For example in *phakic intraocular lens (PIOL) implantation* document on page 3 you could change to:

**What is PIOL implantation?**

...(insert answer)...

**Is PIOL implantation right for me?**

...(insert answer)...

**What is the most common type of implant?**

Visian ICL is the most common implant used in the UK and worldwide.

**How does it work?**

It is a soft flexible implant and sits behind the pupil in front of the lens. You can't see or feel the implant and you don't need to clean it.

		You could also use graphics and images to make the information more visually appealing to the reader.		
Royal College of Surgeons of England	Patient Information: laser vision correction /Patient Information: phakic intraocular lens (PIOL) implantation/ Patient Information: refractive lens exchange	<p><b>Patient Friendly Language</b></p> <p>From writing our patient information we know patients find text engaging if it is easy to read and understand and that throughout the text, everyday language should be used.</p> <p>For example in the <i>Patient Information: phakic intraocular lens (PIOL) implantation</i> document paragraph 2.2. “spectacles” could be changed to “glasses”, “particularly” could be changed to “especially” and “relatively inexpensive” to “quite cheap”.</p> <p>Other advice we have received is that clinical words should be avoided and instead patient friendly terms should be used. For example in same document the term phakic intraocular lens is not a patient friendly term, is there a way to describe this that makes it easy for</p>	Lay feedback we have on readability is generally very positive. Care is required to avoid unintended negative connotations when using words like cheap, and over-simplification can detract from clarity.	Spectacles changed to glasses throughout the patient information documents.

		<p>patients to actually understand what it is?</p> <p>It has also been suggested to us that all patient information should have short easy to read sentences. For example in the <i>Patient Information: laser vision correction</i> document paragraph 4.4 all of the sentences could be split into two sentences.</p> <p>Our experience is also that patients do not like to be referred to as patients.</p>		
Royal College of Surgeons of England	<p>Patient Information: laser vision correction /Patient Information: phakic intraocular lens (PIOL) implantation/ Patient Information: refractive lens exchange</p>	<p><b>Content</b></p> <p>The key messages that we are promoting to our patients are the following</p> <ul style="list-style-type: none"> <li>• The patient should find the right surgeon and hospital to perform the procedure</li> </ul> <p>The surgeon should have the appropriate skills and experience to perform the procedure. They should also find out what surgeon's and hospital's insurance does and doesn't cover them for</p>	We hope to add a checklist for patients to work through before refractive surgery which will include advice in these areas.	

The hospital should be registered with the regulator.

- They should fully research the procedure.
- They should research all available treatment options.
- They should find out about the possible risks of all the treatment options. They should also think about what will happen if there are complications, either immediately after the procedure or later on.
- They should ask about the likely outcome of their procedure and how long results are likely to last.
- Expectations: They should talk to the surgeon about what they would consider to be successful surgery.
- Aftercare: They should find out what is and isn't covered. They should also find out who will pay if something doesn't go to plan?
- Costs: They should ask for a breakdown of all planned and possible costs, including future

		surgery and possible complications.		
Royal College of Surgeons of England	Advertising and Marketing Standards	<p><b>Section titles and purpose of the document</b></p> <p>We think that it would be helpful to make clear what the overall purpose of this document is. For example, we think the RCOphth should make it clear in the introduction the purpose of the document is to lay out the current regulators and regulations and then what the RCOphth would like to happen going forward. This could for example make it clear that the first section is a summary of what the RCOphth's key points are on advertising and marketing standards for refractive surgery. At the moment although it is called "summary" it is not immediately clear if these are recommendations by the RCOphth or a summary of ASA's regulations. We wondered whether improved clarity might be achieved by calling section 4 "next steps and recommendations" again to make it very clear what the section is about.</p>	<p>The purpose of the document is stated by the title which is Advertising and Marketing Standards.</p> <p>The Summary is a list of RCOphth's key points and are quite specific to vision correction (e.g. 1.4).</p> <p>Section 4 outlines the standards in more detail. The only area for which there is no clarity is enforcement and recommendations for enforcement are indicated within this section.</p>	<p>To clarify the following introductory comment has been added:</p> <p>"The purpose of this document is to provide specific advertising and marketing standards for refractive surgery. The document outlines current regulations and regulators, current references and sources which provide the basis for these standards. Section 1 summarizes key recommendations."</p>

Royal College of Surgeons of England	Advertising and Marketing Standards	<p><b>Content</b></p> <p>We believe the key principles of advertising and marketing for cosmetic surgery should be that information is factual, clear and not misleading. Advertising and marketing should be realistic, ethical, honest and responsible. Also people shouldn't be pressured into making a decision by special offers.</p> <p>In section 4 you could add some points from <a href="#">Professional Standards for Cosmetic-Surgery April 2016</a> . For example from <i>Professional Standards for Cosmetic Surgery</i> you could add in something like “Your marketing activities must not target children or young people, through either their content or placement” from page 12. Also you could add in something on “If a medical assessment is needed before an intervention can be carried out, your marketing must make that clear” from page 15.</p>	<p>RLE and Laser vision correction is not provided to Children or Young people below the age of 18 (usually 21).</p> <p>Other standards that relate to the care pathway specifically indicates a medical assessment by the surgeon is required before surgery. It is therefore not necessary to indicate this in advertising material. Patients are not treated on the same day and all need a preoperative evaluation.</p>	

<p>Royal College of Surgeons of England</p>	<p>Standards for Patient Information and Consent for Refractive Surgery</p>	<p><b>Content</b></p> <p>We agree that consent should be obtained by the operating surgeon in a two stage process with there being a cooling-off period to allow the patient to reflect on the decision.</p> <p>You may want to include some points from the consent section from <a href="#">Professional Standards for Cosmetic-Surgery April 2016</a> page 10-11. For example you may want to add in “You must tell the patient they can change their mind at any point “. You could also add in some information from the section “Being clear about fees and charges” to the <i>Standards for Patient Information and Consent for Refractive Surgery</i> document.</p>	<p>We have now combined the Professional Standards outputs into a single document ‘Professional Standards in Refractive Surgery’ in the same format as the CSIC standards April 2016<sup>5</sup> which incorporates this and other relevant points.</p>	<p>Key points from GMC and CSIC advice will be included in the unified standards document ‘Professional Standards in Refractive Surgery’.</p>
<p>Optical Confederation</p>	<p>General Comments</p>	<p>Please view comments in submitted document</p> <p><a href="https://www.rcophth.ac.uk/wp-content/uploads/2016/08/Optical-Refractive-surgery-Confederation-Consultation-Response.pdf">https://www.rcophth.ac.uk/wp-content/uploads/2016/08/Optical-Refractive-surgery-Confederation-Consultation-Response.pdf</a></p>	<p>We have a patient information output in preparation explaining roles of the different professionals within the care team. This will go out to public consultation later in 2016. We are already clear (4.5) that ‘preparatory information may</p>	<p>Subsequent to 16 April 2016 guidance from the GMC and the Royal College of Surgeon’s Cosmetic Surgery Interspecialty Committee, we are preparing a unified standards document building in patient information and consent plus guidance in other</p>

			include written material, video material or advice from suitably trained non-medical staff'.	areas that will go back out to public consultation later in 2016.
Optical Confederation	Standards for Patient Information and Consent	<p>Please view comments in submitted document</p> <p><a href="https://www.rcophth.ac.uk/wp-content/uploads/2016/08/Optical-Confederation-response-refractive-Surgery-Annex-A.pdf">https://www.rcophth.ac.uk/wp-content/uploads/2016/08/Optical-Confederation-response-refractive-Surgery-Annex-A.pdf</a></p> <p><a href="https://www.rcophth.ac.uk/wp-content/uploads/2016/08/OC-response-to-refractive-surgery-annex-Ai.pdf">https://www.rcophth.ac.uk/wp-content/uploads/2016/08/OC-response-to-refractive-surgery-annex-Ai.pdf</a></p> <p><a href="https://www.rcophth.ac.uk/wp-content/uploads/2016/08/OC-response-to-refractive-surgery-annex-B.pdf">https://www.rcophth.ac.uk/wp-content/uploads/2016/08/OC-response-to-refractive-surgery-annex-B.pdf</a></p>	<p>We will again take 2 clear working days to the RSSWG for discussion (4.6). 1 week was agreed as a compromise with other parties calling for 2 weeks in line with CSIC recommendations.</p> <p>Special order IOLs are normally supplied on a sale or return basis. We are hoping that these standards will filter through to lens providers who are not already in line with this practice. Very few lenses are genuinely bespoke: although there may be no bank at the provider for less commonly used implants; a bank would normally be maintained at the company. So there should be no special barrier to supplying lenses on a sale or return basis.</p> <p>The existing wording provides for triage through non-medical staff (6.1). "Although calls may be triaged through non-medical</p>	

			staff; immediate onward communication to the surgeon on-call should be available.”	
Optical Confederation	Advertising and Marketing Standards	<p>Please view comments in submitted document</p> <p><a href="https://www.rcophth.ac.uk/wp-content/uploads/2016/08/OC-response-to-refractive-surgery-annex-Aii.pdf">https://www.rcophth.ac.uk/wp-content/uploads/2016/08/OC-response-to-refractive-surgery-annex-Aii.pdf</a></p>	<p>This is not correct. The GMC in their most recent document “Guidance for Doctors who offer Cosmetic interventions”<sup>3</sup> which also covers refractive surgery RCOphth recommendations are in complete alignment with “Maintaining Trust” Items 46 -56.</p> <p>The CSIC and Keogh report also in recommendation 29 advise The RCS Interspecialty Committee should develop code of ethical practice developed for all practitioners of cosmetic interventions, and this should include standards to ensure that any advertising is conducted in a socially responsible manner. Substitute RCOphth for RCS.</p> <p>Refer to recent GMC guidance items numbered 46 – 56.</p> <p>Also refer to Keogh report<sup>6</sup> Recommendation 31</p>	

			<ul style="list-style-type: none"> <li>• The Review Committee considers that the following advertising practices are socially irresponsible and should be prohibited by the professional registers' codes of practice: <ul style="list-style-type: none"> <li>o Time-limited deals</li> <li>o Financial inducements</li> <li>o Package deals, such as 'buy one get one free' or reduced prices for two people such mother and daughter deals, or refer a friend</li> <li>o Offering cosmetic procedures as competition prizes.</li> </ul> </li> </ul> <p>See also recommendation 30 from the Keogh report: CAP should extend its guidance note on cosmetic surgery advertising to cover non-surgical cosmetic procedures, and the sponsoring of TV and other programmes.</p>	
Optical Express	General Comments	<p>Please view comments in submitted document</p> <p><a href="https://www.rcophth.ac.uk/wp-content/uploads/2016/08/RCO-OE-">https://www.rcophth.ac.uk/wp-content/uploads/2016/08/RCO-OE-</a></p>	<p>Standards for patient information (pp9 and the following)</p> <p>3.1 "Any claims for superior outcomes must be supported by independent audit or peer-</p>	

[Consultation-response-submitted-080616.pdf](#)

reviewed clinical evidence”

Q. What is meant by independent audit

A. Aim = an extension of the National Ophthalmology Database in which PRO data is completed on-line (not in the provider’s office) and submitted for independent analysis.

3.2 See altered text:

4.2 Pre-op consultation - deemed essential to the mutual understanding between patients and surgeons required for consent in cosmetic and lifestyle procedures including refractive surgery (CSIC guidance 16 April 2016 and public comment from Keogh 16 April 2016).

See current wording - allows for work-up and preliminary advice from non-medical staff. But the procedure choice options are determined in a conversation with the operating surgeon which must occur prior to the day of surgery. There was no contradictory statement from

3.2 'together with standardised information on alternative treatment choices not available at that provider.'

Bruce Allan (RSSWG chair) at any stage of the Industry Day. The one-week cooling-off period is a compromise between CSIC guidance (2 weeks – strongly supported by the RCOphth Lay Advisory and Professional Standards Groups) and the minimum suggested (1 working day) which takes into account the array of procedure options available to refractive surgery patients and the quality of life impact of a poor result. This was discussed again at the July 13<sup>th</sup> meeting of the RSSWG. Where surgeons depart from this recommendation, it should be the exception, not the rule, and the reasons for doing so should be recorded clearly in patient records.

4.7 There is no problem with charging a fee for a refractive surgery consultation. This is independent of any decision to proceed with treatment.

Standard procedure information - LVC

4.1 Definition of stability of prescription - see MacKenzie GE 2008 'reproducibility of spherocylindrical prescriptions' added to source references.  $\pm 0.50$  approximates the 95% confidence interval around manifest refraction measurement.

Standard procedure information - RLE

5.3 RLE is identical to modern cataract surgery - this issue was addressed at the industry consultation day. The operations technically are identical, and the inclusion of this statement in standardised patient information is intended to help patients to understand RLE. But the patient groups addressed are different. The primary aim in cataract surgery is to address failing vision. The primary aim in refractive surgery is to reduce dependence on spectacles and contact lenses. GMC guidance is clear that additional checks and balances are required in consent

		<p>for cosmetic and lifestyle procedures including refractive surgery (see above).</p> <p>3.3 Changed to 12 months' free f/u</p> <p>4.1 The current wording on age is not prescriptive and is clearly for general guidance only. 'includes most patients under 50' is not the same as saying all patients under 50. Retinal detachment risk is higher in younger patients (Daien 2015 – source references). We note that OE are arguing in favour of not interfering with the doctor-patient relationship. See appended change in text.</p> <p>6.3 Changed to 'a day or longer'</p> <p>7.2 Permanent serious loss of vision - this is one of the most difficult areas for clear advice. 1 in 500 and 1 in 1000 are widely quoted for serious visual loss after cataract surgery. There is very little published on RLE (a different patient group). Permanent serious visual loss is defined as Corrected Distance</p>	<p>"12 months"</p> <p>'Your surgeon will advise on your best treatment options after reviewing your test measurements and your eye health.'</p> <p>'a day or longer'</p>
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			<p>Visual Acuity &lt; driving standard. EuroQuo cataract data (Lundstrom et al) and Cataract NOD (Day et al) suggests 2% and 5% final CDVA &lt; 0.3 for patients without comorbidity. Not all these patients were refracted accurately however, and lower base acuities are normal in older patients. Unpublished RLE data from OE (email 24/3/16) suggested 1/1000 patients with CDVA &lt; 1/2500 for patients with starting CDVA 0.00 or better. Data from one provider, however large, is vulnerable under-reporting however, since patients with serious problems may often be cared for in the hospital medical system. Also, most patients are not referred by their operating surgeon (Levinson et al JCRS 2008).</p> <p>Standard patient information - PIOLs</p> <p>3.2 Changed to 12 months' free f/u</p> <p>4.2 see above</p>	<p>"12 months"</p>
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			5.3 see above	
Optical Express	Advertising and Marketing Standards	<p>Please view comments in submitted document  <a href="https://www.rcophth.ac.uk/wp-content/uploads/2016/08/RCO-OE-Consultation-response-submitted-080616.pdf">https://www.rcophth.ac.uk/wp-content/uploads/2016/08/RCO-OE-Consultation-response-submitted-080616.pdf</a></p> <p>16. The Summary section provides and overview of the document. Section 3. Provides a very short overview of current advertising regulators and regulations.</p> <p><i>It is unclear why the draft guidelines include standards on advertising and marketing, what expertise the RCO has to comment on this, or its ability to enforce any proposed guidelines. Furthermore it is unclear as to the intended aim of this document.</i></p> <p><i>The statement that “those providers with more resources will obtain better coverage and in turn access to the public” indicates that an aim of this document may be to reduce the advantage that the multiple providers have in terms of advertising spends compared to the independents. This could be</i></p>	<p>The inclusion of Advertising and marketing standards is in alignment with the CSIC and Keogh:</p> <p>(Keogh Recommendation 29) The RCS Interspecialty Committee should develop code of ethical practice developed for all practitioners of cosmetic interventions, and this should include standards to ensure that any advertising is conducted in a socially responsible manner. (Substitute RCS for RCOphth).</p> <p>This comment has been reproduced out of context and in reality states: <i>“Those providers with more resources will obtain better coverage and in turn access to the public <b>and this is the reality of a competitive world”</b>.</i></p> <p>This fully acknowledges the competitive nature of advertising. The statement provides background information and the latter portion omitted in</p>	

*considered anti-competitive. This is distinctly outside the remit of the RCO and the draft guidelines.*

*Optical Express will continue to follow the Advertising and Marketing Guidance of the regulators in the field of Advertising and Marketing, such as the ASA.*

1.1. The Royal College of Ophthalmologists believes the Medical Director of the advertising provider must take responsibility for the final content of advertising and marketing media. Non-compliance with either the ASA code of practice or recommendations in this document may be considered an infringement of “Good Medical Practice”<sup>7,8</sup> and thus reportable to the General Medical Council.

*The intended aim of this recommendation seems to be to bypass the Advertising Standards Association, the regulator responsible for advertising, by reporting a provider’s Medical Director to the GMC. This is clearly unacceptable. Advertising is not the responsibility of the Medical Director*

Optical Express’s response clarifies that **there is no intention of reducing the advantage multiple providers have in terms of spend but to: “ensure advertising is conducted in an ethical and responsible manner.”**

The GMC in their most recent document “Guidance for Doctors who offer Cosmetic interventions” which also covers refractive surgery make clear under Maintaining Trust Items 46-56. Specifically note point 56: **You must not allow your financial or commercial interests in a cosmetic intervention, or an organisation providing cosmetic interventions, to affect your recommendations to patients or your adherence to expected good standards of care.**

Item 54. **You must not knowingly allow others to misrepresent you or offer your services in ways that would conflict with this guidance.** Marketing directors do not have the medical

*and the GMC is not responsible for advertising guidelines. Multiple providers employ the services of a Marketing Director who is responsible for Advertising and Marketing. A Medical Director has clinical responsibilities. This threat to report Medical Directors to the GMC is a form of professional blackmail that*

knowledge to judge whether marketing material is unethical or misleading or in contravention to GMC standards. Doctors working within an organization are therefore put at risk if they provide care to patients who have been marketed to in an unethical or misleading manner. Medical Directors have a **duty of care** to the doctors whom they lead within the organization. It therefore makes perfect sense that they should oversee and ratify all marketing material.

## 4 References

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<https://www.rcseng.ac.uk/publications/docs/professional-standards-for-cosmetic-practice/>
6. 'Review of the Regulation of Cosmetic Surgery Interventions (Department of Health 2013)  
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