Refractive Surgery Guidelines Consultation: Optical Express Response

Optical Express has had concerns about the formation and process of the Royal College of Ophthalmology's (RCO) Refractive Surgery Standards Working Group (RSSWG) from the outset. These concerns have been raised with the Officers and Working Group Chair of the RCO by senior Optical Express executives. Unfortunately, the draft guidance on refractive surgery suggests that RSSWG has not heeded these concerns, and we remain very worried that the guidance, the evidence in support and the current consultation is inadequate. We sincerely hope that RSSWG and the RCO will consider this response in detail and address the flaws we have identified in the draft guidance before finalising any new guidance on refractive surgery,

As background, Optical Express undertakes over six (6) in every ten (10) refractive surgery procedures performed in the UK. Optical Express has a bespoke Electronic Medical Records (EMR) and Patient Reported Outcomes (PRO) system at all clinics. Together with clinical diligence and oversight, the EMR provides a wealth of clinical and patient reported outcomes on hundreds of thousands of procedures. Decisions endorsed by the Medical Advisory Board of Optical Express are supported by analysis of this data. Optical Express has offered access to this data to the RCO Working Party for the development of these guidelines. However, this offer was not taken up by the RCO.

Despite being a NICE accredited organisation, NICE guidelines have not been followed by the RSSWG. The NICE guideline development process recommends issuing a call for evidence to all stakeholders during the development phase. If the RSSWG had done so, we could have provided useful evidence much earlier in the process. Optical Express data has provided the foundation for numerous scientific articles. In fact, the safety and efficacy of refractive surgery performed at Optical Express is well established in peer reviewed ophthalmic publications, as referenced in this document.[1-24] Many of these publications report on clinical as well as patient-reported outcomes in tens of thousands of patients. The size and scope of these Optical Express studies are significantly greater than almost all other reports in the literature. Included are multiple comprehensive analysis of patient satisfaction, risks, complications and side effects of surgery using sophisticated statistical methods, such multivariate regression far beyond, for instance, anything in the current RCO audit of cataract surgery. This has given Optical Express an unprecedented understanding of how to further improve patient care in the delivery of refractive surgery. In addition, there are articles which describe the Optical Express model in detail, such as the methodology to more precisely define patient suitability for surgery, effectively managing patients who have suffered a complication or developed a side effect after surgery, the role of biostatistics in improving patient outcomes and sound clinical governance using an International Medical Advisor Board.

In the spirit of helping the RCO craft meaningful and evidence-based guidance, Optical Express will continue to offer its data and analysis, especially concerning outcomes and patient satisfaction. As is demonstrated by the referenced articles, Optical Express has gone to great lengths to advance and improve the refractive procedures we provide to our patients as well as contributing to the world-

wide body of knowledge on best practices. We consider it a monumental travesty that the RSSWG has not even considered utilizing this readily available resource. Instead, the draft guidance appears to be based on assumptions and innuendo rather than any kind of robust evidence. As such, it is substantially flawed.

The Working Party's membership, terms of reference, scope and unrepresentativeness have all indicated a distinct bias towards the interests of low volume independent providers. The RSSWG comprises of four Refractive Surgeons, three of whom are low volume independent providers who stand to benefit substantially from the new proposals. One Optometrist is part of the RSSWG, though this Optometrist has no practical experience of undertaking pre and post-operative refractive surgery consultations and hence does not interact with refractive surgery patients. The Lay Representative to the RSSWG cannot possibly represent the interests of patients who are either considering refractive surgery or have undergone the procedure. She has not had a refractive procedure and stated at the Industry Day on 11th May that she would never consider having refractive surgery. This does not suggest open mindedness and is another example of a serious flaw in the makeup of the RSSWG.

The composition of the RSSWG is not reflective of modern day refractive surgery practice in the UK (where the majority of procedures are performed by multiple-clinic groups, such as Optical Express) either in terms of its clinical and professional members or its lay members. This is noticeably at odds with the Refractive Surgery Standards Working Group which published standards in 2011. That group comprised of twenty two (22) individuals and had a more balanced mix of speciality and representation in comparison to the 2015 group. More recently, the Royal College published guidance entitled Commissioning Guide: Cataract Surgery in February 2015. This guidance was supported by the Clinical Council for Eye Health Commissioning and followed NICE processes. The Guidance Development Group who drafted this comprised of seventeen (17) individuals of a range of specialities. The failure of the current RSSWG to ensure even a basic reflection of modern refractive surgery practice is clearly not in the best interests of patients and has given rise to a situation where the RSSWG has had the limited 'benefit' of a dangerously unrepresentative group of voices.

The publication of these draft refractive surgery guidelines validate OE's concerns regarding the composition of the RSSWG as they clearly favour a particular model of practice, without any clear justification. The lack of balance and clear objectivity on the Working Group is reflected in these documents. It is also clear that insufficient reference has been made to clinical studies and evidence regarding outcomes and best practice. This has resulted in draft guidelines that are not in the best interests of patients, being overly restrictive and forcing patients to seek unnecessarily costly treatment which many cannot afford, with no increase in patient safety or outcomes.

The draft guidelines indicate a perspective that is unduly skewed towards the interests of the low-volume independent ophthalmologists who made up the majority of the Working Group's membership. The guidelines disproportionately focus on the involvement of ophthalmologists, reducing the role of optometrists, and unjustifiably support the model used by low-volume providers to the detriment of the multiple providers. No clinical studies, peer reviewed research or statistical

evidence is given to justify the elements of the draft guidance which are more restrictive than the guidance currently in force, and nowhere does the guidance reflect that optometrists themselves have substantial responsibilities due to being regulated by the General Optical Council. The paternalistic focus on ophthalmologists is unnecessary and will do nothing for patient access or patient safety.

In short, the process of arriving at draft guidelines should have been evidence based - it was not. It should have been compliant with NICE Guidelines so far as possible - the RCO have accepted that it was not. It should have been conducted objectively and it with an open-mind by a representative working party - it was not.

Response in Summary

Following the criteria specified by the College in its call for contributions to the consultation on the draft Refractive Surgery Guidelines, this response focuses on the following aspects of the recommendations published so far. Specific comments in relation to elements of the guidance are provided further on in this letter.

The comprehensiveness and applicability of the documents:

The draft guidelines are not comprehensive, nor applicable to the whole refractive surgery sector. The current drafts show little understanding of the manner in which refractive surgery is provided in the community and focus too narrowly on one model, most commonly provided by independent, low-volume providers. The draft guidelines are not applicable for the majority of procedures undertaken in the UK today as almost all are undertaken in the multiple setting by different providers. In addition, some sections of the guidelines are overly prescriptive, would disrupt the provider-patient relationship and unnecessarily restrict the provision of best care for patients.

The content and clarity of the documents and their suitability for different environment:

The content is in many places misleading and it is often not clear as to the purpose or intended aim of many of the recommendations. 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. Moreover, the guidance goes above and beyond corresponding guidance issued by the General medical Council and Advertising Standards Authority. There is a lack of clarity throughout, with sections being poorly worded and edited, resulting in guidelines likely to increase confusion among patients, providers and the public.

Whether the advice looks straightforward and is usable by service providers and service users:

The advice is not straightforward and in some instances would require providers to significantly alter their service models, without providing any evidence or justification as to why the recommendations are necessary or how they would benefit patients. The advice also creates conflict between procedures performed in the refractive surgery sector and identical procedures performed on an NHS basis. There is a significant lack of understanding as to when some aspects of the guidance would therefore apply. This will create confusion and risk for providers, surgeons, other healthcare professionals, and notably patients.

The interpretation of the evidence available to support its recommendations:

The draft guidelines are supported by very little evidence throughout. It is clear that there has been no thorough review of clinical studies and peer-reviewed research, and many of the recommendations are plainly based on misconceived assumptions and misguided preconceptions or anecdotes, rather than relevant data. The necessity of the more draconian recommendations in the draft guidance (such as in relation to advertising and the requirement that the surgeon be involved in taking consent from a patient at all stages) is still wholly unclear, and appears to be based on prejudice rather than any firm evidence. In a number of instances recommendations are completely arbitrary.

The likely impact on patient groups affected by the standards:

Patient groups will be adversely affected by these draft guidelines, with their access to care significantly reduced. The Chair of the RSSWG stated at the Industry Day on 11th May 2016 that in the UK refractive surgery has a four percent (4%) penetration rate and, of those patients who proceed with refractive surgery, ninety five percent (95%) are satisfied with their outcome. Any guidance must strike a balance of attempting to improve patient satisfaction rates whilst not reducing access to care. Anecdote, isolated cases or sensational media coverage should not cloud the perspective of the RSSWG against the views of the tens of thousands of patients who elect to undergo community refractive surgery in the UK each year and who report very high satisfaction rates.

No other provider has performed such extensive research using very large datasets into the low percentage of patients that are dis-satisfied with their refractive procedure as Optical Express. This is evidenced in the sample sizes of the peer review publications referenced[1-24]. To this end we at Optical Express have an unrivalled understanding of the reasons why a small number of patients may be dissatisfied after surgery. It is therefore disappointing and naive of the Working Party to have declined the offer of data input from the provider of the majority of surgical procedures in the UK, and another indicator of the RSSWG's apparently closed-mind. Utilising the resources and information available through Optical Express would have helped the RSSWG and been in the best interests of UK refractive surgery patients.

The likely impact / ability of service providers to implement the recommendations:

It will be very difficult for the multiple providers to implement the recommendations as they currently stand. Key recommendations of the RSSWG are not supported by evidence and some run contrary to the scientific analysis of tens of thousands of patient outcomes. In deciding what is in the best interests of the patient, the clinicians of the multiple providers will be placed in the invidious position of regarding the RCO guidance as going beyond their requirements as GMC registrants and which fails to do anything to improve patient safety or access. It would greatly undermine the role of the Royal College of Ophthalmologists' in Refractive Surgery should these providers and their clinicians feel professionally bound to follow an alternative approach.

Do the standards achieve their intended aim(s)?

Although the RSSWG sought to develop, promote and uphold improved standards for the benefit of patients, the draft guidance clearly fails to do this. The standards have not been drafted in the best interests of patients and do nothing to improve public confidence in refractive surgery. There is no basis to think that the current guidelines will increase access to care for those patients that are potential candidates for refractive surgery. They appear based on a pre-conception which is itself unsupported by any evidence and there is a notable lack of reference within the standards to evidence supporting them or to the needs and wishes of patients. This has resulted in guidelines that will not benefit patient choice or safety. For the reasons set out in this response, the draft guidance does nothing to improve patient safety while, perversely, limiting access to care.

To justify the draft guidance there should be a comparative analysis of the efficacy of different treatment models in terms of outcomes, standard of care and patient satisfaction. Instead the RSSWG appears to have assumed in advance that a particular model of care must be used in all circumstances without any empirical basis to establish whether it is more or less satisfactory than any other, or whether there is scope for multiple models of care.

It is evident that the needs and wishes of prospective and past patients have not been properly investigated or understood. To our knowledge, the Patient Engagement Day held on 18th May 2016 did not have a representative balance of attendees. Proper perspective would be achieved if the mix of patients that had experienced a satisfactory outcome (95%) was contrasted to those that were dissatisfied (5%). Furthermore, the lay representative on the working party cannot possibly represent patients who would either seek refractive surgery or had undergone the procedure, as she has not undergone refractive surgery and has publically stated that she would never consider it.

The guidelines (and the process which led to them) also undermine the roles, experience and skills of registered optometrists (and potentially ophthalmic nurses) in the patient information and consent process. In doing so, access to care will be reduced, and public confidence in these eye care professionals will be undermined. The primary gate-keeper of eye care services in the UK is the optometrist. Effectively utilizing optometrists to the fullest extent of their skills and training will improve the productivity of the ophthalmic surgeon, ensure better access and enhance patient care.

Instead, the guidance appears to work on the assumption that optometrists have nothing to offer as part of a team providing care beyond being acting at all times under the explicit direction of the surgeon. That is wrong-headed and, unsurprisingly given the make-up of the RSSWG, fails to reflect the reality of the vast majority of refractive surgery. Again, we note that there is no evidence in the draft guidance or any of the statements or documents associated with it explaining why this should be.

A significant conflict will be created by undermining the role of the Optometrist. These eye care professionals are able to provide important elements of care, including the informed consent, for the NHS that would be denied in the private refractive surgery sector. What is the justification for creating such a conflict?

A significant conflict will also be created among patients that have a cataract. The guidance refers to Refractive Lens Exchange, but not Cataract procedures. It is therefore taken that the RCO and Clinical Council Commissioning Guide for Cataract Surgery published in February 2015 will apply to Cataract procedures. However, there is no clinical difference between the two types of surgery. The RCO has provided no explanation reflecting on or justifying the distinction.

Effect on Clinicians

The RCO's guidelines should support surgeons in making appropriate clinical decisions. The guidelines should not dictate a model which may be suitable in some settings but inappropriate in others. The current drafts would significantly restrict the surgeon's ability to make independent clinical decisions. The guidelines are very prescriptive and disrupt the doctor-patient relationship to the extent that it will interfere with best patient care. Surgeons are entrusted to make decisions in the best interests of their patients; this includes the ability to delegate care such as elements of the consent process to members of their team under supervision. We all agree that the ultimate decision regarding a patient's suitability for surgery is the treating surgeon, who must also ensure that the patient provides their informed consent to proceed, but this does not mean that there is any benefit from excluding other qualified healthcare professionals from being part of the overall process.

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 would significantly restrict the duties that optometrists could carry out, undermining the profession and having an adverse effect on the wider refractive surgery team and patient care. The effect of this misplaced guidance would be to reduce access to care for patients and adversely affect the affordability of care. Requiring the treating surgeon to carry out aspects of the pre and post-operative care currently undertaken by optometrists would restrict patients' access to care and needlessly increase surgeon workload.

The refractive surgery team, specifically the surgeon and optometrist, need to work closely together to provide safe, high-quality care to patients. However, the draft guidelines devalue and diminish the

role of the optometrist in refractive surgery. Effectively mandating that most, if not all aspects of the consent process may only be carried out by the treating surgeon is a prime example of how these guidelines unnecessarily devalue the role of the optometrist. There is no evidence suggesting that this is necessary, beyond the apparent presumption unsupported by any clear evidence that optometrists have no role other than under the direct control of the surgeon. In current practice, trained General Optical Council registered optometrists do perform important elements of the consent process under the supervision of the treating surgeon. The evidence we have provided of large volumes of safe, clinically appropriate surgery with high satisfaction rates directly contradicts this, yet to date the RSSWG has refused to take it into account. The RSSWG guidelines should provide guidance to surgeons compatible with the General Medical Council's own guidance on how to properly delegate while maintaining overall responsibility for ensuring the patient provides their informed consent to proceed with surgery.

It was discussed and accepted at the industry engagement day on 11th May that trained optometrists can determine patients' suitability for refractive surgery and make a preliminary treatment recommendation. The RSSWG guidelines should reflect this important role that optometrists currently provide in the great majority of procedures carried out in the UK, and should leave the question of the amount of time patients need for reflection to the surgeon's own judgement, taking into account the invasiveness, complexity, permanence and risks of the intervention, how many intervention options the patient is considering and how much information they have already considered about a proposed intervention.

The conflicts between the RCO draft Refractive Surgery guidelines and the RCO and Clinical Council Commissioning Guide for Cataract Surgery (published in February 2015) will be confusing to clinicians and patients. If a patient with a cataract seeks surgical options in the private sector does their care fall under the cataract or the refractive surgery guidance? Many cataract patients today wish to have the unaided distant and near vision that Multifocal Intraocular lenses can provide. Would the choice of one of these premium intraocular lenses dictate which guidelines apply, and why would that matter? What even defines a cataract? If the patient has a best corrected visual acuity (BCVA) of 6/10 due to nuclear changes which of the two conflicting guidance would apply? What if the patient has a cataract with reduced BCVA of 6/7.5, or if the patient has increased light scatter due to their crystalline lens and a BCVA of 6/6? The draft refractive surgery guidelines do not address these important issues and will undoubtedly result in considerable confusion, consternation and risks for everyone. In addition, the disparity in guidelines between the care provided at the NHS and private practice cannot possibly help patient perception of refractive surgery. The College's position on this issue is inconsistent and muddled.

Effect on Patients

Access to care for patients would be significantly reduced by these draft guidelines. Currently tens of thousands of patients receive refractive surgery each year in the UK, with over 95% reporting good outcomes and high levels of patient satisfaction. This level of patient satisfaction is considerably higher than procedures performed to improve appearance (i.e. cosmetic). Unnecessary restrictions proposed by these guidelines, and the promotion of an independent surgeon-focussed model ahead of other models, will significantly increase the cost of providing the procedure. These costs would be passed onto patients, and 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 RCO's purpose to champion safe surgery and improve the lives of patients.

The extra costs that would result from these guidelines would be to the distinct detriment of the patients who would be needlessly denied life-changing surgery. The guidelines do not provide any evidence-based justification to suggest that their recommendations would improve safety, procedure outcomes or patient satisfaction. Denying patients safe, high-quality treatment cannot be in their best interest, yet is precisely what the effect of these proposals will be. We strongly recommend that the RCO reconsiders its proposals and give greater attention to the importance of maintaining and improving patients' access to care.

Optical Express has clinical and patient reported outcomes on tens of thousands of consecutive laser eye surgery and refractive lens exchange patients. One such outcome is the patient's postoperative perception as to whether they were properly consented for surgery. There was no statistical difference in responses between those patients who met with their treating Surgeon prior to the day of their surgical procedure and those patients who met with their Surgeon for the first time on the day of their procedure. Where is the evidence that the RCO draft guidance, which requires the surgeon to consent the patient ahead of the day of surgery, improves the consent process?

In a recent announcement regarding the introduction of new GMC guidance for cosmetic procedures, Sir Bruce Keogh described laser eye surgery procedures as 'lifestyle procedures'. This reflects the difference that surgery can make to people's lives, and the benefit it brings to the lives of so many patients. The public scandals associated with cosmetic surgery which precipitated Sir Bruce's review of cosmetic surgery have not been experienced in the refractive surgery sector. As noted at the recent Industry Day, the vast majority of refractive surgery procedures are performed without complication and patient satisfaction is over 95%. It would be inequitable and discriminatory to prevent future patients from benefitting from these lifestyle procedures, as so many patients have already benefitted, without valid, evidence-based justification of the need to do so.

The idea promulgated that the Keogh report into cosmetic surgery and the GMC guidance obliges the RCO to take these stances is bogus – they do not. The GMC is clear that the principles of its guidance

on cosmetic surgery should apply to refractive surgery and we support this. This does not however give the RCO licence to invent its own narrative beyond this.

Response to Individual Recommendations

Standards for Patient Information and Consent for Refractive Surgery

1. Section 3.1 – "Provider-specific promotional and advertising materials are part of the consent process, and should not conflict with patient information. Any claims for superior outcomes must be supported by independent audit or peer-reviewed clinical evidence."

It is not clear what 'independent audit' means in this context and it is impossible to ascertain what the likely impact on service providers would be without further clarity. Provider-specific promotional and advertising processes currently include independent review. Materials follow codes set out by the Advertising Standards Authority and so the intended aim of this recommendation is unclear.

2. Section 3.2 – "Provider-specific information should include details of fees charged, possible additional costs, continuity of care, the extent of any aftercare provided, and information on relevant alternative treatment choices not available at that provider".

It is not clear what would be defined as 'relevant alternative treatment choices not available at that provider'. Where would a provider be expected to draw the line in terms of what alternative treatments are 'relevant', how would this help the patient, and what is the intended aim of this recommendation?

3. Section 4.2 – "Responsibility for the consent process must not be delegated: the surgeon performing the procedure must 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 must be with the operating surgeon, and must 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 advice or care from."

This recommendation is not clear in its intention or phrasing. There is no evidence to support the recommendation, it may result in patients receiving a lower quality of care and would be impractical for providers to implement. Optical Express has compelling evidence that contradicts this recommendation.

- *It is unclear what is intended by 'responsibility for the consent process must not be delegated'. It is already the case that the operating surgeon has ultimate responsibility for the consent process and must personally ensure the patient provides their informed consent to proceed.*
- *What is the intended aim of the recommendation that 'the consultation at which the procedure recommendation is made must be with the operating surgeon'? What evidence demonstrates that it is necessary to improve safety for the operating surgeon to perform this consultation than another eye care professional? Is there any evidence that either a decision on suitability or the procedure recommendation could not be made by another surgeon or a suitably trained and registered Optometrist? What is the motivation behind this recommendation?*
- *What is the intended aim of the recommendation that this consultation 'must not occur on the day of surgery'? Why is the day of surgery not the most appropriate time for this consultation? Why does the guidance introduce such a requirement when the General Medical Council's guidance on cosmetic interventions (which was introduced to deal with a genuine and pressing public health issue) leaves this within the surgeon's own discretion? What if the patient's health or suitability has altered between the day of consultation and the day of surgery? What evidence is there to support this recommendation or suggest its necessity?*

This recommendation is not in the best interests of patients and would disproportionately affect multiple providers and the optometrists they employ. As there is no evidence to support this recommendation, its intended aim is not clear. It appears to be based on an unsubstantiated assumption, propagated by independent surgeons, that the operating surgeon is necessarily the most appropriate person to provide other aspects of patient care. Patients would suffer from reduced access to care and the loss of the range of skills provided by a truly multi-disciplinary team.

At the Industry Day it was discussed and confirmed by the Chair of the Working Party (Bruce Allan) as well as other members that an Optometrist can determine a patient's suitability for the different refractive surgery procedures, and in turn can make a preliminary recommendation to the patient. The recommendation would need to be confirmed by the treating Surgeon prior to surgery. The refractive surgery guidance needs to be amended to reflect this important role of the Optometrist.

The standard Optical Express ocular health and visual symptoms questionnaire, provided to all patients after surgery, contains an evaluation of the patients' perception of the quality of their consent. The result of an analysis of consecutive procedures showed that the quality of consent was not different whether they first met with their treating Surgeon prior to or on the Day of Surgery. At Optical Express ***all*** *patients are given the opportunity to consult with their treating Surgeon prior to the Day of Surgery. This consultation is provided without cost to the patient regardless as to whether it is in advance of, or on the Day of Surgery. The vast majority have historically elected to meet with their treating Surgeon on the day of the procedure, despite the option to meet with them prior being available. This was irrespective of whether the patient had a laser eye surgery or a Refractive Lens Exchange procedure. The sample size for the analysis was 3,240/315 patients for laser eye surgery (first met surgeon on day of surgery/met surgeon ahead of the day of surgery) and 768/179 patients for refractive lens exchange.*

4. Sections 4.5 to 4.7 discuss the consent process in more detail.

    a. Section 4.5 states "Consent for refractive surgical interventions should include a 2-stage process in which consent forms are taken away from the consultation at which the procedure recommendation is made by the operating surgeon, and patients are given an open line of communication with their surgeon (email, telephone, or optional repeat consultation) for follow up questions during a cooling off period."

As noted above, the optometrist's role in determining a patient's suitability and making a preliminary treatment recommendation was discussed and confirmed by the Chair of the Working Party (Bruce Allan) as well as other members at the Industry Day on 18th May 2016. This recommendation needs to be amended to reflect this.

    b. Section 4.6 states that "Surgery must not take place on the day on which the procedure recommendation is made. A minimum cooling off period of 1 week is recommended between the procedure recommendation and surgery."

As noted above, the recommendation that 'surgery must not take place on the day on which the procedure recommendation is made' is not justified on the grounds of safety, outcomes or patient interest, nor is it supported by any clinical evidence. Further, it goes beyond the General Medical Council's requirements. We ask the RSSWG to provide evidence as to the necessity of this recommendation. It is also not clear why the cooling off period of 1 week has been recommended. Is there any evidence to suggest 1 week as the most appropriate period of time? Has this time period been chosen completely arbitrarily? There needs to be evidence provided to back up the necessity for this recommendation and why this schedule has been chosen.

    c. Section 4.7 states that "There should be no pressure to proceed. Specifically, patients should not be asked for a deposit for surgery, offered time limited discounts, or a refund of the initial consultation fee. Rates of conversion to surgery should not be used as a performance measure for surgeons, optometrists or other staff."

This statement is clumsily worded and contradictory in the message it portrays. It reads that it is not acceptable to take a deposit for surgery for a patient (which may be fully refundable to the patient), but that it is acceptable to charge the patient professional consultation fees that are not refundable to the patient. There are a multitude of eye care professionals involved in a patient's treatment to include the treating Ophthalmic Surgeon, Anaesthesiologists, Registered Nurses and surgical support staff. The funding of their time has to be covered. Furthermore for many patients, a bespoke refractive solution, such as a toric Intraocular Lens, has to be ordered specifically to meet the patient's clinical

requirements. Taking a deposit signifies commitment on the part of the patient to proceed with surgery should they provide Informed Consent. It is common place in many facets of medical procedure and in other industries for a deposit to be provided by a patient or customer particularly where, as is the case with refractive surgery, there are costs incurred by the provider which are irrecoverable.

Patient Information: laser vision correction

5. Section 4.1 – Who is suitable for laser vision correction? "You must be over 18 years of age and have a stable spectacle prescription. This is normally defined as no change greater than 0.5 units (0.5D) in the last two years."

This definition of stability of prescription has no basis in clinical practice, peer review literature, large clinical studies or our data and experience. Where has such a restrictive guideline originated? No reference is provided.

One aspect of consent is informing the patient of the range of outcomes and the need for a subsequent further (enhancement) procedure. The draft guideline on stability will not prevent, nor likely reduce, the possibility of further procedures but it will needlessly reduce the number of patients who could undergo refractive surgery. Why would we deny a patient who has had a 0.50 dioptre change in their prescription over the last year, which meets the widely accepted stability guidelines, the opportunity to have a life changing refractive surgery procedure? Such a prescriptive guideline is not in the best interests of patients or clinicians.

Based on our experience, we recommend that a prescription should be considered unstable if any of the following conditions apply:

1. *any refractive condition or refractive change that appears to be associated with pathologic conditions, such as keratoconus, abnormal/borderline Pentacam or nuclear sclerosis;*
2. *greater than 1.00 D difference Manifest and Cycloplegic sphere;*
3. *documented increase in myopia > 1.00D per year annualised;*
4. *documented increase in cylinder > 1.00D per year annualised; and/or*
5. *myopic patients under the age of 30 with no refractive history.*

6. Section 5.3 – "RLE is identical to modern cataract surgery, but performed with the main aim of increasing freedom from spectacles. RLE is often preferred to laser vision correction for patients in the retirement age group in which the early stages of cataract are common. In RLE, the natural lens is replaced with a lens implant. A variety of different implants are used including multifocal lenses designed to reduce reliance on spectacles for near, intermediate and distance vision."

"RLE is identical to modern cataract surgery" - the significance of this has not been sufficiently recognised by the draft guidelines. Many patients with a cataract will have a multifocal lens implanted as part of their procedure. Furthermore this does not mitigate the medico-legal risks that surgeons would face if one procedure is covered by two sets of conflicting guidelines.

We agree that whether a patient underwent an RLE or a cataract procedure, they should all be properly consented. The complications of RLE and cataract are identical and the expected visual outcomes, assuming no co-morbidity and an identical type of IOL, are similar. The difference between the two procedures rests entirely on potentially different set of expectations. However, similar to Laser Eye Surgery, Phakic IOL surgery and Refractive Lens Exchange, a cataract procedure is elective. In only rare cases would cataract surgery represent a medical necessity for the health of the eye. Most cataract procedures performed in the UK should be considered as a 'lifestyle procedure', meaning that the intention is to improve the style, type and/or quality of life of the patient. The implantation of an intraocular lens of a very specific power during a cataract procedure is intended to reduce the need for spectacles and improve the uncorrected vision, thereby enhancing the lifestyle of the patient. This is identical to the intention of refractive lens exchange.

The draft guidelines pose some critical questions that need to be addressed: What guideline should be followed in the case of a cataract procedure – the RCO Cataract Guideline of 2015 or the proposed Refractive Surgery guidelines?

- *What guideline should be followed in the case of a patient who seeks refractive surgery, but in the course of examinations is found to have early signs of a cataract?*
- *What part does the determined best corrected visual acuity or type of cataract play in what guidance is followed?*
- *What difference would it make to what guideline is followed if a multifocal IOL is implanted to provide improved distant and near vision?*

The draft recommendation notes that RLE is often preferred to laser vision correction for patients in the retirement age group in which the early stages of cataract are common. How should a patient in the early stages of a cataract not to be considered as a cataract patient? Regardless of the patient's expectation, they will undergo an identical procedure as NHS patients but under a completely different standard of care. How could this be morally justified? It is clear that having two sets of guidelines for identical procedures presents an ethical, legal and public perception problem for the RCO, its members

and the NHS. For instance, the NHS could be open to accusations that it was not following the RCO's procedural guidelines if a cataract patient treated on the basis of the 2015 Guidelines experienced a complication.

All patients in these procedures have an expectation of an improvement in vision as a result of surgery which includes a refractive element. There must be a single set of guidelines for what are identical procedures.

Patient Information: refractive lens exchange

7. Section 1.2 - this section commences by stating that "RLE is identical to modern cataract surgery".

We agree with this statement for the reasons outlined earlier in this consultation response.

8. Section 3.3 –"Follow up clinic visits and treatment for any problems resulting from surgery are usually included in the procedure cost for up to six months after surgery. Laser adjustments to focus are often required to obtain the best result from RLE. These are also normally included in the procedure fee."

This states that follow up clinic visits and treatment for any problems resulting from surgery are usually included in this cost for up to six months after surgery. We suggest this is a too narrow period of time. It is not clear why six months has been chosen as the 'usual' period of time. We suggest that the RCO should recommend 12 months as our evidence indicates that this is an appropriate period of time for further treatment to be included in costs.

9. Section 4.1 – "If you are over 50 years of age with a spectacle prescription higher than the normal range for laser eye surgery, you are likely to be suitable for RLE."

This statement lacks clarity and could be misinterpreted. It could be read to imply that being over 50 and having a high spectacle prescription are preconditions for suitability for RLE. A patient reading this may understand that RLE surgery should only be undertaken by patients over the age of 50 years, and only if the patient has a spectacle prescription higher than the normal range for laser eye surgery. In fact RLE may be suitable for many other patients, while those over 50 and with a high prescription can

be more suitable for RLE than other refractive procedures. We recommend taking a less prescriptive approach, one that does not interfere with the doctor-patient relationship, and delete this section.

10. There is further guidance on this at Section 5.2 – "Laser eye surgery or PIOL implantation are generally better options than RLE for younger patients who still have a clear, flexible natural lens. This includes most patients under 50 years old. Laser vision correction is a relatively low risk option for many patients over 50 years of age with a lower prescription; but the balance shifts as you get older and both flexibility and clarity of the natural lens diminish. RLE is the default option for vision correction surgery in the (65+) retirement age group, but laser vision correction may still be a better alternative for patients with no signs of cataract and good eye surface health."

This section is too prescriptive, can interfere with best clinical judgment and should be deleted. It makes no reference to any evidence or clinical studies and uses sweeping generalisations such as 'generally better' and 'default option' without any reasoned support. This is not helpful for patients. While certain procedures may be more suitable for different groups of patients, every patient must be treated as an individual and should receive a procedure recommendation based on their personal needs. Much more emphasis should be placed the eye care team's assessment and recommendation rather than generalities. Are these guidelines stating that a hyperopic presbyope patient of age 45 that wishes spectacle independence for distance and near should never be considered for an RLE procedure? What if the patient is 49 years old?

11. Section 6.3.-"Some centres offer surgery for both eyes on the same day. More commonly, second eye surgery is delayed for a week or longer to ensure that the recovery in the first eye is progressing well. The focus outcome in the first eye can also be used to help guide lens selection for the second eye. The surgery typically takes about 20 minutes per eye. You can return home on the same day as surgery".

The use of 'more commonly' here is misleading for patients. A patient may reasonably expect that this is the preferred method of providers. There is no proof that more RLE procedures in the UK are performed on this basis rather than on the same or consecutive days. In fact, Optical Express perform more refractive surgical procedures than any other private provider. The vast majority of our IOL procedures are performed on a consecutive day basis. As such, your statement is factually incorrect. The same response applies to section 6.3 of the document entitled Patient Information: phakic intraocular lens (PIOL) implantation

12. Section 7.2 – "Permanent, serious loss of vision is significantly more common after RLE than after laser vision correction or PIOL implantation, affecting approximately one in 500 patients. In the worst scenario, complete loss of vision may occur in the affected eye."

How is 'serious loss of vision defined' and what literature is used to support the contention that this occurs in one in 500 refractive lens exchange patients? More patient-centric information is needed to quantify and qualify the term 'loss of vision'. It is misleading to include the worst case scenario in such close proximity to the statistic regarding serious loss of vision. A patient reading this may erroneously infer that complete loss of vision affects one in 500 patients.

Patient Information: phakic intraocular lens (PIOL) implantation

13. Section 3.2 – "Your clinic should be clear from the outset about the total cost of the procedure. Follow up clinic visits and treatment for any problems resulting from surgery are usually included in this cost for up to six months after surgery. Vision stabilizes quickly after PIOL implantation, but problems resulting from PIOL implantation, cataract in particular, may occur many years later."

This states that follow up clinic visits and treatment for any problems resulting from surgery are usually included in this cost for up to six months after surgery. We suggest this is a too narrow period of time. It is not clear why six months has been chosen as the 'usual' period of time. We recommend that it should be 12 months as our evidence indicates that this is an appropriate period of time for further treatment to be included in costs.

14. Section 4.2 – "You need to be over 18 years of age and have a stable spectacle prescription. This is normally defined as no change greater than 0.5 units (0.5D) in the last two years."

This definition of stability of prescription has no basis in clinical practice, peer review literature, large clinical studies or our data and experience. Where possibly has such a guideline originated? The term 'normally defined' is entirely fictitious as there is no way this definition should be considered 'normal'. Based on our experience, we recommend that a prescription should be considered unstable if any of the following conditions apply:

1. *any refractive condition or refractive change that appears to be associated with pathologic conditions, such as keratoconus, abnormal/borderline Pentacam or nuclear sclerosis;*
2. *greater than 1.00 D difference Manifest and Cycloplegic sphere;*

3. *documented increase in myopia > 1.00D per year annualised;*
4. *documented increase in cylinder > 1.00D per year annualised; and/or*
5. *myopic patients under the age of 30 with no refractive history.*

15. Section 5.3 – "Older patients with a high spectacle prescription are more at risk of getting a cataract after PIOL implantation, and they have already lost most of the flexibility of focus provided by the natural lens. So after 50 years of age, RLE is the usually the best option if you are unsuitable for laser vision correction."

The wording of this section lacks clarity. References to 'usually' and 'best option' are unhelpful for patients. Again, the reference to '50 years of age' may suggest that RLE is only suitable for patients over this age, this may be considered confusing for patients.

Advertising and Marketing Standards for Refractive Surgery

16. The Summary section (1.1 – 1.8) provides an overview of the document. Section 3 provides a very short overview of current advertising Regulators and Regulations.

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.

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 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.

17. Section 4.11 – "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"[7, 8] 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 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 is entirely inappropriate.

Overall, we believe that the draft guidance and consultation in general are seriously lacking, both in terms of logic and in the evidence in support. It is not clear why the RSSWG has drafted the guidance in the terms it has, beyond having a vague sense that 'something must be done'. As we have made clear in this response and the enclosures, there is no sound basis for the RCO proposals and they suffer from a substantial number of serious errors. We very much hope that the RCO will address the problems we have outlined in such a way that maintains patient safety while ensuring effective access to affordable care, and we would be happy to discuss our comments further before the guidance is finalised.

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