

Consultation Document

Standards for Patient Information and Consent for Refractive Surgery

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1 Summary

- 1.1 Some principles in guiding consent to treatment in refractive surgery are laid out below. The foundation for these recommendations is distilled from the Keogh Report, General Medical Council, NHS, Royal College of Surgeons, and American Academy of Ophthalmology Guidance. Although the list is not exhaustive, these recommendations are designed to emphasise some aspects of communication with patients that are particularly relevant to refractive surgery.

2 Standardised patient information

- 2.1 Up to date, independent, standardised, evidence-based patient information in plain English should be easily available for refractive surgery procedures (published on RCOphth; NHS Choices; Parliamentary Ombudsman websites).
- 2.2 Standardised patient information should explain the procedure, suitability, benefits, risks, and alternatives.

3 Information specific to the provider

- 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.
- 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.

4 The consent process

- 4.1 Written consent forms should not differ in tone or content from the patient information for procedures, and should take the form of an appropriate standard wording appended to the patient information which has been available to the patient throughout.

- 4.2 ~~Responsibility for the consent process must not be delegated to~~ The General Medical Council requires that the surgeon performing the procedure must personally ensure that the patient provides their informed consent to be satisfied that the patient is happy to proceed with surgery, and that this responsibility must not be delegated ~~is aware of the risks, and has realistic expectations for the outcome.~~ However the surgeon may delegate to registered and appropriately trained optometrists or ophthalmic nurses important steps in the informed consent process. This includes taking a detailed history or discussing the motivation for and expectations of the procedure, providing preparatory information (which may

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include written or video material) discussing the risks and benefits of surgery, determining suitability for surgery and making a preliminary procedure recommendations. The surgeon must confirm the preliminary recommendation prior to surgery. , the consultation at which the procedure recommendation is made must be with the operating surgeon, and must not occur on the day of surgery. The final consent and confirmation to proceed with surgery must be taken by the operating surgeon or confirmed with the patient by the operating surgeon on the day of the procedure. At every stage, patients should be clearly informed about which staff they will meet and who they are receiving advice or care from and that ultimate responsibility for go ahead like with the surgeon.

Comment [1]: As originally drafted, this goes beyond the GMC guidelines; nor does it show understanding or respect for the roles of other registered professionals within the clinical team.

4.3 Information in the consent conversation should be tailored to suit ~~fit~~ the patient, aiming to help them make informed ~~balanced~~ choices, and highlighting any areas of particular risk or benefit for them as individuals.

4.4 Surgeons should consider their patients' wellbeing and seek expert advice from colleagues if they are concerned that a patient may not cope well with either the surgery itself or the recovery period.

4.5 Consent for refractive surgical interventions should include a 2-stage process in which consent forms are taken away from the consultation ~~when~~ at which the preliminary procedure recommendation is made by either the operating surgeon, optometrist or ophthalmic nurse. Patients should then be given the opportunity to discuss further with their surgeon (face to face or otherwise such as video conference) in advance of the day of surgery. The surgeon must confirm that the patient has all the information they require, including about the risks and range of outcomes in advance of the patient giving their consent to proceed. ~~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.~~

4.6 Surgery must not take place on the day on which the preliminary procedure recommendation is made. A minimum cooling off period of ~~1 week~~ 2 clear working days is recommended between the recommendation ~~procedure recommendation~~ and surgery.

4.7 There should be no pressure to proceed at any time. ~~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.

Comment [2]: There is consensus that two working days as a minimum would be more convenient for some patients. For example who have flown in to the UK expressly to have the quality of UK refractive surgery.

Comment [3]: In some cases a bespoke made to order non-refundable IOL will be required for the patient. The deposit confirms provisional commitment from the patient, pending completion of their consent.

5 The procedure

5.1 Pre-treatment instructions should include a clear explanation of what to expect during the surgery, with instructions about how the patient can help the procedure to go smoothly and reassurance about discomfort or disconcerting lights, sounds or smells which are normal during surgery.

5.2 Surgery under local anaesthetic should not be performed in silence. It is helpful to keep up a reassuring dialogue, talking patients through the surgery and explaining when they are likely to experience sensations such as pressure in the eye, temporary loss of vision, a bright light, a burning smell, or fluid running over the eye.

6 Aftercare instruction

— ~~6.1 Additional written discharge information detailing what to expect after surgery.~~ —

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aftercare instructions and an open line of communication (mobile or 24 hour telephone number) with the operating surgeon, ~~or~~ an experienced refractive surgeon on-call, optometrist or ophthalmic nurse should be available at discharge from surgery. Although calls may be triaged through non-medical staff; immediate onward communication to the surgeon on-call should be available.

7 Discharge information

- 7.1 After the final review appointment, further written discharge information should explain the need for any ongoing eye health care and any problems to look out for after follow up is complete.

8 References

1. The Keogh report: review of the regulation of cosmetic surgery interventions <https://www.gov.uk/government/publications/review-of-the-regulation-of-cosmetic-interventions>
2. GMC guidance on consent: patients and doctors making decisions together http://www.gmc-uk.org/guidance/ethical_guidance/consent_guidance_index.asp
3. Plain English guidance on consent at NHS Choices <http://www.nhs.uk/conditions/consent-to-treatment/pages/introduction.aspx>
4. AAO guidance on consent in refractive surgery <http://www.aao.org/patient-safety-statement/informed-consent-guidelines-2>
5. AAO guidance on marketing in refractive surgery <http://www.aao.org/ethics-detail/policy-statement--guidelines-refractive-surgery-ad>
6. GMC guidance for doctors who offer cosmetic interventions http://www.gmc-uk.org/static/documents/content/Guidance_for_doctors_who_offer_cosmetic_interventions_080416.pdf
7. Professional standards for cosmetic surgery <https://www.rcseng.ac.uk/publications/docs/professional-standards-for-cosmetic-surgery/>