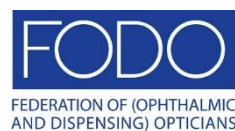
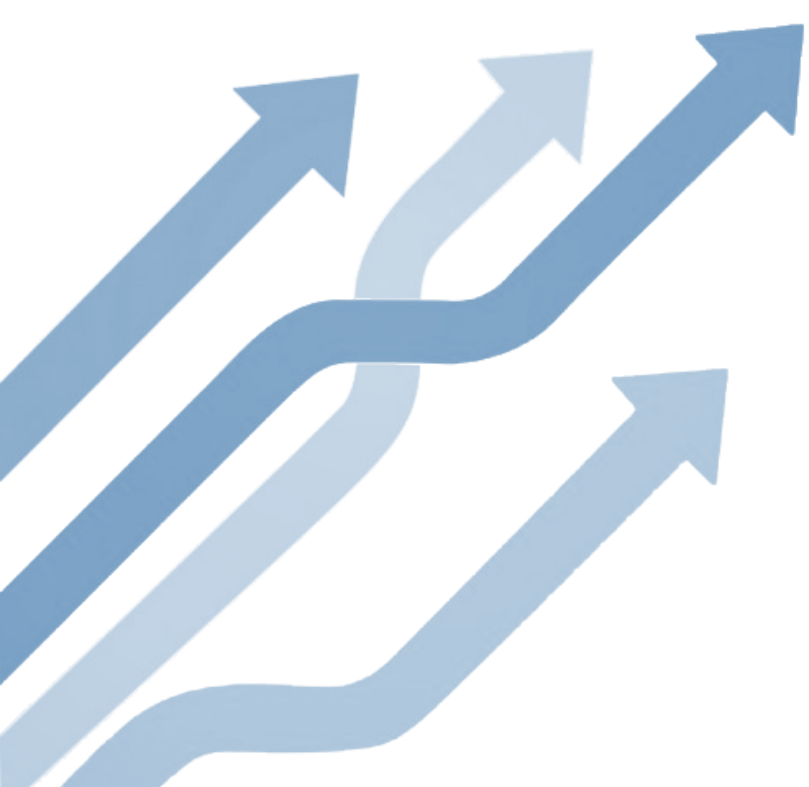


# MULTI-DISCIPLINARY PROFESSIONAL STANDARDS FOR REFRACTIVE SURGERY PROVIDERS AND CLINICAL TEAMS

June 2017



**The Association  
of Contact Lens  
Manufacturers**



**Association of British  
Dispensing Opticians**



**FMO**

# Multi-disciplinary Professional Standards for Refractive Surgery Providers and Clinical Teams

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# 1 Introduction

- 1.1 These standards have been developed by and for refractive surgery providers, ophthalmic surgeons, optometrists, dispensing opticians and other healthcare professionals engaged in the examination, care of and the delivery of surgical procedures to refractive surgery patients and for the information of refractive surgery patients and prospective patients.
- 1.2 Refractive surgery is defined as a surgical procedure where there is an intended visual gain through the correction of a refractive error and/or dysfunctional lens syndrome. This includes laser eye surgery (LASIK, LASEK, PRK, AK and SMILE), refractive lens exchange, phakic intra-ocular lens procedures, corneal lens inlays, radial keratotomy and similar refractive improvement surgical procedures. The intended refractive gain is a reduced dependence on optical appliances. It is noted that, surgically, refractive lens exchange is all but identical to modern day cataract surgery.
- 1.3 Within these standards the term:

‘**Clinician**’ refers to any eyecare professional involved in the care of refractive surgery patients – pre-, during and post-surgery - including ophthalmic surgeons, optometrists, orthoptists, contact lens opticians, dispensing opticians, ophthalmic nurses, anaesthetists and clinical scientists

‘**Provider**’ refers to any legal person, public body, business, limited or other partnership or sole trader engaged in the provision of refractive surgical or related clinical services to the public

‘**Clinical team**’ refers to a team of health professionals from different disciplines (e.g. ophthalmology, anaesthetics, optometry, optics, nursing, clinical science) working together to address a refractive condition for a particular patient

## General Medical Council Guidance

- 1.4 Refractive surgery is primarily a functional procedure not a cosmetic one, as defined by the General Medical Council (GMC).
- 1.5 The GMC uses a broad definition of cosmetic intervention:  
*“By cosmetic interventions we mean any intervention, procedure or treatment carried out with the primary objective of changing an aspect of a patient’s physical appearance. This includes surgical and non-surgical procedures, both invasive and non-invasive.”*

- 1.6 Whilst refractive surgery does not fall within this definition, the GMC's view is that refractive surgery shares many similarities with cosmetic surgery and should therefore be covered within the scope of its 2016 [Guidance for Doctors who offer cosmetic interventions](#)<sup>1</sup>.
- 1.7 The GMC also states it believes "this guidance offers a framework that other professions would find useful". We agree and have taken up this suggestion.
- 1.8 Where appropriate, therefore, these latest multi-professional standards reference the GMC's *Guidance for Doctors who offer cosmetic interventions* which in turn references other GMC guidance for doctors, in particular [Good Medical Practice \(latest update - April 2014\)](#)<sup>2</sup>. Like all guidance, these should apply when relevant but are not absolute and do not override other professional duties.
- 1.9 In particular each healthcare professional must work within their scope of practice as laid down by their regulator: the GMC for Ophthalmic Surgeons and Anaesthetists; the General Optical Council (GOC) for Optometrists, Dispensing Opticians and Contact Lens Opticians; the Nursing and Midwifery Council (NMC) for Nurses; and the Health and Care Professions Council (HCPC) for clinical scientists.

### Remit of these Standards

- 1.10 Whilst the principles underpinning the GMC guidance are sound, the guidance itself is by definition uni-professional and designed only for doctors. However many ophthalmologists now deliver care as part of multi-professional teams through community refractive surgery providers, rather than in traditional NHS systems or small independent practices.
- 1.11 By improving efficiency, stream-lining processes and making better use of skill mix and technology - whilst maintaining safety and excellent outcomes as absolute requirements - new community models are able to offer refractive surgery to those who would benefit from it but for whom the previous high costs would have been a significant barrier. GMC guidance, as well as the guidance of other regulators, needs to be applied appropriately in changing circumstances, new care models and delivery environments.

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<sup>1</sup> General Medical Council, *Guidance for Doctors who offer cosmetic interventions*, London 2016. (URL: [www.gmc-uk.org/Guidance\\_for\\_doctors\\_who\\_offer\\_cosmetic\\_interventions\\_210316.pdf\\_65254111.pdf](http://www.gmc-uk.org/Guidance_for_doctors_who_offer_cosmetic_interventions_210316.pdf_65254111.pdf))

<sup>2</sup> General Medical Council, *Good Medical Practice*, London, 2014 (latest update). (URL: [www.gmc-uk.org/guidance/good\\_medical\\_practice.asp](http://www.gmc-uk.org/guidance/good_medical_practice.asp))

## Application of these Standards

- 1.12 By following their regulators' guidance and these new standards as appropriate, community providers and clinicians will continue to offer high quality care and clinical outcomes under current, new and evolving models of care.
- 1.13 These standards are evidence-based, patient-centred and reflect good practice in refractive surgery provision to which all providers and clinicians involved in delivering refractive surgical care in the community can be held to account.
- 1.14 They will be regularly updated as clinical practice, technology and patient expectations advance.

## Dataset and Data

- 1.15 FODO, ABDO, ACLM and FMO, founding members of the Optical Confederation, are working with the Royal College of Ophthalmologists and other bodies to develop a national refractive surgery dataset and national database. Our aim is that such a database, to which all providers would submit data, should be contracted to an independent third party such as a university and funded by an agreed levy. This will enable data to be used to analyse and promote the benefits and risks of refractive surgical procedures in an independent and scientific manner for the benefit of all.

## Development and Review of Standards

- 1.16 These multi-disciplinary professional standards for providers and clinical teams have been developed with the input of an Expert Panel consisting of a range of clinicians and providers working in the refractive surgery field. A full list of the members of the Expert Panel is available at Annex 2.
- 1.17 The open and inclusive development process of these standards included an eight week open consultation. Further details of the consultation and the bodies consulted can be found on our website.
- 1.18 These standards will be formally reviewed through an open and consultative process two years from the date of publication in June 2019.
- 1.19 The National Institute for Health and Care Excellence is currently developing a clinical guideline for the management of cataracts in adults. These standards will be reviewed in the light of this guideline once it has been published.

## 2 Knowledge, skills and performance

### The GMC says:

*You must recognise and work within the limits of your competence and refer a patient to another practitioner where you cannot safely meet their needs.*

*Before carrying out an intervention for the first time yourself, or supervising others performing it, you must make sure you can do so safely, e.g. by undergoing training or seeking opportunities for supervised practice.*

*You must take part in activities to maintain and develop your competence and performance across the full range of your practice.*

*You must keep up to date with the law and clinical and ethical guidelines that apply to your work. You must follow the law, our guidance and other regulations relevant to your work.*

*You must seek and act on feedback from patients, including information on their satisfaction and physical and psychological outcomes. You must use this, and feedback from colleagues, to inform your practice and improve the quality of your work.*

*You must make sure your annual appraisal covers the whole of your practice.*

### In addition, in community refractive surgery:

- 2.1 Every eye care professional involved in refractive surgery should ensure that their skills and knowledge are up to date in line with the requirements and guidance of their health regulator.
- 2.2 Ophthalmic surgeons should
  - comply with the General Medical Council's continuing professional development (CPD) requirements, which should include activities relating to refractive surgery
  - maintain an accurate and up-to-date portfolio of supporting information about their clinical activity, including areas for improvement
  - participate in annual appraisals covering their refractive surgical practice
  - have regard to relevant guidance issued by the Royal College of Ophthalmologists, their employer or any other relevant body
  - support the training and development needs of the other healthcare professionals that are working as part of the multi-disciplinary team.

### 2.3 Anaesthetists should

- comply with the General Medical Council's continuing professional development (CPD) requirements, which should include activities relating to refractive surgery
- maintain an accurate and up-to-date portfolio of supporting information about their clinical activity, including areas for improvement
- participate in annual appraisals covering their refractive surgical practice
- have regard to relevant guidance issued by the Royal College of Anaesthetists, their employer or any other relevant body
- support the training and development needs of the other healthcare professionals who are working as part of the multi-disciplinary team.

### 2.4 Optometrists should

- comply with the General Optical Council's continuing education and training (CET) requirements as appropriate to their work in refractive surgery<sup>3</sup>
- participate in team audit and case reviews
- participate in annual appraisals covering their roles in refractive surgical practice
- have regard to relevant guidance issued by the College of Optometrists, their employer or any other relevant body
- support the training and development needs of the other healthcare professionals who are working as part of the multi-disciplinary team.

### 2.5 Dispensing Opticians should

- normally be contact lens registered with the General Optical Council depending on their role
- comply with the General Optical Council's continuing education and training (CET) requirements as appropriate to their work in refractive surgery
- participate in team audit and case reviews
- participate in annual appraisals covering their roles in refractive surgical practice
- have regard to relevant guidance issued by the Association of British Dispensing Opticians, their employer or any other relevant body
- support the training and development needs of the other healthcare professionals who are working as part of the multi-disciplinary team.

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<sup>3</sup> For optometrists the same amount of additional points is recommended over the three year CET cycle as independent prescribing optometrists are required to complete.

## 2.6 Ophthalmic nurses should

- comply with the CPD requirements of the Nursing and Midwifery Council as appropriate to their work in refractive surgery
- participate in team audit and case reviews
- participate in annual appraisals covering their roles in refractive surgical practice
- have regard to relevant guidance issued by the Royal College of Nursing, their employer or any other relevant body
- support the training and development needs of the other healthcare professionals who are working as part of the multi-disciplinary team.

## 2.7 Ophthalmic clinical scientists should

- comply with the CPD requirements of the Health and Care Professions Council as appropriate to their work in refractive surgery
- participate in team audit and case reviews
- participate in annual appraisals covering their roles in refractive surgical practice
- have regard to relevant guidance issued by their employer or a relevant body
- support the training and development needs of the other healthcare professionals who are working as part of the multi-disciplinary team.

## 2.8 Any other healthcare professionals or persons engaged in supporting refractive surgery in the community should

- be trained and have demonstrated their skills (e.g. by being appropriately certified by the manufacturer of the equipment they use or their approved trainer) and competences in the roles that they carry out
- participate in team audit and case reviews as appropriate
- participate in annual appraisals covering their roles in refractive surgical practice
- have regard to relevant guidance issued by their employer or a relevant body
- support the training and development needs of the other healthcare professionals who are working as part of the multi-disciplinary team.

## 2.9 All non-clinical staff should

- be trained and have demonstrated their competences in the roles they carry out in relation to refractive surgical services
- participate in team audit and case reviews as appropriate
- participate in annual appraisals covering their roles in refractive surgical practice
- have regard to relevant guidance issued by their employer or a relevant body
- support the training and development needs of the other healthcare professionals who are working as part of the multi-disciplinary team.



## 3 Safety and quality

### The GMC says:

*To help keep patients safe you must follow the guidance on establishing and participating in systems and processes that support quality assurance and service improvement, as set out in Good Medical Practice and our related explanatory guidance. In particular, you must:*

- a) comply with any statutory reporting duties in place.*
- b) contribute to national programmes to monitor quality and outcomes, including those of any relevant device registries.*
- c) routinely monitor patient outcomes, and audit your practice, reporting at least annual data.*
- d) report product safety concerns to the relevant regulator – in the UK this is the Medicines and Healthcare products Regulation Agency (MHRA).*

*You should share insights and information about outcomes with other people who offer similar interventions, to improve outcomes and patient safety.*

*You must tell patients how to report complications and adverse reactions.*

*You must be open and honest with patients in your care, or those close to them, if something goes wrong and the patient suffers or may suffer harm or distress as a result.*

*N/A – refers to injectable cosmetic medications*

*You must seek and act on evidence about the effectiveness of the interventions you offer and use this to improve your performance.*

*You must provide interventions based on the best available up-to-date evidence about effectiveness, side effects and other risks.*

### **In addition, in community refractive surgery it is recommend that:**

- 3.1 The surgeon who is to carry out the procedure should confirm with the patient at a pre-surgical, consultation
  - a) patient identification (forenames and surname, date of birth)
  - b) the eye to be operated on
  - c) any drug allergies are recorded in a way that they will be clear to all members of the clinical team

- d) for IOL procedures - implant make and model
  - e) for laser eye surgery procedures - the sphere, cylinder, axis and refractive target
  - f) that the patient fully understands the procedure, risks and range of associated outcomes
  - g) their informed consent to the procedure has been provided, recorded in the patient record and all relevant documentation has been completed.
- 3.2 All essential elements of the pre-surgical consultation must be recorded within the patient record.
- 3.3 All registered clinicians / providers involved in refractive surgery must be covered by appropriate professional indemnity insurance.
- 3.4 In the event that complications occur that cannot be satisfactorily remedied by the provider and consequently trust has broken down between the patient and provider, the surgeon who carried out the procedure or other member of the clinical team, providers should support the patient in accessing an appropriate independent dispute resolution service. If requested by the dispute resolution service, the provider should fund any costs of corrective surgery according to agreed criteria and depending on the circumstances of each individual case.<sup>4</sup>
- 3.5 All registered clinicians have a professional duty of candour and must be open and honest with patients when things go wrong. Patients must be made aware of their opportunities to complain and should be informed of their rights to complain to the relevant regulator or seek mediation through the dispute resolution service.
- 3.6 Each individual involved in the use of diagnostic or treatment equipment must have been trained and certified in its use by the manufacturer or their approved trainer.
- 3.7 All clinicians should participate in clinical networks to allow discussion and review of complex cases where appropriate to build the collective safety and knowledge base.
- 3.8 All providers must ensure that any medicines, implants or other medical devices comply with the guidelines of the [Medicines and Healthcare Products Regulatory Agency](#)<sup>5</sup>.

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<sup>4</sup> The FODO, ABDO, ACLM and FMO propose to appoint an independent dispute resolution service for their members and to develop agreed criteria for the service with the Royal College of Ophthalmologists and other sector partners

<sup>5</sup> URL: [www.gov.uk/government/organisations/medicines-and-healthcare-products-regulatory-agency](http://www.gov.uk/government/organisations/medicines-and-healthcare-products-regulatory-agency)

## 4 Safe environment

### The GMC says:

*You should be satisfied that the surgical environment is safe, suitably equipped and staffed and complies with any relevant regulatory requirements.*

### In addition, in community refractive surgery:

- 4.1 The treatment facility must be registered with the relevant health regulator of the particular jurisdiction, for example the Care Quality Commission (CQC) in England, Healthcare Improvement Scotland (HIS) in Scotland, Healthcare Inspectorate Wales (HIW) in Wales and the Regulation and Quality Improvement Authority (RQIA) in Northern Ireland.
- 4.2 All clinicians involved in refractive surgery or aftercare must be satisfied with the clinical environment, leadership, staff skill mix and equipment available at all times. While all team members have a duty to report any concerns, the ultimate authority on this matter is the surgeon who will carry out the procedure, in consultation with the provider.
- 4.3 All equipment must be suitable for the purpose, properly maintained in line with the manufacturer's instructions and checked before each operation.
- 4.4 All team members have a professional duty to report any concerns about any of the above, under their regulators' code/standards of conduct and contract.

## 5 Communication, partnership and teamwork

### **The GMC says:**

*You must communicate clearly and respectfully with patients, listening to their questions and concerns and considering any needs they may have for support to participate effectively in decision making.*

### **Seeking patients' consent**

*You must be familiar with the guidance in Consent: patients and doctors making decisions together. In the following paragraphs we've highlighted key points from the guidance, which are important to protecting patients' interests in relation to cosmetic interventions.*

### **Responsibility for seeking consent**

*If you are the doctor who will be carrying out the intervention, it is your responsibility to discuss it with the patient and seek their consent – you must not delegate this responsibility. It is essential to a shared understanding of expectations and limitations that consent to a refractive surgery intervention is sought by the doctor who will perform it, or supervise its performance by another practitioner.*

### **Responding to requests for refractive surgical interventions**

*If a patient requests an intervention, you must follow the guidance in Consent, including consideration of the patient's medical history. You must ask them why they would like to have the intervention and the outcome they hope for, before assessing whether the intervention is appropriate and likely to meet their needs.*

*If you believe the intervention is unlikely to deliver the desired outcome or to be of overall benefit to the patient, you must discuss this with the patient and explain your reasoning. If, after discussion, you still believe the intervention will not be of benefit to the patient, you must not provide it. You should discuss other options available to the patient and respect their right to seek a second opinion.*

*When you discuss interventions and options with a patient, you must consider their vulnerabilities and psychological needs. You must satisfy yourself that the patient's request for the cosmetic intervention is voluntary.*

*You must explain any monitoring or follow-up care requirement at the outset. You must tell patients if implanted medical devices may need to be removed or replaced and after how long.*

*You must tell prospective patients if alternative interventions are available that could meet their needs with less risk, including from other practitioners.*

### ***Discussing side effects, complications and other risks***

*You must give patients clear, accurate information about the risks of the proposed intervention and any associated procedures, including anaesthesia and sedation, following the guidance in Consent (paragraphs 28-36).*

*You must talk to the patient about any adverse outcomes that may result from the proposed intervention, paying particular attention to those the patient is most concerned about. You must talk about the potential adverse physical and psychological impact of the intervention going wrong or failing to meet the patient's expectations.*

### ***Giving patients time for reflection***

*You must give the patient the time and information they need to reach a voluntary and informed decision about whether to go ahead with an intervention.*

*The amount of time patients need for reflection and the amount and type of information they will need depend on several factors. These include 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.*

*You must tell the patient they can change their mind at any point.*

*You must consider whether it is necessary to consult the patient's GP to inform the discussion about benefits and risks. If so, you must seek the patient's permission and, if they refuse, discuss the reasons for doing so and encourage them to allow you to contact their GP. If the patient is determined not to involve their GP, you must record this in their notes and consider how this affects the balance of risk and benefit and whether you should go ahead with the intervention.*

### ***Being clear about fees and charges***

*You must explain your charges clearly, so patients know the financial implications of any decision to proceed to the next stage or to withdraw.*

*You must be clear about what is included in quoted prices and what other charges might be payable, including possible charges for revision or routine follow-up.*

Refractive surgery is normally performed in adults with capacity for consent. Where this is not the case, paragraphs 30-35 of the GMC guidance apply.

In addition, in community refractive surgery:

### Consent process

- 5.1 The surgeon who is to carry out the procedure is responsible for the overall consent process including discussion with the patient in advance of surgery of risks, benefits, range of associated outcomes, alternatives to surgery and final consent on the day of surgery itself.
- 5.2 This duty cannot be delegated even though other trained staff may carry out information giving, preliminary assessment and options consideration with the patient as part of the process as below.
- 5.3 If a patient is identified as clinically suitable for a procedure by a trained clinician, who may or may not be an ophthalmic surgeon, that clinician should:
  - obtain or be aware of the patient's previous refractive history
  - discuss the patient's expectations, options, alternatives to surgery, potential risks (complications and side effects), range of associated outcomes and likely benefits of procedures with them
  - be aware that some of this information may be more effectively communicated by showing the patient an information video which can be used as a reminder and to improve the patient's comprehension in the face-to-face discussion which should always take place irrespective of any multi-media or other format information provided
  - agree with the patient a preliminary recommendation of the most appropriate procedure based on the patient's clinical suitability and lifestyle requirements.
- 5.4 This is the start of the informed consent process. Any information and discussion should be tailored to suit the patient, aiming to help them make balanced choices and highlighting any areas of particular risk, benefit or associated outcomes to them as individuals. The key elements of this discussion and choices made must be recorded in the patient record.
- 5.5 Information provided to the patient must make clear that the decision to proceed with surgery depends ultimately on final agreement between the surgeon who is to perform the procedure and the patient about how best to meet the patient's clinical needs and expectations plus the patient's suitability and readiness for surgery.
- 5.6 The first priority for all providers, clinicians and trained ancillary staff will be the patient's well-being and clinicians should seek expert advice from colleagues or other healthcare professionals, such as the patient's GP, if they are concerned that a patient may not cope well with either the surgery itself or the recovery process.

- 5.7 Patients should be given information on how to prepare for the procedure day, what to expect on the day of surgery, what to expect as a follow-on to the procedure and what to do in an emergency.
- 5.8 The patient should be advised to review the patient information to ensure they fully understand what has been presented to them prior to their next interaction with a clinician. This allows the patient to reflect on the risks, benefits and range of outcomes of the recommended procedure in their own time and allows them to formulate any questions that they wish to ask.
- 5.9 As well as being informed, patients should also be empowered to make their own decisions regarding their care.
- 5.10 The patient must have a discussion with the surgeon performing the procedure in advance of the day of surgery. In some circumstances, with the agreement of the clinician provisionally confirming suitability and the treating surgeon, this may be conducted by videoconference or telephone in line with normal tele-medical practice. The surgeon must have access to the patient's clinical records for review prior to any discussion taking place and comprehensive notes of the discussion must be made and retained in the patient record.
- 5.11 Patients should always be recommended to meet the surgeon who will be performing the procedure face-to-face in advance of the day of surgery. However, in cases where the patient desires to meet their surgeon only on the day of surgery, this choice should be respected provided that
- a videoconference or telephone discussion between the patient and the surgeon takes place in advance of the day of surgery
  - it is made clear that the ultimate decision on a patient's suitability rests with the treating ophthalmic surgeon on the day and that they may be unable to proceed with the operation on the day
  - this information and the patient's explicit choices are noted in the patient record.
- 5.12 If the surgeon who is to perform the procedure has any reason (e.g. from a disclosure made by a patient during a virtual or face-to-face consultation) that it would not be appropriate for the patient to proceed to surgery, the surgeon should not proceed to arrange the operation or to allow it to be arranged, before a face-to-face consultation has been held.

## Reflection Period

- 5.13 It is good practice for there to be a reflection period of seven (7) calendar days between the discussion with the surgeon and the day of surgery. In instances where this is not appropriate, and with the agreement of the treating surgeon and the patient, there should be a time lapse of at least forty eight (48) hours between the initial discussion with the surgeon who will carry out the procedure and the day of surgery to enable the patient fully to reflect on their decision and to seek further professional advice if they wish.
- 5.14 More time may be required for this reflection if appropriate in particular when advised by the surgeon who is to perform the procedure or if requested by the patient.

## Second Opinion

- 5.15 Refractive surgery is elective and should always be a considered choice by the patient. The patient's right to a second opinion should always be respected.



## 6 Providing continuity of care

### The GMC says:

*You should consider whether you or a colleague will need to review the patient's response to the intervention and make sure the patient understands whether you recommend a follow-up appointment.*

*You must make sure the patient has the medicines or equipment they need to care for themselves after an intervention.*

*You must make sure that your patients know how to contact you or another suitably qualified person if they experience complications outside your normal working hours.*

*You should give patients written information that explains the intervention they have received in enough detail to enable another doctor to take over the patient's care. This should include relevant information about medicines or devices used. You should also send this information, with the patient's consent, to their GP, and any other doctors treating them, if it is likely to affect their future healthcare. If the patient objects to the information being sent to their doctor, you must record this in their notes and you will be responsible for providing the patient's follow-up care.*

### In addition, in community refractive surgery:

- 6.1 In modern community refractive surgery, although the treating ophthalmologist retains overall clinical responsibility for the outcomes of the surgery, other registered professionals and trained staff may undertake various clinical and administrative roles within a multi-professional clinical team.
- 6.2 An example list of the different skills and roles of the different healthcare professionals involved in modern community eye surgery is set out for information at Annex 1.

### Multi-disciplinary Team Working

- 6.3 To demonstrate skilled leadership and excellent team communication, a multi-disciplinary professional team should ensure:
  - an unwavering focus on the well-being of the patient at all times
  - use of a single, easily transferable and accessible clinical/patient record (with the patient's consent) ideally in electronic format
  - all clinicians working within their skills and professional standards, including demonstrating effective clinical leadership and handover
  - communication with the patient's GP and referring optometrist (both with the patient's permission) throughout the patient's refractive or cataract surgery journey.

## Before the day of surgery

- 6.4 The patient should be fully involved in all decisions about their care. Pre-intervention information, whether in electronic format or hard copy, should include a clear explanation of what the patient can expect on the day, during the procedure and afterwards, reassurances about pain control, sensations, lights and smells and how the patient can help the procedure go smoothly.
- 6.5 All such information, whether in electronic format or hard copy, should be in plain English and where appropriate approved by an independent body e.g. Crystal Mark by the Plain English Campaign.
- 6.6 If the patient is found to be clinically suitable for a procedure, the examining clinician will make a preliminary recommendation about the most appropriate ophthalmic procedure based on the patient's expectations, clinical suitability and lifestyle requirements.
- 6.7 The Informed Consent process outlined in Section 5 must always be completed. Potential risks (complications and side-effects), benefits, alternatives, what to expect from the proposed procedure and the range of associated outcomes should have been discussed with the patient and key elements of the discussion recorded in the patient record.
- 6.8 Whether as part of the above or separately, the operating surgeon must also have a discussion with the patient about the benefits, risks and range of associated outcomes of the procedure, ideally in person, but as a minimum by teleconference or by telephone depending on the patient's expressed wishes. Again the key elements of this discussion should be recorded in the patient record.
- 6.9 If an examining clinician at any stage identifies any unresolved medical issues, input may need to be sought from the patient's General or Specialist Practitioner prior to any intervention being undertaken. In all circumstance of unresolved medical issues, the patient must meet and discuss these with the surgeon who will carry out the procedure prior to the day of surgery.

## On the day of surgery

6.10 The surgeon who will carry out the procedure must see the patient for a clinical examination and face-to-face discussion on the day of surgery to confirm

- the patient's suitability, understanding of the risks, benefits and possible outcomes, plus willingness and readiness for surgery
- their consent to proceed.

The operating surgeon must be fully satisfied that the patient has given informed consent to the planned surgery.

6.11 The surgeon will finalise the treatment plan and agree this with the patient. These details should be recorded in the patient's record, including a copy of the patient's written consent.

6.12 The surgical procedure must be completed with all due care and skill. The operating surgeon must:

- talk the patient through each step of the surgical procedure as applicable
- examine the patient after recovery before they leave the clinic
- assure themselves that the patient understands the aftercare and follow-up requirements, including what to do and whom to contact in an emergency, before being discharged.

## Discharge on day of surgery

6.13 All patients and their carers/supporters should be issued with written information about aftercare and follow-up (including about pain relief, hygiene and what to do in the case of an emergency) in plain English approved by an independent body, e.g. Crystal Mark by the Plain English Campaign.

6.14 Patients and their carers/supporters should also be given the opportunity to ask questions of a registered clinician including if they wish the operating surgeon.

## After the day of surgery

- 6.15 All refractive surgery patients should be seen in-person the day following surgery by an appropriate eye care professional, with the operating surgeon available to provide any necessary advice or support to the examining clinician or patient as appropriate.
- 6.16 Further postoperative follow-ups should be undertaken by the appropriate eye care professional
- as clinically necessary in the immediate post-operative period
  - and at one month and three months post-operatively to check and record visual and ocular outcomes.

In the case of any complication being identified by an eye care professional, the treating surgeon should be alerted and be appropriately involved in any patient management decisions.

- 6.17 At least one postoperative follow-up should record patient-reported outcome measures (PROMs) particularly the patient's satisfaction with the visual and ocular outcomes and their experience of care.
- 6.18 Any enhancement or secondary procedure required, for example to correct the residual outcome by laser, surgical elimination of astigmatism, rotation or re-implantation of an intra-ocular lens is the responsibility of the provider and usually the same surgical team. Any fees for corrective care should be clearly explained and discussed with the patient prior to their being asked to give consent for the procedure.
- 6.19 Regular eye examinations should be recommended as clinically appropriate for all refractive surgery patients.
- 6.20 Final discharge information should include details of the procedure the patient has undergone, the medical device, clinical results and any recommendation for future eye examinations intervals which the patient can give to any optometrist, GP or hospital they attend in future.
- 6.21 Copies of this discharge information should be provided (with the patient's consent) to the patient's GP, their regular or referring optometrist.

## 7 Record keeping

### **The GMC says:**

*You should organise your care records in a way that allows the identification of patients who have been treated with a particular device or medicine in the event of product safety concerns or regulatory enquiries.*

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

- a) Any data protection requirements*
- b) Our Confidentiality guidance*
- c) Guidance published by the UK health departments, even when the interventions are provided outside the National Health Service.*

### **In addition, in community refractive surgery:**

- 7.1 At all stages, thorough and detailed clinical records must be kept.
- 7.2 As set out in Paragraph 6.5, it is good practice for all eye care professionals involved in a patient's care to have access to and use a shared (ideally electronic) patient record or easily accessible or transferable, with the patient's consent.
- 7.3 Information in the patient record should be used for analysis, both in terms of clinical and patient reported outcomes.
- 7.4 Once a national refractive surgery dataset has been agreed across the sector and an independent national database similarly established, the data collected under Paragraph 7.3 should include the information listed in the minimum dataset.

## 8 Working with colleagues

### **The GMC says:**

*You must make sure that anyone you delegate care to has the necessary knowledge, skills and training and is appropriately supervised.*

*You must work effectively with healthcare professionals and others involved in providing care. You must respect the skills of colleagues within multidisciplinary teams and support them to deliver good patient care.*

*You must ask for advice from colleagues if the patient has a health condition that lies outside your field of expertise and that may be relevant to the intervention or the patient's request.*

*You must make sure you build a support network of experienced professional colleagues who can support and advise you. You should ask for advice when you treat patients who may need psychological or other expert assessment or support.*

### **In addition, in community refractive surgery:**

- 8.1 These principles should apply to all registered clinicians working in multi-professional refractive surgery clinical teams.

## 9 Maintaining trust

### The GMC says:

#### **Honesty**

*You must always be honest and never misleading about your skills, experience, qualifications, professional status and current role.*

#### **Communicating information about your services**

*When advertising your services, you must follow the regulatory codes and guidelines set by the Committee of Advertising Practice.*

*You must make sure the information you publish is factual and can be checked, and does not exploit patients' vulnerability or lack of medical knowledge.*

*Your marketing must be responsible. It must not minimise or trivialise the risks of interventions and must not exploit patient's vulnerability. You must not claim that interventions are risk free.*

*If patients will need to have a medical assessment before you can carry out an intervention, your marketing must make this clear.*

*You must not mislead about the results you are likely to achieve. You must not falsely claim or imply that certain results are guaranteed from an intervention.*

*You must not use promotional tactics in ways that could encourage people to make an ill-considered decision.*

*You must not provide your services as a prize.*

*You must not knowingly allow others to misrepresent you or offer your services in ways that would conflict with this guidance.*

### **In addition, in community refractive surgery:**

- 9.1 Advertising and marketing has a legitimate and important role in providing information to patients and raising awareness of the choice of providers available. In a community refractive surgery setting it is normal for provider organisations to engage in advertising and marketing, rather than members of clinical teams. Nevertheless any clinicians involved in advertising or marketing should follow any guidance set down by their professional body, regulator or such bodies as the Advertising Standards Agency (ASA).

9.2 All providers who use advertising and marketing to raise awareness of their services should comply with the recommendations of the UK regulatory authorities for marketing and advertising – the Advertising Standards Authority (ASA), the Code of Non-broadcast Advertising, Sales Promotion and Direct Marketing, Committee of Advertising Practice (CAP), and Pricing Practices Guides.

9.3 In addition providers should ensure that their marketing practices adhere to the following principles

- All advertising and marketing practices used by providers should be socially responsible, intended to raise awareness of the choice of providers and procedures available
- Patients should not be intentionally misled about the risks of procedures
- Unsuitable or vulnerable patients should not be targeted
- Providers should not offer financial inducements which would allow patients who are otherwise unsuitable for surgery to proceed with treatment
- Any price promotions should be socially responsible and must not affect treatment decisions made by the clinical team
- Data supporting all claims and statements must be available for independent verification
- All endorsements must be true, evidence-based and verifiable
- All patients' suitability for treatment must be assessed by the clinical team prior to a procedure recommendation being made. The clinical team must decline to treat any unsuitable patient.
- All patients deemed suitable, who elect to proceed, must complete the Informed Consent process. Ultimately, the treating surgeon must be satisfied that consent has been provided.



## 10 Honesty in financial dealings

### **The GMC says:**

*You must be open and honest with your patients about any financial or commercial interests that could be seen to affect the way you prescribe for, advise, treat, refer or commission services for them.*

*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.*

### **In addition, the following principles apply to community refractive surgery:**

- 10.1 Any fees associated with surgery, including deposits, must be transparent and explained clearly to patients from the outset. Patients must be made aware of the terms associated with the refund of any deposit.

## 11 Annex 1

Examples of the skills and roles of the different healthcare professionals involved in modern community refractive eye surgery are set out in Table 1 below. Every attempt will be made to keep this as up to date as possible but technology and skill mix is changing all the time so for the latest information or in any cases of query patients are advised to consult their provider.

**Table 1**

Diagnostic Test	Trained Technician / Assistant/ Trained Dispensing Optician	Ophthalmic Nurse	Dispensing Optician (with contact lens registration)	Optometrist	Ophthalmic Surgeon
Auto-refractor	Capture Scan	Capture Scan	Capture Scan & Interpret Output	Capture Scan & Interpret Output	Capture Scan & Interpret Output
Auto-keratometry	Capture Scan	Capture Scan	Capture Scan & Interpret Output	Capture Scan & Interpret Output	Capture Scan & Interpret Output
Focimetry	Capture Scan	Capture Scan	Capture Scan & Interpret Output	Capture Scan & Interpret Output	Capture Scan & Interpret Output
Non Contact Tonometry	Capture Scan	Capture Scan	Capture Scan	Capture Scan & Interpret Output	Capture Scan & Interpret Output
Contact Tonometry	No Role in Capture	Capture Scan	Capture Scan	Capture Scan & Interpret Output	Capture Scan & Interpret Output
Specular Microscopy	Capture Scan	Capture Scan	Capture Scan	Capture Scan & Interpret Output	Capture Scan & Interpret Output
Biometry	Capture Scan	Capture Scan	Capture Scan	Capture Scan & Interpret Output	Capture Scan & Interpret Output
Abberometry	Capture Scan	Capture Scan	Capture Scan & Interpret Output	Capture Scan & Interpret Output	Capture Scan & Interpret Output
Topography	Capture Scan	Capture Scan	Capture Scan & Interpret Output	Capture Scan & Interpret Output	Capture Scan & Interpret Output
Ultrasound Pachymetry	No Role in Capture	Capture Scan	Capture Scan & Interpret Output	Capture Scan & Interpret Output	Capture Scan & Interpret Output
Optical Coherence Tomography (OCT)	Capture Scan	Capture Scan	Capture Scan	Capture Scan & Interpret Output	Capture Scan & Interpret Output
Visual Fields	Capture Scan	Capture Scan	Capture Scan	Capture Scan & Interpret Output	Capture Scan & Interpret Output
Fundus Photography	Capture Scan	Capture Scan	Capture Scan	Capture Scan & Interpret Output	Capture Scan & Interpret Output

## 12 Annex 2

These multi-disciplinary professional standards for providers and clinical teams have been developed by an Expert Panel comprising a range of senior clinicians and providers working in the refractive surgery field.

The Expert Panel consists of:

Jan Venter	-	Ophthalmic Surgeon
David Teenan	-	Ophthalmic Surgeon
Mary Spellman	-	Ophthalmic Nurse
Amy Richardson	-	Optometrist
Dagobert Lerch	-	Anaesthetist
Dan Reinstein	-	Ophthalmic Surgeon
Stephen Hannan	-	Optometrist
Clare O'Donnell	-	Optometrist
Andrew Price	-	Dispensing Optician with contact lens registration
CT Pillai	-	Ophthalmic Surgeon

To inform their work, focus groups and interviews with refractive surgery patients from across the UK were conducted to ensure the standards were informed by a wide range of patient feedback.

We would like to thank them and everyone who input into the development of these multi-professional standards for their openness, hard work, time and dedication. Without them these standards would not have been possible.



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