Cataracts in adults: management

Consultation on draft guideline - Stakeholder comments table
12/05/2017 to 23/06/2017

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Alcon Eye Care UK	Appendix C: Review protocols	20	39 40	Clarification Question: We would like to inquire why "comparative observational studies" were included in the study design for RQ20, yet all non-RCTs were excluded from the review?	Thank you for your comment. This protocol was written such that comparative observational studies would only be included if no data from randomised controlled trials were identified. Since randomised controlled data were identified, observational data were therefore not included. The committee discussed whether additional observational study data were likely to be valuable on top of the RCTs identified, and decided they would not add sufficiently to decision making. This decision is captured in the evidence to recommendations section of this chapter. However, we agree the way the protocol was phrased did not make this 100% clear, and apologise for any misunderstandings this may have caused.
Alcon Eye Care UK	Appendix D: Review search strategies	14	89	Selection of Search Terms The Committee has acted unreasonably by failing to include "age-related macular degeneration" or AMD in the search terms. According to the Manual: "*Comprehensively identifying search terms may present challenges. For example, for public health or social care reviews many databases do not use a controlled vocabulary for indexing records. Sometimes controlled vocabularies are used but do not include terms that adequately cover the search concept(s), which often*	Thank you for your comment. We entirely agree that it is important for search strategies to be comprehensive. For this question we were only interested in studies looking at the implantation of tinted lenses after cataract surgery. A search strategy comprised of just those two concepts was agreed to be the most sensitive and appropriate one to use. Including AMD in the search strategy, for example in the form of: "Terms for cataracts AND terms for macular degeneration AND terms for tinted lenses"

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				cross a number of disciplines. In addition, the use of natural language varies between studies, and concepts may not be described in a consistent way. ***In light of these challenges, the development of a search strategy should always be an iterative process between the information specialist(s), the Developer and, when necessary, the Committee and NICE staff with a quality assurance role*** (emphasis added).[17] RQ20 considers the effectiveness of BLF IOLs in delaying the onsets of AMD. Thus, AMD should be at the heart of research for evidence to answer the very question. Therefore, it is inappropriate to completely omit the term from the search strategy entirely. This may have prevented the Committee from taking into account relevant evidence and overstating the importance of other evidence. **Clarification Question:** Please could you explain why the terms "age-related macular degeneration" or AMD were excluded as search terms from the search strategy? **Reference:** [17] Manual, page 84.	will retrieve only a subset of the papers found in the search undertaken. A search containing only terms for cataracts and macular degeneration would therefore not be appropriate since this would not be focused on the specific interventions of interest in this review. NICE has a number of approaches to ensuring relevant papers are not missed in reviews, including assessing papers raised by stakeholders through the consultation process. No additional relevant randomised controlled trials have been brought to our attention through any of these methods, and we are therefore confident that no important information has been excluded from the review.

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Alcon Eye Care UK	Appendix E: Evidence tables	240	General	Quality of Evidence We would like to draw attention to the Meta-analysis of postoperative colour vision in the blue light spectrum under mesopic light condition conducted in Zhu et al. (2012) and a number of methodological problems inherent in this analysis, as follows: 1. Substantial heterogeneity. 2. Lack of a Prospective Analysis Protocol 3. Omission of raw data used to arrive at summary estimates 4. Multiplicity 5. Selection bias 6. Measurement bias • **Heterogeneity** ➢ Firstly, we would like to point out that there was a substantial level of heterogeneity present in this meta-analysed data (I-squared of 61.7%), more than should be considered acceptable for guideline development. According to the Cochrane Handbook: "50% to 90%: may represent substantial heterogeneity" ➢ To further expand on this point, in Greco et al. (2013), the authors make the point that when high heterogeneity is evident, individual data should be not pooled and definitive conclusions	Thank you for your comment. The committee agreed that there were a number of methodological limitations with the Zhu study, Therefore, rather than respond to each of these points individually, they agreed the most robust approach was to remove the Zhu review as a source of data, and redo the meta-analysis and quality assessment based on the underlying primary studies. This reanalysis has now been completed, and all results reported in the guideline are now based on an analysis of the primary papers, not on the Zhu review. As a consequence of this reanalysis, there are now no significant differences (in either benefits or harms) between blue-light and ultraviolet-light filtering lenses, other than a difference in colour vision under mesopic light conditions. Please note: the recommendations around lens design and material have been removed to allow for further consideration.

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				should be drawn when more studies become available. • **Lack of a Prospective Analysis Protocol** ➢ In addition, we would like to draw attention to the fact that a prospective analysis protocol, which should specify the objectives of the analysis, and which methods are going to be used appears to be missing in Zhu et al. (2012). The PRISMA (Preferred Reporting Items Systematic Reviews and Meta-Analysis) guidelines recommend the prior registration of this protocol of any systematic review and meta-analysis. ➢ The paper by Zhu et al. (2012) does not mention such a prospective protocol, and therefore it is our considered view that it is very possible that the analyses pursued may have been driven by the results they were seeing as they looked through the data. To ensure rigorous methodological approach a priori factors should be identified which are likely to influence the treatment effects. This is also not documented in the Zhu et al. (2012) paper. ➢ **Omission of raw data** • It is unclear from the paper exactly how the estimate of treatment effect was derived for each study. In order to make the analysis reproducible,	

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				a meta-analysis should present the actual raw data from each paper in addition to the derived summary estimate used in the meta-analysis (Liberati et al. 2009). For example, for colour vision plots (Figures 6 and 8) Neumaier et al. (2012) is represented twice (with different estimates) on the forest plots. There is no indication in the paper what these two assessments mean. • **Multiplicity** ➢ In addition, we would also like to draw attention to the issue of multiplicity, which is clearly present in the Zhu et al. (2012) analysis: Nine separate tests of significance were conducted in this paper. As more and more of these tests are conducted, the chance that at least one of those tests gives an incorrect conclusion increases. When 9 tests of significance at the alpha=0.05 level are conducted the actual overall Type I error (alpha) is no longer 5% (0.05), but rather 36.9%. That is, there is approximately 37% chance that one of those 9 conclusions is incorrect. So the fact that 1 of the 9 showed a significant result is possibly due to chance alone rather than there actually being a difference between BLF IOLs and other IOLs under mesopic conditions. • **Measurement & Selection bias**	

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				➢ We would like to draw to the Committee's attention that this subgroup meta-analysis is subject to both measurement bias and selection bias, as is detailed in the Zhu et al. paper: "***different follow-up times*** and less reporting of postoperative visual adverse events ***could cause selection bias***. Several studies lacked sufficient data for analysis, ***or involved different measurement methods, or used different units of measurement,*** or not used a standard questionnaire to assess: ***all of these could cause measurement bias".*** • Measurement bias: ➢ Estimates were pooled from two different measurement scales (Roth 28 hue test & the Farnsworth-Munsell test). ➢ The number of errors were assessed in different units and levels of mesopic conditions [(Wang et al. (2010): 30 lux; Neumaier-Ammerer et al. (2010): 10 lux; Mester et al. (2008): 3 cd/m2)]. • Selection bias: ➢ The data used to assess colour vision in mesopic conditions was extracted at different follow-up times (Wang et al. (2010): 3 months; Neumaier-	

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				Ammerer et al. (2010): 2 months; Mester et al. (2008): 12 months). ➢ This is particularly concerning given the time it takes for the adaptation of the visual system post-cataract surgery Delahunt et al. (2004) (This point is further elaborated on in comment 16) Further, it is unclear how exactly the standard mean differences were arrived to n the Zhu et al. (2012) paper. We would like to ask the Committee to provide such information and also comment on the fact the 2 out of the 4 estimates arrived at in the meta-analysis were non-significant: Neumaier-Ammerer et al. (2010) [SMD=0.55, 95%CI (-0.11, 1.21)] Mester et al. (2008) [SMD=0.37, 95%CI (-0.09, 0.83)] As reflected on above, this study has inherent methodological flaws which brings into question the robust nature of the results presented in Zhu et al. (2012) and by association the validity of the recommendation "do not use blue-light filtering intraocular lenses in cataract surgery, unless as part of a research study". On the basis of the above we ask the Committee to exclude the Zhu et al. (2012) study from this review. **References:**	

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				(28) GRECO, T., ZANGRILLO, A., BIONDI-ZOCCAI, G. & LANDONI, G. 2013. Meta-analysis: pitfalls and hints. Heart Lung Vessel, 5, 219-25. (29) Cochrane Handbook: 9.5.2 Identifying and measuring heterogeneity http://handbook.cochrane.org/chapter_9/9_5_2_identifying_and_measuring_heterogeneity.htm (30) LIBERATI, A., ALTMAN, D. G., TETZLAFF, J., MULROW, C., GØTZSCHE, P. C., IOANNIDIS, J. P. A., CLARKE, M., DEVEREAUX, P. J., KLEIJNEN, J. & MOHER, D. 2009. The PRISMA statement for reporting systematic reviews and meta-analyses of studies that evaluate healthcare interventions: explanation and elaboration. BMJ, 339.	
Alcon Eye Care UK	Full	General	General	<u>Development of the Review Question</u> We are aware that the exact details of a guideline's scope may only become clear during the consultation and development process and new areas might be identified for investigation. However, we have concerns about the timing and scoping of review question 20. **Factual Background:** We set out below our understanding of the background to the review question and recommendation.	Thank you for your comments. We can confirm that the timelines you set out are correct. It is important to note that the 'key issues and questions' section of the scope is not an exhaustive list of all the questions that will be covered in the guideline, but rather a list of key questions identified at that stage, which are subject to further change and refinement by the guideline committee. We would draw your attention to section 1.3 of the final scope (key areas that will be covered). One of the issues listed in the section is 'selection and types of

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				In 2014, the Department of Health requested that the National Institute for Health and Care Excellence ("**NICE**") develops a Guideline on cataracts in adults: management (the "**Guideline**"). NICE convened the Committee to develop the Guideline. Between 25 February and 25 March 2015, the Committee consulted on a draft scope for the Guideline ("**Draft Scope**"). *Section 1.5 - Key issues and questions* of the Draft Scope contained 32 questions[1]. These questions did not cover the effects of tinted lenses in preventing progression of AMD. The responses from stakeholders also did not address this point. According to the Committee's meeting minutes of 8 July 2015: *"The group finalised the review questions and agreed the associated review protocol."* According to these minutes, there were 34 review questions[2]. Based on the minutes from subsequent meetings we assume that the Committee decided to add four questions to the 34 review questions it had initially agreed. We suspect that this included what is now review question 20 ("**RQ20**"): *"Are tinted lenses effective in preventing the progression of age-related macular degeneration compared with colourless lenses in cataract surgery?"* Subsequent meeting minutes from 14 March 2016 indicate that the Committee passed the review protocol for RQ20 on this date[3].	intraocular lens.' The question of blue-light versus ultraviolet-light filtering lenses is clearly contained within the question of appropriate intraocular lens selection, and therefore the question included does fall within the published scope of the guideline.

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				The meeting minutes of 20 July 2016 show that RQ20 was presented and that the Committee ***drafted one research recommendation"*** (emphasis added)[4]. We note that these notes only refer to a research recommendation and are silent to any other recommendations. Subsequently, on 12 August 2016, the Committee published a final scope ("**Final Scope**") which consisted of 34 questions in *section 1.5 Key issues and questions*[5]. The Final Scope **did not** include RQ20. During its meeting on 16 December 2016, the *"Committee reviewed the recommendations drafted at a previous meeting concerning intraocular lenses and redrafted these as a result of the discussion."*[6] On 12 May 2017, the Committee published its draft guidance for consultation (the "**Draft**"). The Draft considers tinted and colourless lenses on pages 107 to 111. The Committee reviewed the evidence provided on RQ20 and, as a result, made the following recommendations: • *"Recommendations: 22. Do not use blue-light filtering intraocular lenses in cataract surgery, unless as part of a research study."* ("**Recommendation 22**")	

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				• *"Research Recommendations: 9. What is the long-term effectiveness of blue light filtering IOLs in reducing the incidence and/or progression of age-related macular degeneration?"* ("**Research Recommendation 9**") Further, on 24 May 2017, the Committee published a document entitled "Cataracts in adults: management Review questions"[7]. This document covered 38 review questions, including RQ20. Our understanding is that this document covers the final 38 review questions. We note that this was initially published on 5th April 2017 as part of the pre-consultation documents; the versions however, are identical. We consider that in arriving at Recommendation 22, the Committee failed to act in accordance with NICE procedures, including the NICE manual on "Developing NICE guidelines"[8] (the "**Manual**"), as we will explain in more detail below in the sections to follow. **Clarification Question:** Given the general lack of transparency of the process, we experienced some difficulty piecing this together, we therefore would be grateful if you could confirm that the facts outlined above are correct. **References:**	

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				[1] https://www.nice.org.uk/guidance/gid-cgwave0741/documents/cataracts-draft-scope2. [2] https://www.nice.org.uk/guidance/gid-cgwave0741/documents/minutes. [3] https://www.nice.org.uk/guidance/gid-cgwave0741/documents/minutes-16. [4] https://www.nice.org.uk/guidance/gid-cgwave0741/documents/minutes-19. [5] https://www.nice.org.uk/guidance/gid-cgwave0741/documents/final-scope-2. [6] https://www.nice.org.uk/guidance/gid-cgwave0741/documents/minutes-21. [7] https://www.nice.org.uk/guidance/gid-cgwave0741/documents/review-questions-2. [8] https://www.nice.org.uk/process/pmg20/chapter/introduction-and-overview.	

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Alcon Eye Care UK	Full	General	General	<u>Failure to allow Stakeholders to comment on the change in Scope or submit evidence</u> Not only was the decision to introduce RQ20 outside the Final Scope procedurally unfair, it is compounded by the subsequent failure to allow stakeholders to comment on the expanded Final Scope or submit evidence on an issue that has resulted in a significant negative recommendation for BLF IOLs. Although comments on amendments to refine the scope are not "generally allowed" according to the Manual, this would be an exception since, as already indicated above, the inclusion of RQ20 is a such a fundamental departure from the Final Scope. According to the Manual, the Committee may invite stakeholders "*with a significant role or interest*" to submit evidence, where there is reason to believe that there is *"relevant evidence in addition to that identified by searches."*[14] In its assessment, the Committee acknowledges that there is a lack of evidence "*on the long term effectiveness of blue light filtering lenses with regard to the incidence or progression of age-related macular degeneration.*" The absence of evidence is not surprising given that any use of BLF IOLs to prevent or slow the progression of AMD is not based on the approved indication for use. In the absence of sufficient evidence, the Committee should	Thank you for your comment. As discussed above, we have reviewed the process and can confirm that no procedural rules have been violated by the inclusion of a question on blue-light filtering lenses with the 'selection and types of intraocular lens' section of the published scope, nor do we agree its inclusion represents a change to that published scope. The committee was satisfied (as detailed in the evidence to recommendations section of this chapter) the evidence available from RCTs would not be significantly improved by the inclusion of additional observational evidence. The committee therefore agreed not to expand the review to include non-RCT evidence, and not to conduct a call for evidence for this review question. However, notwithstanding the process points detailed above, the committee has reconsidered the evidence on blue-light lenses as a result of a reanalysis of the data (excluding the Zhu meta-analysis as a source of data). As a consequence of this reanalysis, there are now no significant differences (in either benefits or harms) between blue-light and ultraviolet-light filtering lenses other than a difference in colour vision under mesopic light conditions.

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				have requested additional evidence or comments from relevant stakeholders and we believe the Committee acted unreasonably in failing to do so. **Reference:** [14] Manual, page 86.	Please note: the recommendations around lens design and material have been removed to allow for further consideration.
Alcon Eye Care UK	Full Appendix E: Evidence Tables	General	General	<u>Assessment of Relevant Evidence</u> It was unreasonable for the Committee to limit itself by relying only on data from RCTs. Given that use of BLF IOLs to prevent, or slow the progression of AMD is not based on the approved indication for use for which the products have been developed, it is understandable that there is a lack of RCT data to support this. Moreover, unlike the pharmaceutical sectors, it is not unusual for companies not to generate RCT data supporting the performance and effectiveness of many medical devices. This is because the EU Medical Devices Directive 93/42/EC allows companies to combine their own study data and data from the peer-reviewed literature when compiling a device's technical file. It was therefore unreasonable for the Committee to rely only on RCT data for its assessment. Moreover, the review protocol specifies that the Committee should have considered RCT and	Thank you for your comment. This protocol was written such that comparative observational studies would only be included if no data from randomised controlled trials were identified. Since randomised controlled data were identified, observational data were therefore not included. The committee discussed whether additional observational study data were likely to be valuable on top of the RCTs identified, and decided they would not add sufficiently to decision making. This decision is captured in the evidence to recommendations section of this chapter. However, notwithstanding this point, the committee has reconsidered the evidence on blue-light lenses as a result of a reanalysis of the data (excluding the Zhu meta-analysis as a source of data). As a consequence of this reanalysis, there are now no significant differences (in either benefits or harms) between blue-light and ultraviolet-light filtering lenses other than a difference in colour vision under mesopic light conditions.

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				comparative observational data, seemingly acknowledging that there might not be sufficient RCT data to make an appropriate assessment. The Manual also envisages that the Committee should use non-RCT data when RCT data are unavailable, *e.g.*: "*the type of evidence that gives the best 'fit' depends on the type of question. For example, a randomised controlled trial is often the most appropriate type of study to assess the efficacy or effectiveness (including cost effectiveness) of an intervention.* ***However, other study designs (including observational, experimental or qualitative) may also be used to assess effectiveness, or aspects of effectiveness.*** *These may include ways of delivering services, or the experience of people using services and how this contributes to outcomes. For some topics, there is* ***little evidence from scientific studies,*** *or the evidence is weak or contradictory. In these cases, we* ***look for evidence from other sources*** *to see if it concurs or differs ('triangulation')"* (emphasis added).[19] The Manual further clarifies: *"****RCTs*** *provide the most valid evidence of the effects of interventions. However,* ***such evidence may not always be available****. In addition, for many health and social care interventions it can be difficult or unethical to assign populations to control and intervention groups (for*	Please note: the recommendations around lens design and material have been removed to allow for further consideration.

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				example, for interventions which aim to change policy)" (emphasis added).[20] The Manual discusses various sources that the Committee may consider in the review. It is clear that much depends on the nature and scope of the guideline, as well as the available evidence. For example, the Manual states that in some circumstance a small number of sources may suffice. However, when assessing *e.g.* complex interventions, "*evidence may be more widely scattered across sources.*"[21] The Manual covers a range of sources, ranging from scientific to colloquial literature. It also acknowledges that while "*NICE prefers data from head-to-head RCTs to compare the effectiveness of interventions*"; such data may not always be available. In that case, the Committee may need to rely on "*indirect treatment comparison.*"[22] The Committee may also consider conference abstracts. These rarely contain sufficient information to judge their value. Nevertheless, they may contain other relevant information.[23] Specifically, on review questions on the effectiveness of a certain intervention, the Manual states: "*it may be more efficient to search for systematic reviews, followed by controlled trials followed by observational studies. This prevents unnecessary searching and review work."*[24] Given the clear basis for relying on non-RCT data not just	

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				in the general procedural guidance but also the review protocol itself, ignoring such evidence is inappropriate. **References:** [19] Manual, page 15. [20] Manual, page 63. [21] Manual, page 81. [22] Manual, page 103. [23] Manual, page 92/93. [24] Manual, page 84.	
Alcon Eye Care UK	Full	General	General	<u>Transparency</u> The Committee failed to act in a transparent manner when arriving at the draft recommendations. Under general principles of public law, public bodies need to act in a fair and transparent manner. In addition, according to the Manual: *"[w]hen developing guidelines, NICE involves people who might be affected by the guideline recommendations in a collaborative and transparent way."*[57]	Thank you for your comment. The inclusion of a review question on blue-light filtering lenses within the 'selection and types of intraocular lens' area of the scope was discussed and agreed by the whole guideline committee, and the wording of this question was published as part of the pre-consultation documents in April 2017. The committee's reasoning for both the recommendation and research

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				As we have noted above, the meeting minutes suggest that the Committee decided to add RQ20 during one of its meetings. However, the minutes do not record (1) who proposed additional review questions; (2) the exact wording of these questions and (3) any discussions about them that might explain how this came about. Moreover, we note that the Committee approved Research Recommendation 9 during its meeting on 20 July 2016. However, during its meeting on 16 December 2016, the Committee amended the recommendations in relation to RQ20 *"as a result of the discussion."* However, it is not clear (1) which circumstances lead the Committee to revisit this point and (2) the discussions on this point that ultimately lead to the change in the recommendations. The lack of reasoning and inability for Alcon to submit comments and evidence on these matters lacks transparency. **Reference:** [57] Appendix D to the Manual, para. 38.	recommendation made are detailed in the evidence to recommendations section of that chapter. However, notwithstanding the process points detailed above, the committee has reconsidered the evidence on blue-light lenses as a result of a reanalysis of the data (excluding the Zhu meta-analysis as a source of data). As a consequence of this reanalysis, there are now no significant differences (in either benefits or harms) between blue-light and ultraviolet-light filtering lenses other than a difference in colour vision under mesopic light conditions. Please note: the recommendations around lens design and material have been removed to allow for further consideration.
Alcon Eye Care UK	Full	648 - 650	139	We are concerned that the current version of the guideline does not fully recognize the potential advantages of innovative femto-laser assisted cataract surgery (FLACS). FLACS brings advances to conventional phacoemulsification surgery with multiple studies supporting improved precision and accuracy, as	Thank you for your comment. The randomised controlled trial evidence considered in the thoroughgoing systematic review for this guideline, including a Cochrane review, does not support the conclusion of some cohort studies that "Femtosecond laser technology has the potential to improve safety,

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				well as improved treatment outcomes of cataract surgery. FLACS technology is continuously evolving and has the potential to be the gold standard of cataract surgery in the future (Ranka and Donnenfeld 2015). The 2016 American Academy of Ophthalmology (AAO) preferred practice pattern guidelines have acknowledged "Femtosecond laser technology has the potential to improve safety, accuracy, and clinical outcomes". We are therefore concerned that the draft recommendation to not use FLACS outside a research setting inhibits innovation in the NHS, preventing patients from benefiting from such technology. We therefore ask that the 'evidence to recommendation' section for laser assisted cataract surgery (section 10.1.6, page 137) be updated to reflect that although the evidence to support widespread implementation of Femtosecond laser cataract surgery into the NHS is still being generated, the benefits of FLACS have been demonstrated in complex cases, such as in patients with low endothelial cell-counts (Chen et al. (2016); Kohnen et. al., 2016) and/or with dense cataracts (Roberts et al. (2016), as well as in patients benefitting from enhanced precision and accuracy (Roberts et al., 2016). **References:**	accuracy, and clinical outcomes". We are aware that 2 large RCTs (FACT and FEMCAT), at least 1 of which will include a parallel economic analysis, are due to publish in 2018. Details of both have been passed to the NICE surveillance team, and there are processes by which a rapid, targeted update of that part of the guideline can be undertaken, should that new evidence imply the recommendations need to be reviewed. It is important to emphasise that the decision to recommend FLACS in research was also a reflection of the economic evidence that does not support the technology as a cost-effective alternative to standard surgical approaches.

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				(84) RANKA, M., DONNENFELD, E.D. 2015. Femtosecond laser will be the standard method for cataract extraction ten years from now. Survey of ophthalmology, 60(4), 356–60. (85) OLSON, R. J., BRAGA-MELE, R., CHEN, S. H., MILLER, K. M., PINEDA, R., II, TWEETEN, J. P. & MUSCH, D. C. 2017. Cataract in the Adult Eye Preferred Practice Pattern. Ophthalmology, 124 (2), P1-P119. (86) CHEN, X., CHEN, K., HE, J.,YAO, K. 2016. Comparing the Curative Effects between Femtosecond Laser-Assisted Cataract Surgery and Conventional Phacoemulsification Surgery: A Meta-Analysis.PLoS One, 11(3):e0152088. (87) KOHNEN T, ET AL. Metaanalysis and systematic review of femtosecond laser lens surgery and conventional lens surgery: a systematic review and meta-analysis (2016) Conference abstract: European Society of Cataract and Refractive Surgeons meeting 10/09/16 (88) ROBERTS, T.V., LAWLESS, M., SUTTON, G. AND HODGE, C., 2016. Update and clinical utility of the LenSx femtosecond laser in cataract surgery. Clinical Ophthalmology (Auckland, NZ), 10, 2021-2029.	

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Alcon Eye Care UK	Full	24	523	We welcome the overall approach being taken by the Guidelines Development Committee in relation to these guidelines, and we are pleased with the recommendation that there should be no visual acuity thresholds for referral for cataract surgery. This is an important and progressive step that will mean better outcomes for patients in the NHS.	Thank you for your comment and endorsement of the recommendation.
Alcon Eye Care UK	Full	25	581 - 582	We would like to highlight that 'on-axis' incisions may not be the most effective treatment strategy for the correction of pre-operative corneal astigmatism in cataract patients. 'On-axis' incisions are difficult to perform as they require uncomfortable surgical positioning and can only minimally correct astigmatism (Rubenstein et al., 2013). The evidence base to support their effectiveness in the correction of pre-operative corneal astigmatism is quite sparse, based only on 1 RCT (page 124, section 8.4.6.3). We are concerned that by implementation of these recommendations astigmatic cataract patients in the NHS will not be provided the opportunity to make informed decisions on the existing treatment options for astigmatism correction. Furthermore, findings from a large longitudinal retrospective database study using NHS, UK cataract surgery data (Anderson DF et al., 2017) indicates that 'on-axis' surgery is performed only in 24% of cases, reflecting that this procedure is not an option preferred by surgeons in the NHS for the correction of pre-operative	Thank you for your comment. The committee agreed that the evidence base for 'on-axis surgery' (as well as that for LRIs) was not particularly strong, and therefore agreed it was only appropriate to make this recommendation at the 'consider' level. They further agreed that they may not be appropriate for all individuals. However, with the committee feeling it was not appropriate that toric lenses be recommended for routine use (due to a lack of evidence on their cost-effectiveness) the committee agreed that it was important to raise awareness of other surgical techniques that may help to manage post-operative astigmatism.

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				astigmatism in cataract patients. In addition, this study demonstrated that although 'on-axis' incision surgery does not induce astigmatism, it is not effective in correcting pre-operative corneal astigmatism. **Reference:** (74) RUBENSTEIN, J.B., RACITI, M. et al. 2013. Approaches to corneal astigmatism in cataract surgery. Curr Opin Ophthalmol, 24, 30–34.	
Alcon Eye Care UK	Full	25	581 - 582	We would like to highlight that corneal incisional surgical methods (OCCI, LRI/PCRI) may not be the most effective treatment strategy for the correction of pre-operative corneal astigmatism in cataract patients. The evidence base to support their effectiveness in the correction of pre-operative corneal astigmatism is quite sparse, based only on 1 RCT (page 123, section 8.4.6.2). We are concerned that by implementation of these recommendations astigmatic cataract patients in the NHS will not be provided the opportunity to make informed decisions on the existing treatment options for astigmatism correction. Furthermore, studies outlined below indicate that LRIs are effective only in cataract patients with low levels of astigmatism, are associated with complications, and have a less predictable effect in the post-operative phase.	Thank you for your comment. The committee agreed that the evidence base for 'on-axis surgery' (as well as that for LRIs) was not particularly strong, and therefore agreed it was only appropriate to make this recommendation at the 'consider' level. They also agreed that they may not be appropriate for all individuals. However, despite not recommending toric lenses for routine use (due to a lack of evidence on their cost-effectiveness) the committee agreed that it was important to raise awareness of other surgical techniques that may help to manage post-operative astigmatism. The committee noted that the benefits of these techniques (in particular in people with higher levels of astigmatism) were unlikely to be as great as those

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				• Amesbury and Miller (2009) reported that PCRIs are useful only for treating a small amount (1–1.5 D) of astigmatism in cataract patients. They highlight that the risks associated with PCRI/LRIs outweigh their benefits when used to correct PEA >1.5D. • Saragoussi et al. (2012) reported that astigmatism correction with PCRI/LRIs may not be predictable due to the variations in corneal wound healing at the corneal epithelium level • Findings from a RCT in astigmatic cataract patients show that LRI/PCRIs are effective only in patients with low degrees of astigmatism (<1.5D) and effectiveness may wane over time (Liu et al., 2014). Indeed, the potential negative effects and limitations associated with surgical interventions such as LRIs, as outlined above, may be responsible for low application of LRIs/PCRIs/OCCIs in the NHS. Findings from a recently completed large longitudinal retrospective database study using NHS, UK cataract surgery data (Anderson DF et al.; 2017) indicate that LRIs/PCRIs/OCCIs are recorded in less than 1% of a selected sample of eyes undergoing cataract surgery between 2005-2015. The 2010 cataract surgery guidelines by the Royal College of ophthalmologists, UK also noted "for astigmatism correction, incisional surgery may be less predictable in both effect-size and stability than toric implants".	seen with toric lenses, but agreed that the absence of the significant additional costs associated with toric lenses meant that they were likely to represent a more cost-effective option.

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				References: (75) AMESBURY, E.C., MILLER, K.M. 2009. Correction of astigmatism at the time of cataract surgery. Curr Opin Ophthalmol, 20, 19–24. (76) RUBENSTEIN, J.B., RACITI, M. et al 2013. Approaches to corneal astigmatism in cataract surgery. Curr Opin Ophthalmol, 24, 30–34. (77) SARAGOUSSI, J. 2012. Preexisting astigmatism correction combined with cataract surgery: Corneal relaxing incisions or toric intraocular lenses? J Fr Ophtalmol, 35(7), 539-45. (78) LIU, ZHIPING, et al. Toric intraocular lens vs. peripheral corneal relaxing incisions to correct astigmatism in eyes undergoing cataract surgery. 2016. *眼科学报* 29.4, 198-203.	
Alcon Eye Care UK	Full	25	571	In addition we are pleased to see the recommendation to offer square-edged hydrophobic acrylic lenses to people having cataract surgery, to reduce the risk of posterior capsule opacification. The thorough analysis done by the Committee is complemented and supported by a recently completed multicentre, retrospective cohort study using	Please note: the recommendations around lens design and material have been removed to allow for further consideration.

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				anonymised electronic medical records of 52,000 eyes from 39,000 cataract patients from a selected sample of 7 NHS (National Health Service) ophthalmology clinics across the UK. **References:** (1) Ursell P et al. (2017) A multicentre, retrospective cohort study comparing the real-world incidence of Nd:YAG laser capsulotomy procedure to treat posterior capsular opacification (PCO) in the first 3 years after cataract surgery among hydrophobic and hydrophilic acrylic monofocal intra-ocular lenses (IOLs). Abstract submitted and accepted for presentation at ESCRS 2017. Manuscript in development. Target journal: Journal of cataract and refractive surgery. Study report available to the committee on request (commercial in confidence).	
Alcon Eye Care UK	Full	25	576	We are concerned with the negative recommendations on the use of multifocal IOLs in the NHS. Multifocal IOLs can provide improved vision at all distances and correct the symptoms of presbyopia after cataract surgery (de Silva et al., 2016, Rosen et al., 2016). The Cochrane meta-analysis which synthesized the evidence from different randomized clinical trials concluded that multifocal IOLs significantly improved	Thank you for your comment. The committee agreed that there are established additional costs associated with multifocal lenses (both the costs of the lenses themselves, and additional pathway costs). The clinical evidence does demonstrate some benefits with multifocal lenses (e.g. increased spectacle independence) but also some harms such as an increase in glare and halos. In the absence of robust evidence on outcomes such as quality of life, that

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				uncorrected near vision vs. monofocal IOLs, without compromising distance vision (de Silva et al., 2016) The spectacle independence achieved with multifocal IOLs is sustained over long-term (de Silva et al., 2016, Rosen et al., 2016). We are concerned that although many NHS cataract patients may want to achieve greater spectacle independence following cataract surgery, they would not have the access to multifocal IOLs due to these negative recommendations. Patients' options during cataract surgery are therefore limited to monofocal IOLs making them highly depending on spectacles for post-operative vision correction. **References:** (58) DE SILVA, S. R., EVANS, J. R., KIRTHI, V., ZIAEI, M. & LEYLAND, M. 2016. Multifocal versus monofocal intraocular lenses after cataract extraction. The Cochrane Library. (59) ROSEN, E., ALIÓ, J. L., DICK, H. B., DELL, S. & SLADE, S. 2016. Efficacy and safety of multifocal intraocular lenses following cataract and refractive lens exchange: Metaanalysis of peer-reviewed publications. Journal of Cataract & Refractive Surgery, 42, 310-328.	would enable the trade-offs between these benefits and harms to be quantified, the committee agreed that the current evidence base did not support multifocal lenses as being a cost-effective use of NHS resources.

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Alcon Eye Care UK	Full	25	581	We support the Committee recommendations to correct pre-operative corneal astigmatism in cataract patients in the NHS. Uncorrected astigmatism post-cataract surgery affects visual and refractive outcomes, leads to higher spectacle dependence; and is associated with low satisfaction with vision which could in turn affect patient's vision related quality of life. Available evidence suggests that pre-operative corneal astigmatism is one of the most prevalent refractive errors in cataract patients. Findings from a recently completed longitudinal (2005-2015) retrospective database study conducted on >110,000 eyes using NHS, UK cataract surgery data (Anderson DF et al.; 2017) indicate that: • There is a significant burden of pre-operative corneal astigmatism in the UK cataract population. 78% of eyes presenting for cataract surgery in the NHS have pre-operative corneal astigmatism ≥0.5D, 42% ≥1.0D, and 11% ≥2.0D. • Post-cataract surgery 90%, 58% and 16% of eyes had post-operative residual astigmatism of ≥0.5D, ≥1.0D and ≥2D, respectively. • These data indicate that astigmatism is currently not addressed in the NHS during cataract surgery and that post-operative astigmatism may potentially worsen compared to pre-operative astigmatism levels.	Thank you for your comment. The committee agreed it was important to correct pre-existing astigmatism using any techniques that represented a cost-effective use of NHS resources. The importance of appropriate management of astigmatism is supported by the references provided.

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				• Post-operative residual astigmatism is associated with poorer post-operative UDVA which may adversely impact vision related quality of life in patients. In addition, Kim et. al. (2010) reported that post-operative residual astigmatism in age-related cataract patients is associated with indirect productivity loss and high spectacle burden. **References:** (72) ANDERSON, D.F., DAY, A.C., DHARIWAL, M. et al. Residual Post-Operative Astigmatism in Cataract Patients Implanted with Standard Monofocal Intraocular Lenses (IOLs) in the UK. Poster presented at 2017 Annual Royal College of Ophthalmologists Congress, Liverpool, UK. Manuscript in submission to JCRS journal) Study report available on request (commercial in confidence). (73) KIM, H., LIM, S., CHO, B. et al. Astigmatism and Cost of Post-Cataract Surgery Spectacle wear in Korea. Published in 4th Asia Pacific Conference; Abstract #PSS6:A563.	
Alcon Eye Care UK	Full	27	648 - 650	Due to the clinical benefits associated with FLACS (decreased Endothelial Cell Loss (ECL) and reduced phaco energy and effective phacoemulsification time(EPT)), we are of the considered view that individual	Thank you for your comment. The decision to recommend FLACS only as part of a trial reflects the economic evidence which does not at the time of

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				NHS trusts assess affordability of FLACS technology based on their own pathway and negotiated pricing agreements with manufacturers.	writing support FLACS as a cost-effective option for cataract surgery. If alternative funding arrangements are available, making these publically available for inclusion in a health economic model this would enable the cost-effectiveness of FLACS to be examined based on these pricing structures. No evidence of meaningful clinical benefit of FLACS compared to standard phacoemulsification approaches was identified.
Alcon Eye Care UK	Full	27	648 - 650	Due to the clinical benefits associated with FLACS (decreased Endothelial Cell Loss (ECL) and reduced phaco energy and effective phacoemulsification time (EPT)), we are of the considered view that individual NHS trusts assess affordability of FLACS technology based on their own pathway and negotiated pricing agreements with manufacturers.	Thank you for your comment. It should be noted that the decision to recommend FLACS only as part of a trial reflects the economic evidence which does not at the time of writing support FLACS as a cost-effective option for cataract surgery. If alternative funding arrangements are available, making these publically available for inclusion in a health economic model this would enable the cost-effectiveness of FLACS to be examined based on these pricing structures. No evidence of meaningful clinical benefit of FLACS compared to standard phacoemulsification approaches was identified.
Alcon Eye Care UK	Full	107	2544 - 2545	Review Question 20 is out of the Final Scope	Please note: the recommendations around lens design and material have been removed to allow for further consideration.

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				RQ20 was not part of the Draft Scope that stakeholders commented on between 25 February and 25 March 2015, which covered 32 questions. The Final Scope included 34 questions, but not RQ20. It appears that the Committee added RQ20 during its meeting on 2 September 2015. However, the discussions and rationale for adding RQ20 are not clear from the meeting minutes. The Manual states that *"[o]nce the final scope has been published no changes should be made to it except in exceptional circumstances."*[9] A Committee may however make amendments in circumstances of policy change, withdrawal of a medicine from the market or inclusion of a NICE technology appraisal in development. Under such circumstances, a senior member of NICE staff responsible for quality assurance makes the decision to amend the scope based on advice from the Committee or developer. Notably, "*[i]f a final scope is amended after publication, registered stakeholders are informed and the revised scope is published on the NICE website. No further consultation on the scope would usually be expected."*[10] According to the Manual: "*[r]eview questions guide a systematic review of the literature. They address only the* ***key issues and questions covered in the scope of the guideline****, and will usually be structured with a framework (for example, using PICO or SPICE)"* (emphasis added). We appreciate that the Manual allows a Committee to	

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				"*translate*"[11] the scope into review questions, as well as to "*refine and agree review questions.*"[12] However, the Manual is also clear that the *"review questions should cover all areas specified in the scope but should not introduce new areas. They will often build on the key questions in the scope and usually contain more detail."*[13] The Final Scope covers "*optimal treatment strategies in cataract surgery*" as a key issue. Specific questions under this heading touch upon the effectiveness of different lens designs in comparison with each other. The Final Scope envisaged 34 questions but the final number of review questions is 38. However, we note that none of the questions covers BLF IOLs, nor do they address delay in the onset or progression of AMD following cataract surgery. Therefore, we consider that by adding RQ20, the Committee did not "*refine*" an area already covered in the Final Scope but have in fact expanded the scope of the guideline. A senior NICE official should have approved such an amendment of the scope and the Committee should have posted the amendment on the relevant NICE website. In failing to do so, the Committee failed to follow NICE procedures. Moreover, because delaying the onset or progression of AMD falls outside the BLF IOLs' (or clear IOLs) approved indications for use, there are arguments that NICE should also have consulted the MHRA before assessing them for that use. Although, the Manual is focussed on medicinal	

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				products, it states in relation to consultations on the Draft Scope: *"Comments are invited from registered stakeholders and respondents. In particular circumstances, comments will also be solicited from the relevant regulatory organisation; for example, the* ***Medicines and Healthcare products Regulatory Agency (MHRA), when the off-label use of medicines is likely to be considered within the guideline****, or when advice is required on regulations related to medicines"* (emphasis added).[1] We consider that NICE should adopt a similar approach before considering uses that are not reflected on the DFU of BLF IOLs. **Clarification Questions:** 1. Please could you provide an explanation as to how RQ20 was introduced at a later stage? 2. Please could you also explain why the Committee did not add it to the final scope published in August 2016, if it is correct that the Committee had already added RQ20 in September 2015?	

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				3. Please could you explain the Committee's rationale for introducing RQ20 at all? **References:** [1] https://www.nice.org.uk/guidance/gid-cgwave0741/documents/cataracts-draft-scope2 [9] Manual, page 39. [10] *Ibid.* [11] Manual, page 51. [12] Manual, page 41. [13] Manual, page 59.	
Alcon Eye Care UK	Full	107	2544 - 2545	The Review Question Notwithstanding our argument that RQ20 is outside the Final Scope, we also consider that RQ20 is too narrow. RQ20 focuses on the effectiveness of BLF IOLs in delaying the onset or progression of AMD only. However, the review protocol[15] and the draft Guideline make it clear that any analysis should also consider a number of other outcomes, including: • visual acuity;	Please note: the recommendations around lens design and material have been removed to allow for further consideration.

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				• colour vision; • sleep problems; • depression; • quality of life; and • resource use and cost. It was unreasonable for the Committee to base its question and the ultimate recommendation on such a narrow assessment of the effects on AMD and colour vision in poor light conditions, when there is a much wider range of relevant post-operation outcomes of BLF IOLs and clear IOLs. There is, for example, strong evidence that BLF IOLs reduce glare relative to their clear lens counterparts, as we have explained in comment 20 below. We note that the Manual defines "effectiveness"[16] as *"[t]he extent to which an intervention produces an overall benefit under usual or everyday conditions. In this manual effectiveness includes cost effectiveness unless otherwise indicated.*" The definition supports the view that any effectiveness review of a medicinal product or medical device should not be limited to one specific aspect but should cover a range of risks and benefits. Conducting such a narrow assessment was therefore also in breach of the Institute's procedures and in fact led to the inappropriate outcome that the Committee failed to answer the original question.	

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				References: [15] Appendix C to the Guideline, page 20. [16] Manual, page 218.	
Alcon Eye Care UK	Full	107 - 111	2542 - 2612	Opening comment As we have already stated, we welcome the overall approach being taken by the Guidelines Development Committee in relation to these guidelines, and we are pleased to see the recommendation that there should be no visual acuity thresholds for referral for cataract surgery. We also support the recommendations being made for lens material, in relation to post capsular opacification (PCO). These are important and progressive steps that will mean better outcomes for patients in the NHS. We do however have a number of significant concerns about the current draft guideline and draft recommendation made in section 8.2 *'Tinted vs colourless lenses'* in relation to blue-light filtering ("**BLF**") intraocular lenses ("**IOLs**"), This draft recommendation wrongfully forces BLF IOLs out of the UK market. Please note that for simplicity in this document we will refer to tinted lenses as **BLF IOLs** and colourless lenses as **clear IOLs**.	Please note: the recommendations around lens design and material have been removed to allow for further consideration.

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				Our significant concerns on the BLF IOLs recommendation fall into four main categories: <u>1. Inconsistencies in the Development of the Review Question</u> • The review question was introduced at a late stage in the guideline development process. • The review question envisages a use that is not within the indications for use of BLF IOLs. Moreover, it was not contained in the published draft or final scope documents, although it is clear from the Guidelines Development Committee (the "**Committee**") minutes on the NICE website that work has been consistently undertaken on this question between November 2014 (question scoping phase) to July 2016 (the final meeting before the final scope was published). • The scope of the review question is too narrow and outside the final scope of the guideline. • Stakeholders have not been afforded the opportunity to comment on the review question and to provide relevant evidence in response to the review question.	

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				This means that the Committee haven't followed a standard guideline development procedure and this has significantly disadvantaged stakeholders. 2. Shortcomings in the Conduct of the Research • The question – '*Are tinted lenses effective in preventing the progression of age-related macular degeneration compared with colourless lenses in Cataract surgery'* has general merit, but the approach used to explore the direct and wider evidence is of questionable justification. • The scope of this question was extended to the assessment of the evidence of comparative efficacy of BLF IOLs vs clear IOLs on visual capabilities including: visual acuity, sleep, colour vision and quality of life, which are of limited relevance to age-related macular degeneration ("**AMD**"). • This approach strays from the intent of the original review question and is inappropriate for the reason that BLF IOLs are not indicated for the prevention of AMD but for the replacement of the human lens to achieve visual correction of aphakia in adult patients following cataract and restore a more natural vision – as stated in various manufacturers' directions for use ("**DFU**").	

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				• The terms used to search for evidence for the age-related macular degeneration question appear not to include any of the following words; *'age-related', 'macular', 'degeneration'* or *'AMD'*. • It is however noticeable that the words *'colour vision'* were included in the search, suggesting a potential bias in the search terms. • The inclusion/exclusion of non-OECD papers appears to have been applied selectively and inconsistently. This means that the approach taken has fallen short of appropriate reasonableness and procedural fairness. <u>3. Procedural shortcomings in the selection of evidence</u> There are a number of inconsistencies in the approach to evidence selection: • The Committee took a very limiting approach to literature research. • The Committee limited itself to randomised clinical trials ("**RCTs**") only and failed to consider other relevant evidence, such as observational studies.	

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				• Specifically, in the AMD literature search two relevant papers have been overlooked. <u>4. Procedural shortcomings in the assessment of evidence</u> The review has not looked at the evidence reporting lower incidence of AMD in patients with BLF IOLs compared to clear lenses, or indeed any of the other positive effects of BLF IOLs for patients such as: • attenuating the impact of glare (which can be a disability when driving – a key outcome for this guideline based on the published scope), • better heterochromatic contrast threshold, • faster photostress recovery, • protection from potential damage caused by the short-wavelength light, which may have a role in ocular melanoma development. In their optical properties, BLF IOLs are very similar to middle aged natural human lenses, which they were designed to mimic. Other shortcomings: • The recommendation will drive inequality and unnecessarily limit choice for both patients and clinicians.	

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				• The recommendation was reached in a non-transparent manner. Below we will explore the full details of these areas of significant concern in the guidelines development. Finally, we wish to point out that for Alcon there is no cost difference and no reported safety concerns between clear versus BLF IOLs. We would further argue that BLF properties have a scientific rationale and merit and have been shown to result in patient-relevant benefits, while there is no conclusive evidence on the harms associated with colour vision. We are therefore strongly requesting that Recommendation 22 is rescinded subject to a review of the evidence we have proposed.	
Alcon Eye Care UK	Full	107 - 111	2542 - 2612	Concluding comments In concluding our comments, we would like to repeat our significant concerns regarding the way the guideline development process has been interpreted in relation to this section. We have identified above a number of procedural and substantive shortcomings in the development process and also highlighted situations	Please note: the recommendations around lens design and material have been removed to allow for further consideration.

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				where the recommendation is unreasonable in light of the available evidence. We would like to emphasise again the following points: The addition of a question not identified in the original scope, which has been developed into a wider range of outcomes not strictly linked to the original question is of considerable concern. The question: '*Are tinted lenses effective in preventing the progression of age-related macular degeneration compared with colourless lenses in Cataract surgery'* has inherent academic relevance and could be addressed initially through the assessment of existing published evidence and consulting relevant experts before taking steps to restrict access to safe and effective BLF IOLs. We have highlighted inconsistencies in the way evidence has been: • Searched for (absence of AMD search terms in the AMD strategic literature review). • Included and excluded (Comparative observational studies outlined in the study design yet excluded from the review) • Used when it does not meet accepted standards (stated quality flaws and certain biases).	

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				• Overlooked, when it reports lower incidence of AMD in patients with BLF IOLs compared to clear lenses (Nagai et al., 2015; Pipis et al., 2015) These factors lead to questions about the process used and conclusions reached by the Committee. The Committee should have access to all the relevant evidence and be fully appraised of its quality and lack of quality. There is no justification for the conclusion that harms can be attributed to the use of BLF IOLs. We have reported the number of patient complaints and adverse events reported in the context of the number of BLF IOLs fitted, which shows a vanishingly small rate of issues with BLF IOLs group over a 5 year period. Extending the question to a range of other outcomes is of questionable relevance to the AMD question but the data clearly demonstrates that for wider visual and QoL capabilities there is equivalence and even benefit for BLF IOLs in terms of: • visual acuity, • sleep, • colour vision and • quality of life.	

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				Only in mesopic conditions was there evidence of lower performance, although again, the data used falls short of expected quality for guideline development. The guideline development process has not addressed the further benefits of BLF IOLs, a further major flaw in the assessment process. The benefits include: • attenuating the impact of glare (which can be disability on driving), • better heterochromatic contrast threshold, • faster photostress recovery, • protection from potential damage caused by the short-wavelength light, which may have a role in ocular melanoma development. We are presenting this case to continue to make a relevant, safe high quality product available to NHS patients. It is important that clinicians and patients have the option of BLF IOLs as they offer relevant advantages over clear lenses, as documented throughout this response. We note that in exceptional circumstances, NICE may consider the need for a further 4-week stakeholder consultation after the first consultation based on:	

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				• Evidence that could significantly alter the guideline that has been omitted from the first draft. In our view this applies to the referenced evidence on AMD, glare disability, toxicity of blue light and other benefits of BLF lenses. • Evidence reviewed that has been misinterpreted in the first draft. For instance the Zhu et al (2012) meta-analysis and the sub-set of papers within Zhu pertaining to colour vision. We believe that these criteria have been met and are therefore convinced that in the absence of conclusive evidence with respect to harm caused by BLF IOLs and substantial evidence in the literature reporting that BLF IOLs do not impair visual acuity, contrast sensitivity, photopic, scotopic or colour vision, nor do they affect the sleep-wake cycle, BLF IOLs should continue to be available for use in patients undergoing age related cataract surgery. We request that Recommendation 22 is rescinded based on a review of the evidence we have proposed.	
Alcon Eye Care UK	Full	109	General	Quality of Evidence	Please note: the recommendations around lens design and material have been removed to allow for further consideration.

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				We would like to draw the Committee's attention to a mistake in Table 4 in Wang et al. ("Number of errors under different light conditions"). In this table, the numbers of errors under the various lighting conditions (400 lux, 30 lux & outdoors) are detailed for a photochromic IOL group and two yellow IOL groups. That is, there is the notable absence of a clear IOL group. It is extremely unclear what the comparator groups are in this table, which is the source of data for the Zhu et al. (2012) meta-analysis on colour vision in mesopic conditions. We believe the lack of clarity or perhaps a blatant mistake in the Wang et al. (2010) paper, further undermines the conclusions on colour vision in this draft guideline.	
Alcon Eye Care UK	Full	109	2585 - 2588	Quality of Evidence *"High-quality evidence from 4 RCTs containing 333 eyes found that people offered a UV-light filtering lens had better postoperative colour vision in the blue light spectrum under mesopic (low light level) conditions compared with those offered a blue-light-filtering lens during cataract surgery".* In this statement, it is reported that the evidence came from 4 high quality RCTs, however, in the original paper	Please note: the recommendations around lens design and material have been removed to allow for further consideration.

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				Zhu et al. (2012) reported that "the overall quality of the studies was not high" and "different follow-up times and less reporting of postoperative visual adverse events could cause selection bias". Indeed, according to Zhu et al. (2012) in Neumaier-Ammerer et al. (2010) it was unclear whether the study was double-blind, while in both Mester et al. (2008) and Wang et al. (2010), sequence generation was unclear. **Clarification Question:** We would like to understand the process by which these studies were assessed as high quality and how they were then passed as meeting the quality standard, given the reported flaws mentioned in the Zhu et al. (2012) paper?	
Alcon Eye Care UK	Full	109	2585 - 2588	<u>Quality of Evidence</u> Related to the quality issue is the specification of lighting in Mester et al. (2008) and Wang et al. (2010). In Mester et al the authors specify incorrectly the illumination on the FM 100-hue test in the BLF studies. The light levels are specified in the cd/m2 unit. The cd/m2 is a measure of the light emitted from a source or reflected from a surface. It is unclear whether the light levels specified in their study were the amounts reflected	Please note: the recommendations around lens design and material have been removed to allow for further consideration.

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				from the Munsell caps or the light coming from the light source used to illuminate the FM 100-hue test. The amount of light falling on the caps (ie. illumination in lux) should be specified to eliminate any ambiguity because the reflectance of the FM 100-hue caps is known. If the light levels specified in this study are the amount from the source, then it is impossible to determine how much light is actually reflected from the caps because the amount will depend on the distance between the light and the caps and the design of the luminaire. Because of this ambiguity, we are uncertain whether the light levels are truly photopic or mesopic. There are no comparable aged related FM norms databases at mesopic light levels. In Wang et al. (2010) the authors reported that the total error score was significantly different between the two IOLs at 30 lux. Although statistically significant, we do not know if the increase in the total error score for the BLF IOL group was within the range expected based on Bowman and Cole (1980) results because Wang et al. (2010) did not report the total error score. The value predicted based on Bowan and Cole's results is an increase by a factor of 1.6 in the phakic population over 60 years. **Reference:**	

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				(27) BOWMAN, K.J., COLE, B. 1980. A recommendation for Illumination of the Farnsworth-Munsell 100-Hue Test. Am J Optom Physiol Opt., 57(11), 839-43.	
Alcon Eye Care UK	Full	109	2585 - 2588	**Clarification Question:** We would like to inquire why the quality assessment of these 3 studies Mester et al. (2008), Wang et al. (2010), Neumaier-Ammerer et al. (2010) is not available in Appendix E: Evidence tables or in Appendix G: GRADE and CERQual Tables?	Thank you for your comment. These three studies were not originally quality assessed as data were taken directly from the Zhu systematic review. However, the data have now been reanalysed based on the primary studies, and the quality assessments of the individual studies are now given in appendix E.
Alcon Eye Care UK	Full	109	2585 - 2585	<u>Quality of Evidence</u> In the Draft guideline and in relation to the meta-analysis performed in Zhu et al. (2012) the following is posited: "High-quality evidence from 4 RCTs containing 333 eyes found that people offered a UV-light filtering lens had better postoperative colour vision in the blue light spectrum under mesopic (low light level) conditions compared with those offered a blue-light-filtering lens during cataract surgery". However, we would like to draw attention to the original paper Zhu et al. (2012) where the authors report that this was in fact 3 studies recruiting 229 eyes Mester et al. (2008), Wang et al. (2010), Neumaier-Ammerer et al. (2010).	Please note: the recommendations around lens design and material have been removed to allow for further consideration.

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				Based on the above we would like to ask the Committee to clarify the following two points: 1. Why does the draft guideline refer to 4 RCTs, when there are only 3 studies included in the meta-analysis? 2. How have the Committee come to the conclusion that there are 333 eyes, when the source information (Zhu et al. 2012) asserts that 229 eyes were recruited?	
Alcon Eye Care UK	Full	110	2597	<u>Selection of Evidence</u> While we agree that there is a lack of studies looking specifically at the effect of BLF IOLs on the incidence and/or progression of AMD after cataract surgery, the reviewed evidence itself (1 systematic review and 4 additional RCTs) shows that there are no significant differences in the other outcomes not specifically related to AMD. These include: • post-op visual acuity, • contrast sensitivity,	Thank you for your comment. As a result of the relatively small number of randomised control trials identified, the committee discussed whether it would be an appropriate use of the limited time available to expand the search to include observational studies, and concluded that they were unlikely to provide sufficiently robust data to be able to make strong recommendations. The two references cited (both observational studies containing small sample sizes) were agreed by the committee to be examples of the types of studies that would not provide sufficiently robust evidence to allow recommendations to be made, and therefore agreed

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				• overall colour vision, • sleep quality, • other aspects of HRQoL. We do not understand the decision not to expand the search criteria to other study designs apart from RCTs (given the lack of available RCT evidence) believing that it would be unlikely to provide any useful evidence. We have identified 2 studies highly relevant to the question of AMD progression in patients with BLF IOLs: 1. Nagai et al. (2015) aimed to observe changes in fundus autofluoroescence 2 years after implantation of BLF and UV filtering IOLs. There were 52 eyes included in the BLF group and 79 eyes in the UV only group. Abnormal fundus autofluoroescence did not develop or increase in the yellow-tinted group; however, progressive abnormal fundus autofluoroescence developed or increased in 12 eyes (15.2%) in the colourless IOL group (p=0.0016). New drusen, geographic atrophy, and choroidal neovascularisation were observed mainly in the colourless IOL group. The incidence of AMD was statistically significantly higher in the colourless IOL group (p=0.042). No harm caused by BLF IOLs was reported. The authors conclude that BLF IOLs might prevent AMD.	that they did not justify an expansion of the search criteria to include non-randomised studies. However, the committee also agreed that they provided further evidence of the value of future research on the issue of whether blue-light filtering lenses after cataract surgery are effective in reducing the incidence or progression of age-related macular degeneration, and that the findings added further support to the need for the research recommendation made on blue-light filtering lenses.

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				2. Pipis et al. (2015) evaluated the effect of BLF IOLs on disease progression in 66 eyes with geographic atrophy (GA) and reported a much slower progression of GA in patients with BLF IOLs compared with the UVF IOL group. SD OCT and advanced RPE software analysis was used to measure lesion size and monitor its progression over one year. There was a statistically significant difference between the groups and the outcome data strongly supports a photoprotective role of BLF IOLs on the progression of the atrophic form of dry AMD. No harm caused by BLF IOLs was reported. Given the direct relevance of these studies to the primary outcome of the AMD research question, we believe that these studies provide useful balancing evidence that should be considered for inclusion by the Committee and not automatically rejected without given due consideration. **References:** (25) NAGAI, H., HIRANO, Y., YASUKAWA, T., MORITA, H., NOZAKI, M., WOLF-SCHNURRBUSCH, U. 2015. Prevention of increased abnormal fundus autofluorescence with blue light-filtering intraocular lenses. Journal of Cataract Refractive Surgery, 41, 1855-1859.	

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				(26) PIPIS, A., TOULIOU, E., PILLUNAT, L.E., AUGUSTIN, A.J. 2015. Effect of the blue filter intraocular lens on the progression of geographic atrophy. Eur J Ophthalmol, 25(2), 128-133.	
Alcon Eye Care UK	Full	110	2597	Inadequate Evidence of Harm We believe that the conclusion made on potential harm of BLF IOLs has been exaggerated, based on inadequate evidence that did not take into consideration other available RCTs or observational studies evaluating the safety of BLF IOLs. The studies included in Zhu et al. (2012) that focus on colour discrimination in photopic and mesopic conditions (Mester et al., 2008, Neumaier-Ammerer et al., 2010, Wang et al., 2010) indicate that the reduction in fine color discrimination is non-existent under photopic light levels and possibly mesopic light levels also. These studies that report inferior mesopic color discrimination for BLF IOLs relative to the clear IOLs show that the discrimination loss is confined to a specific region of the hue circle, but the overall color discrimination is similar for the two types of lenses. Because the aforementioned studies failed to report the total error score, it is difficult to determine whether any change in error score is beyond the value expected for age-matched phakic subjects	Please note: the recommendations around lens design and material have been removed to allow for further consideration.

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				This result and the fact that the quality of life surveys did not report color vision issues with the BLF lenses, indicates that the BLF IOLs are not harmful, but rather the clear IOLs provide marginally better hue discrimination for the blue-blue-green region of the hue circle We would like to highlight the following conclusions from the publications, which represented source data for the Committee recommendation: - Zhu et al. (2012): The results showed that there were no significant differences between best-corrected visual acuity, contrast sensitivity, overall color vision, or in blue light spectrum under photopic conditions between BLF IOLs and UV only filtering IOLs. - The authors report: "We found that most of the literature overwhelmingly demonstrated that there were no detrimental effects of blue light-filtering IOLs on clinical visual recovery, which was consistent with our results. Blue light-filtering IOLs show transmittance curves similar to that of a 53-year-old person's natural crystalline lens to help reduce the potential damage from blue light reaching the retina.	

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				- Our systematic review, as well as other clinical reports, suggests that the blue light-filtering IOLs had postoperative visual performance comparable to the UV light-filtering IOLs, but conclusions regarding color vision are still inconsistent." Therefore, logic dictates that any issue with color vision in the blue light spectrum under mesopic light conditions with a BLF IOL would be the same as with a typical 53 year old person. That is, it would not be an issue. - Mester et al. (2008): The BLF IOL with a yellow chromophore had no effect on contrast vision and visual acuity. The only relatively long-lasting significantly worse performance in functional vision after implantation of BLF IOLs was in colour discrimination under mesopic lighting conditions by an intraindividual comparison. All measured total error scores were within normal range and no patient reported disturbance of colour vision. - The slight disturbance under mesopic conditions is below the threshold of detection using less sensitive study conditions and is in the range of normal colour perception. This explains why, except for 1 reported case in the literature, no permanent complaints of	

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				colour-vision impairment in patients with yellow IOLs have been reported. - Neumaier-Ammerer et al. (2010): The yellow-tinted IOLs were equivalent to the clear IOLs in postoperative contrast sensitivity, visual acuity, and colour perception under photopic conditions. - No differences were found in visual performance between the 2 tested yellow-tinted IOL models. There was a statistically significant difference between the yellow-tinted IOLs and the clear IOLs in colour vision under mesopic conditions. The importance of the effect of BLF IOLs on colour perception and contrast vision in dim light and on circadian perception should be evaluated further in randomised clinical trials and long-term clinical studies to determine whether yellow-tinted IOLs provide the theoretical benefit of protecting the macula. It is also worth mentioning that the Neumaier-Ammerer et al. (2010) study had only a 2 months follow-up period. Delahunt et al. (2004), describes the changes in the light spectrum reaching the retina after removal of cataract and the adaptation of the visual system, which takes about 3 months. Thus, there is a possibility that a longer follow-up period would have borne different results.	

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				- Wang et al. (2010): In conclusion, in patients with photochromic IOLs, the postoperative UDVA and CDVA were similar to those in patients with a yellow IOL or clear IOL. The photochromic IOL and the clear IOL provided better colour vision than the BLF (yellow) IOLs under low-light conditions. It is important to mention that the Wang et al. (2010) study was conducted at 1 site only and all the cataract extractions were performed by the same surgeon. The follow-up period was 3 months, which might be a borderline time period for patients to adapt to the implanted lens as mentioned previously. There are also some basic errors in the presentation of the Wang et al. study. In table 4, the FM 100-hue test results of two yellow IOLs are compared to a photocromic IOL. The results listed in the table do not support the conclusion of the study regarding the clear IOL. Additionally, in this study patients evaluated their visual function and degree of satisfaction after cataract surgery using the Catquest-9SF questionnaire. Glare and photophobia were the main problems after surgery, although these did not have a significant effect on the patients' daily lives. There was no significant difference between any 2 IOL groups in the subjective perceptions	

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				of the patient, suggesting that a patient's subjective discomfort is the same with the photochromic IOL as with the yellow and clear IOLs. We would also like to point out that in 2 out of 3 above mentioned RCTs (Mester et al., 2008 and Wang et al., 2010) colour vision was tested using the Farnsworth-Munsell (FM) 100-hue test, the very test about which the Committee noted concern. The Committee expressed concern in relying on this evidence as the test was originally developed to measure colour vision in young people with normal lenses or normal lenses with spectacles and not for testing colour vision in adults thus may not be applicable to the full population studied. The test was also designed to be used in photopic conditions and is not validated to be performed under mesopic conditions (Roberts et al. 2006). In the 3rd study (Neumaier-Ammerer et al., 2010) colour vision was tested using the Roth 28 hue test – an abridged version of Farnsworth-Munsell. In summary, we do not believe that the presented evidence is convincing in providing sufficient proof of harm caused by the BLF IOLs and does not show correlation between the findings and subjective disturbance of colour vision nor it described the tasks where this deficiency would cause an issue. Further,	

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				none of the studies referenced the results for age-matched phakic patients. We believe that the following additional data should be taken into consideration when evaluating overall safety of BLF IOLs.: <u>Randomised controlled trials:</u> 1. Falkner-Radler et al. (2008) evaluated the effect of BLF IOLs in vitrectomy combined with cataract surgery. 60 patients were assigned randomly to receive an UVF IOL or a BLF IOL. Main outcome measures were intraoperative conditions for the surgeon and the functional outcome. The results showed that there was no significant difference in visual acuity, contrast sensitivity, color vision and glare effect between the two IOL groups. The authors conclude that the yellow-BLF IOLs do not represent an impediment to vitreoretinal surgery, diagnosis, or treatment compared with the clear UV-filter IOLs and they suggest that the routine use of the yellow-tinted IOL in vitrectomy combined with cataract surgery can be recommended. 2. Küchle (2013) compared visual outcomes, contrast sensitivity, color vision and patient satisfaction after implantation of yellow-tinted aspheric IOLs or clear (untinted) IOLs with either	

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				aspheric or spherical designs. 90 patients were randomly assigned to 3 study groups. One-year postoperatively there were no significant differences between the groups in terms of uncorrected and distance corrected visual acuity for far, intermediate and near and for color vision. Contrast sensitivity under all lighting conditions tested and patient satisfaction were similar between the groups with aspheric lenses. The spherical IOL provided slightly worse contrast sensitivity and patient satisfaction. 3. Raj et al. (2005) presented the first RCT study to determine whether implantation of BLF IOL worsens the pre-existing severity of the color defect in congenital partial red-green defectives. In this prospective randomised double-masked analysis 30 consecutive patients with CPRG (Clumped Pigmentary Retinal Degeneration) defect and bilateral cataracts received a Natural IOL (test group) in 1 eye and a single-piece AcrySof IOL (control group) in the other eye. Patients were tested unilaterally to detect CPRG defect using Ishihara pseudoisochromatic plates and the Farnsworth D-15 test. The implantation of BLF IOL did not worsen the pre-existing severity of colour defect in CPRG individuals.	

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				Non-RCTs: 1. Cionni and Tsai (2006) examined the colour perception under photopic and mesopic conditions in patients with bilateral implantation of UV IOLs and BLF IOLs and compared the results with those in a phakic group. In this prospective study, 54 age-matched subjects who passed the Ishihara test and had visual acuities of 20/25 or better were recruited. There were 2 pseudophakic groups (bilateral SN60AT or SA60AT IOLs) and 1 phakic group. The Farnsworth-Munsell (FM) 100-hue test was administered to each subject twice under different conditions. The phakic and AcrySof Natural SN60AT groups were tested under photopic and mesopic conditions. The SA60AT subjects were further divided into subgroups (with and without yellow clip-on lenses) and tested under photopic and mesopic conditions. As expected, color perception was worse in all groups in a mesopic environment than in a photopic environment. There were no statistically significant differences between the test groups. 2. Muftuoglu et al. (2007) compared the photopic and scotopic contrast sensitivity with and without	

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				glare as well as blue colour perception analysed by anomaloscope between eyes with a BLF IOL and eyes with UV filtering IOL. 76 age-matched patients were included in the study. To compare the differences between the 2 IOLs in terms of age, each group was subdivided into 3 groups depending on age. Both types of lenses provided comparable results in regards to glare disability, blue colour perception and contrast sensitivity under photopic and scotopic conditions. Scotopic vision and blue colour discrimination decreased with age with both IOLs. 3. Muñoz et al. (2012) evaluated contrast sensitivity function and colour vision in 56 eyes of 28 cataract patients who had bilateral implantation of orange-tinted, yellow-tinted or clear IOLs were examined. There were no statistically significant differences in chromatic discrimination among the 3 groups of patients in terms of photopic and mesopic contrast sensitivity or colour discrimination. 4. Lavric and Pompe (2014) studied in 60 eyes different aspects of visual function, macular changes and subjective differences between the eye with UV and BLF IOL and the fellow eye with a UV- filtering IOL. The study showed no significant effect of BLF IOL on visual acuity and	

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				no influence on colour perception and contrast sensitivity. After more than 2 years there was no statistical difference seen between the two groups who were examined for macular changes. These studies demonstrate the lack of conclusive evidence of harm on colour vision caused by BLF IOLs and consequently we believe the conclusion made by the Committee is flawed. **References:** (31) DELAHUNT, P.B., WEBSTER, M.A., L., WERNER, J.S. 2004. Long-term renormalization of chromatic mechanisms following cataract surgery. Vis Neurosci, 21(3), 301–307. (32) FALKNER-RADLER, C.I., BENESCH, T., BINDER, S. 2008. Blue Light–Filter Intraocular Lenses in Vitrectomy Combined with Cataract Surgery: Results of a Randomized Controlled Clinical Trial. Am J Ophthalmol, 145, 499–503. (33) KÜCHLE M. 2013. Comparison of visual function with aspheric yellow, aspheric clear and spherical clear intraocular lenses. J Emmetropia, 4, 123-130. (34) RAJ, S.M., VASAVADA, A.R., NANAVATY, M.A. 2005.	

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				AcrySof Natural SN60AT versus AcrySof SA60AT intraocular lens in patients with color vision defects. J Cataract Refract Surg, 31, 2324–2328. (35) CIONNI, R.J., TSAI, J.H. 2006. Color perception with AcrySof Natural and AcrySof single-piece intraocular lenses under photopic and mesopic conditions. J Cataract Refract Surg,32, 236–242. (36) MUFTUOGLU, O., KAREL, F., DUMAN, R. 2007. Effect of a yellow intraocular lens on scotopic vision, glare disability, and blue color perception. J Cataract Refract Surg, 33, 658–666. (37) MUÑOZ, G., BELDA-SALMERÓN, L., ALBARRÁN-DIEGO, C., FERRER-BLASCO, T., FERNÁNDEZ-PORRERO, A. 2012. Contrast sensitivity and color perception with orange and yellow intraocular lenses. Eur J Ophthalmol, 22 (5), 769-775. (38) LAVRIC, A., POMPE, M.T. 2014. Do Blue-Light Filtering Intraocular Lenses Affect Visual Function? Optom Vis Sci, 91, 1348-1354.	
Alcon Eye Care UK	Full	110	2597	<u>Evidence for Glare Disability</u> Although not directly related to the primary outcome of the review question, we welcome the Committee's	Please note: the recommendations around lens design and material have been removed to allow for further consideration.

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				agreement that overall vision and health related quality of life should also be considered as key outcomes. However, we note that complications such as glare and other optical aberrations were part of the PICO criteria for multifocal vs monofocal intraocular lenses in the draft guidelines (page 112, line 2629 Table 26) but were not included in the PICO criteria for tinted (BLF) vs colourless (clear) lenses. We have provided evidence for glare below: • Gray et al. (2011) evaluated in a cross-sectional study the effects of glare visibility on driving performance in 17 patients with BLF IOLs and 17 patients with non-BLF IOLs and found that BLF lenses significantly reduced glare disability and improved the driver's ability to safely execute a left turn at an intersection within oncoming traffic in the presence of glare simulating low-angle sun conditions. The study group had significantly lower glare susceptibility ($p<0.05$) and fewer collisions with the oncoming car. • Hammond et al. (2015) examined visual performance in a randomised masked cross-over clinical study in 154 pseudophakic patients with UVF IOLs. Photostress recovery time and glare disability thresholds were measured with clip-on blue-light-filtering and placebo (clear; no blue-	

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				light filtration) glasses worn over patients' habitual correction. Photostress recovery time and glare disability thresholds were significantly improved (both $p < 0.0001$) when participants used blue-filtering glasses compared with clear non-filtering glasses. Hammond concludes that BLF IOLs may be beneficial under intense lighting conditions. • Hammond et al. (2010) compared visual performance in eyes of 52 patients with contralateral implantation of BLF IOL and clear IOL in a prospective, assessor-masked study performed at least 12 months postimplantation of the appropriate contralateral IOL. Results showed significantly lower glare disability ($p=0.04$), significantly better heterochromatic contrast threshold ($p=0.0003$), and significantly faster recovery from photostress in the eyes with BLF IOLs than in the contralateral control eyes with IOLs that did not filter blue light ($p=0.02$). These studies demonstrate that BLF IOLs confer a patient relevant outcome benefit over clear lenses in terms of glare disability. In this context a reasonable argument could be made that clear lenses cause harm in terms of glare, relative to BLF IOLs. **References:**	

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				(39) GRAY, R., PERKINS, S.A., SURYAKUMAR, R., NEUMAN, B., MAXWELL, W.A. 2011. Reduced effect of glare disability on driving performance in patients with blue light-filtering intraocular lenses. J of Cataract Refract Surg, 37, 38-44. (40) HAMMOND, B.R. 2015. Attenuating photostress and glare disability in pseudophakic patients through the addition of a short-wave absorbing filter. J Ophthalmol, 2015, 607635.] (41) HAMMOND, B.R., RENZI, L.M,, SACHAK, S., BRINT, S.F. 2010. Contralateral comparison of blue-filtering and non-blue-filtering intraocular lenses: glare disability, heterochromatic contrast, and photostress recovery. Clinical Ophthalmology, 4, 1465-1473.	
Alcon Eye Care UK	Full	110	2597	Evidence for Sleep Efficiency We welcome the Committee's agreement that sleep problems should be included in the PICO inclusion criteria in Table 24 on page 107. The RCT already reviewed by the Committee showed no difference between BLF and clear IOLs in terms of circadian rhythm or sleep (Brøndsted A et al; 2015). Another study the Committee has considered showed that BLF IOLs actually improved objective sleep quality and increased sleep efficiency 1 year after cataract surgery (Brøndsted A et al; 2016).	Please note: the recommendations around lens design and material have been removed to allow for further consideration.

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				We have identified three further studies of interest, one of which shows a benefit for BLF IOLs: 1. Wei X et al. (2013) evaluated the effect of the BLF IOL implantation on sleep quality in 40 patients with bilateral cataract using the Pittsburgh Sleep Quality Index (PSQI) questionnaires before cataract surgery and at least 2 months later after the second-eye surgery. The results indicate that BLF IOL had a significantly beneficial effect on the sleep quality of cataract patients. Thus blue-blocking intra-ocular implants could be used routinely during cataract phacoemulsification surgery. 2. Feng et al. (2016) conducted a study comparing different IOL types and their effect on quality of sleep. The binocular BLF IOL and UVB IOL implantations were performed in 60 and 59 cataract patients, respectively. Pittsburgh Sleep Quality Index (PSQI) questionnaires were administered to evaluate the quality of sleep in patients preoperatively, 1 month and 12 months postoperatively. The sleep quality of cataract patients improved after IOL implantation, regardless of the type of IOL.	

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				3. Alexander et al. (2014) assessed the quality of sleep in 961 patients undergoing cataract surgery by administering the Pittsburgh Sleep Quality Index (PSQI) questionnaire. Patients received either an UVB clear IOL or a BLF IOL. Questionnaires were completed four times: 1 month preoperatively and again 1, 6 (UVB IOL only), and 12 months postoperatively. Sleep quality improved significantly following cataract surgery in the short term for the entire cohort, irrespective of the type of lens implanted. The authors concluded that overall sleep quality and sleep latency improves after removal of cataract irrespective of the type of IOL implanted. These data show that implantation of BLF IOL does not have a negative impact on the sleep–wake cycle. In summary we support sleep quality as a key outcome for patients following cataract surgery and believe that the evidence suggests that BLF IOLs are at least as effective as clear IOLs in achieving this outcome, if not slightly more beneficial. **References:** (42) WEI, X., SHE, C., CHEN, D., YAN, F., ZENG, J., ZENG, L., WANG, L. 2013. Blue-Light-Blocking	

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				Intraocular Lens Implantation Improves the Sleep Quality of Cataract Patients. Journal of Clinical Sleep Medicine, 9(8), 741-745. (43) FENG, X., KE, X., YANSHENG, H., HONG, Q. 2016. Impact of blue-light filtering intraocular lens implantation on the quality of sleep in patients after cataract surgery. Medicine, 95(51), e5648. (44) ALEXANDER, I., CUTHBERTSON, F.M., RATNARAJAN, G., SAFA, R., MELLINGTON, F.E., FOSTER, R.G., DOWNES, S.M., WULFF, K. 2014. Impact of Cataract Surgery on Sleep in Patients Receiving Either Ultraviolet-Blocking or Blue-Filtering Intraocular Lens Implants. Invest Ophthalmol Vis Sci., 55, 4999–5004.	
Alcon Eye Care UK	Full	110	2597	<u>Evidence for Health Related Quality of Life</u> We also welcome the Committee's agreement that quality of life should be included (PICO inclusion criteria in Table 24 on page 107) to inform the review question. The RCTs already reviewed by the Committee include a study by Espindle et al. (2005) who found that following cataract surgery, blue-light filtering IOLs improved colour vision, driving, and other aspects of HRQOL in a manner similar to that of a lens that does not filter blue light.	Please note: the recommendations around lens design and material have been removed to allow for further consideration.

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Alcon Eye Care UK	Full	110	2597	Blue-light Toxicity We would like to bring to the Committee's attention that although they recognise that there is a longstanding theoretical argument for why BLF IOLs may have benefits for preventing macular degeneration, the Committee has not acknowledged the potential harms of short wave light on the retina. A2E is one of the chromophores in lipofuscin responsible for the blue light sensitivity of retinal pigment epithelium (RPE). A2E generates singlet oxygen, which, through intermediate products, induces mitochondrial and DNA damage. Thus, the removal of a cataractous lens leaves the RPE vulnerable at an age when its content of blue light-sensitive A2E is high and will continue to increase with the years. Short-wavelength radiation (rhodopsin spectrum), and the blue light hazard (excitation peak 440 nm), have been shown to have a major impact on photoreceptor and RPE function, inducing photochemical damage and apoptotic cell death. Algvere et al. (2006). Studies performed on animal and cellular models were able to demonstrate the toxicity of light and more specifically of the blue spectral range on the RPE and photoreceptor cells.	Please note: the recommendations around lens design and material have been removed to allow for further consideration.

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				• The blue-light exposure in the rat eye promotes oxidation of A2E and iso-A2E to the products that are toxic to retinal tissue. Although high concentrations of A2E may be cytotoxic to the retina, the phototoxicity associated with blue light damage to the retina is in part a result of the formation of toxic A2E oxides. This effect may partially explain the association between blue light induced retinal injury and macular degeneration. Wielgus et al. (2001). • An exposure to blue light (480±20 nm, 75 mW/mm2) induced more cell death on immortalized RPE cells loaded with A2E (ARPE-19 cell line) than green light (545±15 nm, 200 mW/mm2). Sparrow et al.(2000). • A greater toxicity of blue light was confirmed by exposing human RPE cells loaded with lipofuscin during 48 hours to blue-green light (390–550 nm, 2.8 mW/cm2) compared to yellow-red light (550–800 nm, 2.8 mW/cm2). Davies et al. (2001). • Arnault et al. (2013) aimed in their study to define the most toxic wavelengths in the blue-green range on an in vitro model of AMD. Primary cultures of porcine retinal pigment epithelium cells were tested. The loss of cell viability was maximal for wavelengths from 415 to 455 nm.	

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				The authors concluded that this phototoxic spectrum may be advantageously valued in designing selective photoprotection ophthalmic filters, without disrupting essential visual and non-visual functions of the eye. • Marshall et al. (2006) investigated the effect of blue light on the proliferation rates of uveal melanoma cells. The exposure of cells to blue light led to an increase in proliferation in all cell lines compared with the control. The use of BLF IOLs abolished these increases in proliferation in the four cell lines. We are convinced that there is sufficient evidence in the literature pointing out the need for protection against the blue light reaching the retina. BLF IOLs were designed to mimic closely the natural crystalline lens and are intended to restore cataract patients to as close as possible to normal adult human vision. Sparrow et al. (2004) states that the design of intraocular lenses (IOLs) should be based on the properties of the human ocular lens, especially in the transmission properties of the IOL. Artigas et al. (2012) show that not all UV filters incorporated into UVF IOLs offer equal protection from UV light. They go on to state that the filters that provide	

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				greater photoprotection against UV radiation, and blue light, are yellow and orange, and that yellow and orange IOL filters may be best suited for cases requiring special retinal protection. Van Norren and van de Kraats (2007) reported on spectral transmission of IOLs expressed as virtual age, which provides a useful method of comparison of different IOLs regarding their different short-wavelength transmission and absorption characteristics. They demonstrated that a UVF IOL mimics the lens transmission and absorption of a newborn ranging up to a teenager; whereas a BLF IOL, depending on the lens type, is more typical of the transmission seen in early-to-late middle age. Authors believe that the middle-aged IOL offers a good compromise between photoprotection and photoreception. Nolan et al. (2009) provide evidence that implanting an IOL that filters blue light results in augmentation of macular pigment optical density MPOD. Macular pigment (MP), consisting of the carotenoids lutein (L), zeaxanthin (Z) and meso-Z, has a maximum absorption at 460 nm and protects the retina from (photo)-oxidative injury. Greenstein et al. (2007) suggest that given the possibility of increased risks for development of AMD after cataract extraction and the possible benefits of implanting a short-wavelength filtering IOL, the benefits outweigh any	

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				minimum to insignificant effects the IOL may have on dark-adapted spectral sensitivity and hue discrimination. **References:** (45) ALGVERE, P.V., MARSHALL, J., SEREGARD, S. 2006. Age-related maculopathy and the impact of blue light hazard. Acta Ophthalmol. Scand., 84, 4–15. (46) WIELGUS, A.R., COLLIER, R.J., MARTIN, E., LIH, F.B., TOMER, K.B., CHIGNELL, C.F., ROBERTS, J.E. 2010. Blue light induced A2E oxidation in rat eyes – experimental animal model of dry AMD. Photochem. Photobiol. Sci., 9, 1505–1512. (47) SPARROW, J.R., NAKANISHI, K., PARISH, C.A. 2000. The lipofuscin fluorophore A2E mediates blue light-induced damage to retinal pigmented epithelial cells. Invest Ophthalmol Vis Sci, 41, 1981–1989. (48) DAVIES, S., ELLIOTT, M.H., FLOOR, E., TRUSCOTT, T.G., ZAREBA, M., SARNA, T., SHAMSI, F.A., BOULTON, M.E. 2001. Photocytotoxicity of lipofuscin in human retinal pigment epithelial cells. Free Radic Biol Med, 31, 256–265. (49) ARNAULT, E., BARRAU, C., NANTEAU, C., GONDOUIN, P., BIGOT, K., VIÉNOT, F., GUTMAN, E., FONTAINE, V., VILLETTE, T., COHEN-TANNOUDJI, D.,	

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				SAHEL, J.A., PICAUD, S. 2013. Phototoxic Action Spectrum on a Retinal Pigment Epithelium Model of Age-Related Macular Degeneration Exposed to Sunlight Normalized Conditions. PLoS One., 23, 8(8):e71398. (50) MARSHALL, J.C. GORDON, K.D., MCCAULEY, C.S., DE SOUZA FILHO, J.P., BURNIER, M.N. 2006. The effect of blue light exposure and use of intraocular lenses on human uveal melanoma cell lines. Melanoma Res., 16(6), 537-41. (51) SPARROW, J.R. MILLER, A.S., ZHOU, J. 2004. Blue light-absorbing intraocular lens and retinal pigment epithelium protection in vitro J Cataract Refract Surg, 30, 873–878. (52) ARTIGAS, J.M., FELIPE, A., NAVEA, A., FANDINO, A., ARTIGAS, C. 2011. Spectral transmittance of intraocular lenses under natural and artificial illumination - criteria analysis for choosing a suitable filter. Ophthalmology, 118, 3–8. (53) VAN NORREN, D., VAN DE KRAATS, J. 2007. Spectral transmission of intraocular lenses expressed as a virtual age Br J Ophthalmol, 91, 1374–1375. (54) NOLAN, J.M., O'REILLY, P., LOUGHMAN, J., STACK, J., LOANE, E., CONNOLLY, E., BEATTY, S. 2009. Augmentation of Macular Pigment following	

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				Implantation of Blue Light–Filtering Intraocular Lenses at the Time of Cataract Surgery. Investigative Ophthalmology & Visual Science, Vol.50, 4777-4785. (55) GREENSTEIN, V.C., CHIOSI, F., BAKER, P., SEIPLE, W., HOLOPIGIAN, K., BRAUNSTEIN, R.E., SPARROW, J.R. 2007. Scotopic sensitivity and color vision with a blue-light-absorbing intraocular lens. J Cataract Refract Surg., 33(4), 667–672.	
Alcon Eye Care UK	Full	110	2597	<u>Removal from the Market</u> Without prejudice to our arguments that RQ20 is out of the Final Scope and away from the approved indication for use of BLF IOLs, it might have been reasonable for the Committee to ask RQ20 as it is perhaps a question of academic interest. Unsurprisingly, given that the use is not based on the approved indication for use for BLF IOLs, the Committee's review of the available evidence did not produce conclusive evidence one way or the other. Rather, it reviewed the even more limited evidence of an effect of BLF IOLs on colour vision in low light conditions and used this to convert a research recommendation into what is effectively a recommendation removing BLF IOLs from the market. The Committee reached its conclusions based on a flawed review question that failed to cover all considerations that the Committee should have	Please note: the recommendations around lens design and material have been removed to allow for further consideration.

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				addressed. As a result, the Committee reviewed limited evidence and focused on one particular outcome of BLF IOLs without taking into account the wider benefits of BLF IOLs in relation to post-operative care in cataract surgery, which is the actual focus of this Guideline. We consider that recommendation to remove BLF IOLs from the UK market is unreasonable in the light of the evidence before the Committee.	
Alcon Eye Care UK	Full	110	2597	Patient's Right of Choice Recommendation 22 essentially takes away the patient's right to be informed about treatment options and the risks involved. The law is clear that a clinician has to inform fully the patient about his condition, available treatment options and the risks involved. This was recently clarified in the case *Montgomery (Appellant) v Lanarkshire Health Board (Respondent) (Scotland)* [2015] UKSC 11, where the Supreme Court highlighted the importance of patient autonomy and a patient's right to receive information about his condition and the risks of any available treatment. The Manual also emphasises the importance of patient choice: *"For all recommendations, a general principle of NICE guidelines is that people using services and the wider public should be informed of their options and be involved in decisions about their care."*[56]	Please note: the recommendations around lens design and material have been removed to allow for further consideration.

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				In our view, Recommendation 22 takes the choice away from the patient and undermines the doctor-patient dialogue. It prevents and/or undermines the information that physicians must give to patients, both in terms of alternative treatment options but also importantly in terms of risk. **Reference:** [56] Manual, page 168.	
Alcon Eye Care UK	Full	111	2605 - 2612	Safety Concerns Under the EU regime for medical devices, it is the responsibility of notified bodies and competent authorities to assess the safety and performance of medical devices. The MHRA is the UK competent authority. Under the legislative framework, the MHRA has the power to restrict the marketing of medical devices in certain limited circumstances. These include situations where (1) the manufacturer has incorrectly applied the CE-mark and the device did not follow the appropriate conformity assessment; (2) the device presents a risk to patient safety; or (3) where the device does not meet the appropriate standards. Conversely, although we acknowledge that NICE does have responsibility to identify a safety or efficacy issue; this should be in the	Please note: the recommendations around lens design and material have been removed to allow for further consideration.

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				context of a cost-effectiveness assessment regarding the use of resources in the NHS. The Committee states that "*the lack of evidence on the long- term effectiveness of blue light filtering lenses with regards to the incidence or progression of age-related macular degeneration combined with the evidence of some harm from these lenses, specifically on colour vision makes it difficult to justify the use of these lenses in clinical practice."* This statement downgrades BLF lenses to the level of an unapproved experimental treatment in contradiction to our officially approved indication for use, which is first and foremost *"for the replacement of the human crystalline lens in the visual correction of aphakia in adult patients following cataract surgery*". At no point do the instructions indicate that the BLF IOLs may delay the onset or progression of AMD. The Recommendation 22 also creates an unusual situation where millions of implanted lenses without related reported patient complaints and a lack of proven harm in clinical practice, are being labelled as potentially unsafe. In the last 5 years, we have had 2.05 adverse events/ patient complaints per million sold units reported to Alcon's Pharmacovigilance Department relating to	

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<tr><td></td><td></td><td></td><td></td><td>patients with a BLF IOL causing harm related to colour vision. We therefore do not recognise the balance of the statement that BLF IOLs harm colour vision.

Should NICE have any concerns about the safety of BLF IOLs, it should call on the MHRA to take appropriate review.</td><td></td></tr>
<tr><td>Alcon Eye Care UK</td><td>Full</td><td>113</td><td>2645</td><td>Furthermore, we would like to highlight to the Committee that 50% of the 20 studies included in the meta-analysis conducted for this review question are older than 10 years (with two studies 25 years old) and represent redundant models of multifocal IOLs that are not currently used in the clinical practice (see below). We believe that therefore the meta-analysis findings are influenced by inclusion of these old RCTs which do not represent the current state of multifocal IOL technology. We would ask the Committee to modify the meta-analysis and include more recent studies on multifocal IOLs.

Citation | IOL models | Lens type | Currentl in use*
El-Maghraby et al. (1992) | 3M 815LE vs. 3M15LE | Diffractive | No
Haaskjold et al. (1998) | 808X vs. 808D | Diffractive | No
Javitt et al. (2000) | Array SA40N vs. PhacoFlex II SI40NB | Refractive | No</td><td>Thank you for your comment. The committee noted that a number of the included studies were of older lens designs, but also noted that the clinical findings for multifocal lenses (that they provide improvements in levels of spectacle independence, but with increased glare and halos) has remained consistent over the different generations of devices.

Further, the committee noted that the key reason they agreed not to recommend the use of these lenses was concerns over the additional costs (and the associated lack of cost-effectiveness evidence, and that this concern was not influenced by the age of the studies included in the review.</td></tr>
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				Kamlesh et al. (2001) — Progress 3 vs. Flex 65 — Refractive — No Leyland et al. (2002) — Array SA40NB vs. PhacoFlex II SI40N vs. 68STUV Storz — Refractive — No Nijkamp et al. (2004) — Array SA40NB vs. PhacoFlex II SI40N — Refractive — No Percival et al. (1993) — Array PC25 vs. Array MPC25 vs. 3M vs. IOLAB Nuvue — Refractive vs. diffractive vs. refractive — No Rossetti et al. (1994) — 3M vs. 3M — Diffractive — No Sen et al. (2004) — Array SA40N vs. PhacoFlex II SI40NB — Refractive — No Steinert et al. (1992) — Array MPC-25NB vs. Array PC-25NB — Refractive — No *Identified from manufacturers' website.	
Alcon Eye Care UK	Full	115	General	We concur with the Committee's evidence statements in relation to superior post-operative outcomes of unaided and/or corrected visual acuity (distance, intermediate, and near) with multifocal IOLs versus monofocal IOLs.	Thank you for your comment and endorsement of the evidence statements.

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Alcon Eye Care UK	Full	115	General	Spectacle independence is a desired and relevant outcome to some patients. The draft recommendation "Do not offer multifocal intraocular lenses for people having cataract surgery" may impinge on patient ability to make a well-informed choice and instead be restricted to monofocal IOLs. Therefore we ask the Committee to update the guideline to better reflect the proven benefits of multifocal IOLs in terms of improved visual acuity and spectacle independency to support well informed patient decisions.	Thank you for your comment. The Committee agreed that spectacle independence is a relevant and important outcome for many people undergoing cataract surgery. However, NICE has a statutory duty under the Health and Social Care Act to '… have regard to the broad balance between the benefits and costs of the provision of health services or of social care in England' Consequently, NICE considers cost-effectiveness alongside effectiveness in all recommendations it makes, as to make positive recommendations for interventions that are not cost-effective would results in people elsewhere in the system being denied access to more effective interventions. The view of the Committee was that the additional costs associated with multifocal lenses (both higher costs of the lenses themselves and other additional costs in the pathway) meant they were unable to recommend them for use within the NHS.
Alcon Eye Care UK	Full	115	2672 - 2685	We would like to bring to the Committee's attention that the following cost effectiveness studies should be included in the health economics evidence for multifocal IOLs: 1. Lin et al. (2014)	Thank you for your comment. These references were returned from the search conducted as part of the systematic review of health-economic evidence undertaken for this guideline. The Lin et al. (2014) analysis was excluded because the committee made a decision to exclude health economic evidence from non-OECD countries. This decision has been applied

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				a. This study was a cost- effectiveness analysis (CEA) of monofocal and multifocal intraocular lenses (IOLs) for cataract patients in Taiwan. b. The ICER indicated that multifocal IOLs improve spectacle independence vs. monofocal IOLs at an additional cost of $57 to $58 (US dollars) for every 1% of the spectacle-independence rate. c. The authors concluded that multifocal IOLs are a highly cost-effective treatment strategy for cataract patients who choose to be spectacle independent in post-operative period and advocate that cataract patients should be provided the choice of IOLs before cataract surgery. 2. Pagel et al. (2007) a. This was a cost-effectiveness study of multifocal and monofocal IOLs for cataract patients conducted in German healthcare setting. b. An ICER of €63 per additionally gained vision line (near visual acuity) was estimated for multifocal IOLs vs. monofocal IOLs. c. The authors concluded that multifocal IOL cataract surgery is a cost effective	before in NICE guidelines when it was felt that economic evidence from non-OECD countries is of limited value in making recommendations, especially in cases where the population, health service structure and economy are significantly different from the NHS context. Both of these studies express cost-effectiveness using measures other than quality-adjusted-life-years (such as spectacle independence rate, lines of vision gained). The reference case used for health technology assessment as described in the Guideline Manual here https://www.nice.org.uk/process/pmg6/chapter/assessing-cost-effectiveness has been adopted for use in Clinical Guidelines. This reference case cites QALYs as the preferred measure of health effect for a treatment. NICE employs a cost-effectiveness threshold of £20,000 per QALY, and it is difficult to relate studies which report cost-effectiveness relative to natural units to this cost-effectiveness threshold. Indeed, the problems of comparing the cost-effectiveness across health domains when evaluating interventions using natural units or condition specific measures are well documented. For these reasons, this evidence was excluded at the review stage.

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				alternative to the monofocal standard IOLs. We believe that by including these two studies in the health economics review section, the Committee could consider to modify the statement and acknowledge that multifocal IOLs are a cost-effective treatment strategy for cataract patients who desire spectacle independence after cataract surgery. **References:** (65) LIN, J.-C. & YANG, M.-C. 2014. Cost-effectiveness comparison between monofocal and multifocal intraocular lens implantation for cataract patients in Taiwan. Clinical therapeutics, 36, 1422-1430. (66) PAGEL, N., DICK, H. & KRUMMENAUER, F. 2007. Incremental cost effectiveness of multifocal cataract surgery. *Klinische Monatsblatter fur Augenheilkunde,* 224**,** 101-109	
Alcon Eye Care UK	Full	116	2732 - 2741	We recognize that refractive multifocal IOL models are associated with optical aberrations such as glare, haloes and reduction in contrast sensitivity. However, this limitation is significantly lower with diffractive multifocal IOLs models (Xu et al., 2014, Choi et al., 2008). In diffractive multifocal IOLs, concentric rings are arranged in a diffractive grating to split the light equally into two (or	Thank you for your comment. The committee agreed that the presented evidence included in the guideline did demonstrate that rates of adverse events were lower with diffractive as opposed to refractive multifocal lenses, and agreed that if one or the other were to be used, diffractive multifocal lenses would be preferred.

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				more) distinct focal points, for example, near and far (Werner et al., 2006). This reduces stray light from other focal distances, and associated problems of glare and halos. Diffractive multifocal IOLs therefore have a favourable risk-benefit profile compared to refractive multifocal IOLS with a similar improvement in unaided visual acuities and lower adverse events of halos and glare. As a result, they should be recommended as a treatment option for cataract patients who desire greater post-operative spectacle independence. **References:** (67) XU, XIAN, MING MING ZHU, & HAI DONG ZOU. 2014. Refractive versus diffractive multifocal intraocular lenses in cataract surgery: a meta-analysis of randomized controlled trials. Journal of Refractive Surgery 30.9, 634-644. (68) CHOI, J. & SCHWIEGERLING, J. 2008. Optical performance measurement and night driving simulation of ReSTOR, ReZoom, and Tecnis multifocal intraocular lenses in a model eye. J Refract Surg, 24, 218-22 (69) WERNER, L., OLSON, R. J. & MAMALIS, N. 2006. New technology IOL optics. Ophthalmol Clin North Am, 19, 469-83.	However, this did not change the committees overall conclusions that the additional costs of multifocal lenses (both lens costs and pathway costs) were not currently justified by any robust evidence of cost-effectiveness, and therefore it was appropriate to recommend that multifocal lenses (either diffractive or refractive) not be routinely offered in the NHS.

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Alcon Eye Care UK	Full	117	2748	We are very surprised to see that these draft guidelines have stated that the 'explantation rate' with multifocal IOLs is around 10%, however no evidence has been provided to back up this observation. We disagree with the stated 10% lens explantation rate with multifocal IOLs since it does not represent the real world clinical practice. In a large (n=1483 eyes), long-term (2009-2014) retrospective database study (Kermani and Gerten, 2016), overall observed frequency of explantation with multifocal IOLs was only 0.83% (n=12). Moreover, in the 'direction for use' of a multifocal IOL model released by the FDA, only 1 eye out of 566 eyes had lens explantation, a rate of 0.18%: https://www.accessdata.fda.gov/cdrh_docs/pdf4/P040020c.pdf Furthermore, the following information is available in the DFUs for the below multifocal IOLs, evidence which is submitted to the FDA to demonstrate safety and efficacy. ReSTOR Toric IOLs – US Trial: 4 lens replacements in 1145 eyes = 0.35% ReSTOR +3 IOL – ReSTOR +3/+4 – US trial: 2 lens replacements in 594 eyes = 0.34%	Thank you for your comment. This comment has now been deleted, as the committee agreed it was not an accurate number to retain.

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				ReSTOR +2.5 IOL – US Trial: 0 in 310 eyes = 0.00% Clinical study reports for the above trials can be made available to the Committee on request. **Reference:** (70) KERMANI, O., & G. GERTEN. 2016. Explantation of Multifocal Intraoular Lenses-Frequency, Causes and Course. *Klinische Monatsblätter für Augenheilkunde* 233.8, 928.	
Alcon Eye Care UK	Full	120	2797	We would like to bring to the guideline Committee's attention that at least 2 relevant randomized clinical trials that have demonstrated the superiority of Toric IOLs vs. non-Toric IOLs±LRIs were excluded from the evidence review. These RCTs further substantiate the clinical superiority of Toric IOLs vs. non-toric monofocal IOLs±LRIs We have summarized the excluded studies as below: 1. Holland et al. (2010): a. This was a randomized, subject-masked, parallel-group, multicenter, 1-year study conducted in the USA and compared Toric IOLs vs. non-toric monofocal IOLs (n=517). Outcomes assessed were: Visual acuity, IOL position, safety, spectacle need, spectacle	Thank you for your comments. The study by Zhang et al was conducted in a non-OECD country and was therefore excluded from the review, as the protocol states that only studies from OECD countries would be included for this review question. Thank you for drawing the Holland study to our attention. This study was now been added in to the evidence base in the guideline, and does not substantively change the conclusion that toric lenses are a clinically effective way of reducing post-operative astigmatism, and reducing levels of spectacle dependence. However, NICE is required to consider cost-effectiveness alongside effectiveness in all the decisions it makes and, given the additional pathway costs associated with toric lenses, the committee agreed that there was no robust evidence on their cost-

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				independence, quality of vision, and satisfaction with vision. b. At one year postoperatively, best corrected-spectacle distance visual acuity of ≥20/20 was 77.7% in the Toric IOL group versus 69.2% in the non-toric monofocal IOL group. c. Uncorrected distance visual acuity of ≥20/20 was 40.7% in the Toric IOL group versus 19.4% in the non-toric monofocal IOL group ($p<0.05$). d. Mean absolute residual refractive cylinder was 0.59 D in Toric IOL group versus 1.22 D in non-toric monofocal IOL group ($p<0.0001$). e. Six-month spectacle freedom was 61.0% in Toric IOL group versus 36.4% in non-toric monofocal IOL ($p<0.0001$). 2. Zhang et al. (2011): a. This was a randomized, controlled, prospective trial conducted in China that compared patients implanted with bilateral toric and bilateral non-toric spherical IOLs (n=120). Key outcomes that were assessed are: post-operative monocular and binocular distance vision with and without best correction, spectacle independence, and self-reported satisfaction with vision. b. At 6 months postoperatively, binocular uncorrected distance vision was 0.06 ± 0.14	effectiveness that enabled them to make a positive recommendation.

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				logMAR in the toric IOL group, significantly better than the 0.14±0.11 logMAR in the non-toric spherical IOL group ($p<0.05$). c. For eyes with emmetropia as a target, the equivalent of 20/20 uncorrected vision was more likely ($p<0.001$) in the toric IOL group (36% of eyes) than in the non-toric spherical IOL group (4% of eyes). d. No patients in the emmetropia/toric IOL group used distance glasses, as compared to 52% of patients in the emmetropia/spherical IOL group. e. All patients were satisfied or highly satisfied. Quality of distance vision was rated higher by toric IOL patients than by spherical IOL patients ($p<0.05$). **References:** (79) ZHANG, J.S., ZHAO, J.Y., MA, L.W., et al. 2011. Distance vision after bilateral implantation of AcrySof toric intraocular lenses: a randomized, controlled, prospective trial. INT J Ophthalmol., 4, 175-178. (80) HOLLAND, E., LANE, S., JEFFREY, H. et al. 2010. The AcrySof Toric Intraocular Lens in Subjects with Cataracts and Corneal Astigmatism. A Randomized, Subject-Masked, Parallel-Group, 1-Year Study. Am J Ophthalmol., 117, 2104–2111.	

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Alcon Eye Care UK	Full	123	2863 - 2874	We are surprised to see that LRIs have been recommended for the correction of astigmatism on the basis of just one RCT study. Consequently, we believe that such a recommendation is not sufficiently supported by the evidence. This recommendation for LRI`s is even more surprising in the light of available substantial evidence that clearly shows the superiority of toric IOLs vs. LRIs and other surgical interventions. A meta-analysis by Kessel et. al. (2016) that synthesized data from 13 RCTs, demonstrated that toric IOLs are superior to relaxing incisions (+non-toric IOLs) in lowering postoperative astigmatism, improving postoperative uncorrected visual acuity and achieving greater spectacle independence. **Reference:** (83) KESSEL, L., ANDERSEN, J., TENDAL, B. 2016. Toric Intraocular Lenses in the Correction of Astigmatism During Cataract Surgery. A Systematic Review and Meta-analysis. Opthalmology, 123, 275-286.	Thank you for highlighting this publication (Kessel 2016). The paper already forms part of the evidence base for this review question and was included within the guideline. NICE is required to consider cost-effectiveness alongside effectiveness in all the guidelines it produces, and therefore it is not sufficient to only demonstrate that toric lenses are effective in reducing astigmatism, but also that they are a cost-effective use of NHS resources. The committee agreed that the evidence base for LRIs was not particularly strong, and hence the recommendation was made at the weaker 'consider' level. However, since the committee agreed that cost-effectiveness considerations meant it was not possible to recommend toric lenses, they felt it was appropriate to draw attention to the other techniques that can be used to manage post-operative astigmatism.
Alcon Eye Care UK	Full	123	2876 - 2879	We are quite concerned to see that 'on-axis' surgery has been recommended for the correction of astigmatism on the basis of just one low-quality RCT evidence (n=71 eyes). This study compared post-operative reduction in refractive cylinder only and did not compare important	Thank you for highlighting this publication (Anderson 2017). However, the committee agreed that only randomised controlled trials should be considered within the evidence base for this question, and therefore this study was not included.

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				treatment outcomes such as post-operative UDVA and post-operative spectacle independence. Furthermore the outcome of this small RCT (71 eyes) is in contrast to a recently published large RWE study conducted in UK (Anderson et al. 2017). This study demonstrated that although 'on-axis' incision surgery does not induce astigmatism, it is not effective in correcting pre-operative corneal astigmatism. These results are based on retrospective analysis of the change in pre- and post-operative astigmatism in 28,845 eyes treated in NHS centers.	The committee agreed that the evidence base for on-axis was not particularly strong, and hence the recommendation was made at the weaker 'consider' level. However, since the committee agreed that cost-effectiveness considerations meant it was not possible to recommend toric lenses, they felt it was appropriate to draw attention to the other techniques that can be used to manage post-operative astigmatism.
Alcon Eye Care UK	Full	124	2884	The draft guideline states that there was no evidence to demonstrate what impact the clinical benefits of toric IOLs would have on the quality of life of astigmatic patients. However there is evidence that astigmatic cataract patients implanted with Toric IOLs achieve significantly better post-operative satisfaction with vision vs. those implanted with non-Toric monofocal IOLs. Statistically significant treatment differences between two groups (in favor of Toric IOLs) have been demonstrated in a RCT (Zhang et. al., 2011) as well as in an observational study (Mencucci et al, 2013). In Zhang et al. (2011), patients completed a structured questionnaire about their distance vision, at both preoperative and postoperative visits. The questionnaire results (6 months after surgery) indicated that all patients with both IOLs were satisfied or very satisfied with their	Thank you for your comments. The protocol for this review, as specified by the guideline committee, was to include RCTs conducted in OECD countries, and therefore neither of the studies were eligible for inclusion. Further to this, neither study provides evidence on the cost-effectiveness of toric lenses, in the form of evidence sufficiently closely matching the NICE reference case (cost per QALY gained). It is as a result of the lack of relevant cost-effectiveness evidence that the committee made a research recommendation, so that hopefully it will be possible to address this question in future updates of the guidance.

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				distance vision. These satisfaction ratings were similar for both IOLs. In contrast, the quality of uncorrected distance vision (scale: 0 to 6) was rated 5.6 ± 0.7 in the toric IOL group, which was significantly better than the 4.5 ± 0.7 rating in the Spherical non-toric IOL group ($p<0.05$). Mencucci et al. (2013) conducted a prospective, observational study in patients with bilateral cataract and pre-existing astigmatism who underwent unilateral cataract surgery. Patients were implanted with either non-toric spherical IOLs or toric IOLs. Post-operatively, patients with toric IOLs achieved significantly better refractive and visual outcomes when compared to non-toric spherical IOLs. QoL was measured by using the NEI-RQL and results were significantly better for the toric IOLs group compared to the non-toric spherical IOLs group ($P<0.05$). **References:** (81) ZHANG, J.S., ZHAO, J.Y., MA, L.W. 2011. Distance vision after bilateral implantation of AcrySof toric intraocular lenses: a randomized, controlled, prospective trial. INT J Ophthalmol., 4, 175-178. (82) MENCUCCI, R., GIORDANA, C., FAVUZZA, E., et al. 2013. Astigmatism correction with toric intraocular lenses: wavefront aberrometry and quality of life. Br J Ophthalmol., 97, 578–582.	

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Alcon Eye Care UK	Full	124	2884	The superiority of toric IOLs compared to monofocal IOLs with or without corneal relaxing incisions, has previously been demonstrated in the literature (Kessel et al., 2016). In addition, the analysis carried out in this guideline further demonstrates this, as is detailed below: • **Visual acuity (uncorrected distance)** ➢ High-quality evidence from 10 RCTs containing 773 eyes found that people who received a toric intraocular lens had better uncorrected distance visual acuity than those who received a non-toric intraocular lens (with or without limbal relaxing incisions). • **Residual astigmatism – refractive cylinder diopter** ➢ High-quality evidence from 9 RCTs containing 781 eyes found that people who received a toric intraocular lens had lower levels of postoperative astigmatism than those who received a non-toric intraocular lens (with or without limbal relaxing incisions). • **Spectacle independence for distance viewing** ➢ High-quality evidence from 6 RCTs containing 867 eyes found that people who received a toric lens had less spectacle dependence for distance	Thank you for your comment. The committee agreed that the available evidence (including both the Kessel review and that synthesised in this guideline) clearly demonstrates the clinical effectiveness of toric lenses for managing postoperative astigmatism. The committee also agreed that the clinical evidence showed toric lenses were likely to be a more clinically effective option than either limbal relaxing incisions or on-axis surgery. However, when making recommendation, NICE is required to consider the cost-effectiveness as well as the effectiveness of alternative choices, and the committee agreed that it could not be satisfied, in the absence of robust economic evidence, that toric lenses represent a cost-effective use of NHS resources, and therefore they felt unable to recommend their use. The recommendations for on-axis surgery and limbal relaxing incisions are not an indication of the committee believing them to be a clinically superior option to toric lenses, but rather the fact they are not associated with the same significant costs as toric lenses. Since the committee were unable to make a positive recommendation for toric lenses, it agreed it was important for the guideline to draw attention to the other techniques that surgeons can use to manage astigmatism.

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				viewing than those who received a non toric lens (with or without limbal relaxing incisions). It is of concern that the implementation of the draft recommendation: *"Consider on-axis surgery or limbal-relaxing incisions to reduce postoperative astigmatism,"* would prevent astigmatic cataract patients from accessing the best available astigmatism correction treatment (Toric IOLs) and consequently, resign patients to surgical interventions which are infrequently used, for which there is little evidence to support their effectiveness and as the evidence suggests, are likely to result in poorer outcomes compared to Toric IOLs. It is in our considered opinion that the merits of "on-axis surgery" and corneal relaxing incisions for correcting astigmatism have been overvalued in this guideline. We believe that this may act to provide information to patients that does not accurately reflect the current clinical evidence demonstrating the superiority of toric IOLs in treating astigmatism during cataract surgery compared to on-axis surgery or corneal relaxing incisions. Consequently this may impinge on the ability of patients in the NHS to make well informed decisions on the existing treatment options for astigmatism correction. Therefore we ask the Committee to update the guideline to better reflect the clinical superiority of Toric IOLs relative to corneal relaxing incisions for correcting pre-existing astigmatism.	The committee agreed that the evidence base for the use of on-axis surgery and limbal relaxing incisions was not particularly strong, and it was for this reason that the recommendation was made at the weaker 'consider' level.

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Alcon Eye Care UK	Full	135	3119-3120	We concur that FLACs is associated with significantly reduced corneal endothelial cell loss when compared to PCS.	Thank you for your comment.
Alcon Eye Care UK	Full	135	3135	We feel the evidence review conducted to evaluate laser assisted cataract surgery in its current form does not capture all relevant outcomes to compare FLACS vs. conventional phacoemulsification cataract surgery (PCS). We believe that the review question should have included comparative assessment between laser assisted cataract surgery devices and PCS on efficiency parameters (effective phacoemulsification time) and safety parameters (phaco or ultrasound energy) as well as reduced endothelial cell loss. It is well documented in the published evidence that phacoemulsification time and ultrasound energy used during cataract surgery are known to directly cause endothelial cell loss (Chen et. al, 2016; Cho et al, 2010; Hayashi et al, 1996) which may impact corneal endothelium and that in FLACS, phaco energy is reduced as is endothelial cell loss (Chen et. al, 2016; Schargus et al. 2015). **References:**	Thank you for your comment. The review question, and all its relevant outcomes was developed and agreed by the guideline committee at the start of the guideline development process. The currently available randomised controlled trials, including a thoroughgoing Cochrane Review, do not support these conclusions. Whilst we agree that some cohort studies have reported reduced endothelial cell loss and reduced phacoemulsification energies, the study type searched and included as the most appropriate, in this case RCTs, within the review question was determined and ratified by the guideline committee prior to its commencement. We are aware that 2 large RCTs (FACT and FEMCAT), at least 1 of which will include a parallel economic analysis, are due to publish in 2018. Details of both have been passed to the NICE surveillance team, and there are processes by which a rapid, targeted update of that part of the guideline can be undertaken, should that new evidence imply the recommendations need to be reviewed.

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				(89) HAYASHI, K,, HAYASHI, H,, NAKAO, F,, HAYASHI, F. 1996. Risk factors for corneal endothelial injury during phacoemulsification. Journal of cataract and refractive surgery, 22(8), 1079–84. (90) CHO YK, CHANG HS, KIM MS. Risk factors for endothelial cell loss after phacoemulsification: comparison in different anterior chamber depth groups. Korean journal of ophthalmology: KJO. 2010; 24(1):10. (91) SCHARGUS, M., SUCKERT, N., SCHULTZ, T., KAKKASSERY, V., DICK, H.B. 2015. Femtosecond laser-assisted cataract surgery without OVD: a prospective intraindividual comparison. Journal of refractive surgery, 31(3), 146–52.	It should be noted that the decision to recommend FLACS only as part of a trial reflects the economic evidence which does not at the time of writing support FLACS as a cost-effective option for cataract surgery. ECL was not included as an outcome of interest because we did not find evidence, including in the trials in the Cochrane review that the differences in ECL between phacoemulsification and FLACS impacted on key outcomes such as acuity. Furthermore, the existing economic evidence does not suggest that the differences in ECL translate into tangible health economic benefits which would offset the costs of the device, disposables and estate costs associated.
Alcon Eye Care UK	Full	135	3135	We are surprised to see that the clinically relevant outcome of 'circularity of capsulorrhexis' was not considered and evaluated by NICE. Evidence suggests that improved quality of capsulorrhexis enables improved capsule overlap, better intraocular lens (IOL) placement and centration of the IOL. These advantages improve post-operative visual and refractive outcomes (Nagy et. al, 2014). An independently conducted meta-analysis (Chen 2016) synthesized the evidence from individual studies and findings show that the FLACS group had a significantly	Thank you for your comment. The currently available randomised controlled trials, including a recent Cochrane Review, do not support the conclusion of meaningful additional benefits with FLACS. Whilst we agree that some cohort studies have reported other outcomes which do not translate well into key outcomes of acuity, the study type searched and included as the most appropriate, in this case RCTs, within the review question was determined and ratified by the guideline committee prior to its commencement. We are aware that 2 large RCTs (FACT and FEMCAT), at least 1 of which will include a parallel economic

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				higher quality of circularity compared with the PCS group (WMD: 0.06, 95% CI: 0.03 to 0.09, P <.001, I^2 > 50%). A new meta-analysis study (Kohnen et. al, 2016) also demonstrated significantly better circularity in FLACS vs. PCS. **References:** (92) NAGY, Z.Z., TAKACS, A.I., FILKORN, T., KRÁNITZ, K., GYENES, A., JUHÁSZ, É., SÁNDOR, G.L., KOVACS, I., JUHÁSZ, T. AND SLADE, S. 2014. Complications of femtosecond laser–assisted cataract surgery. Journal of Cataract & Refractive Surgery, 40(1), 20-28.	analysis, are due to publish in 2018. Details of both have been passed to the NICE surveillance team, and there are processes by which a rapid, targeted update of that part of the guideline can be undertaken, should that new evidence imply the recommendations need to be reviewed. It should be noted that the decision to recommend FLACS only as part of a trial reflects the economic evidence which does not at the time of writing support FLACS as a cost-effective option for cataract surgery. Circularity was not included as an outcome of interest because we did not find evidence, including in the trials in the Cochrane review that the differences in circularity between phacoemulsification and FLACS impacted on key outcomes such as acuity. Furthermore, the existing economic evidence does not suggest that the differences in outcomes which are poor surrogates for acuity translate into tangible health economic benefits which would offset the costs of the device, disposables and estate costs associated.
Alcon Eye Care UK	Full	137	3199-3202	It appears that 'endothelial cell loss' (ECL), an important post-operative complication of PCS, has not been evaluated while several studies have reported this outcome:	Thank you for your comment. The currently available randomised controlled trials, including a recent Cochrane Review, do not support the conclusion of meaningful additional benefits with FLACS. Whilst we agree that some cohort studies have reported reduced endothelial cell loss and reduced phacoemulsification energies, the study type searched and included as the

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				1. An independently conducted SLR and meta-analysis (Chen et al, 2016) concluded that the mean ECL was significantly lower for patients undergoing FLACS versus PCS at 1 week, 1 month and 3 months after surgery. 2. Schargus et al. (2015) found that ECC significantly decreased in both the FLACS group vs. PCS by 6 months (P=0.046 and P=0.002, respectively). 3. Valery (2014) found that after 3 months of follow up, FLACS patients had significantly lower ECL versus PCS (6.5% vs. 13.2%, no P value reported). Post-operative central corneal thickness (CCT) is another important post-operative safety outcome since it reflects the central corneal edema after surgery (Chen et al 2016).A recent meta-analysis found that post-operative CCT up to 6 months was significantly lower in the FLACS group versus the PCS group (Chen 2016). As noted above, endothelial cell loss is significantly associated with phacoemulsification time and ultrasound energy used during the procedure. An independently conducted meta-analysis (Chen 2016) synthesized evidence from 5 studies reporting mean phacoemulsification power (MP) and cumulative dissipated energy (CDE). Findings show that FLACS required significantly less phacoemulsification power than	most appropriate, in this case RCTs, within the review question was determined and ratified by the guideline committee prior to its commencement. We are aware that 2 large RCTs (FACT and FEMCAT), at least 1 of which will include a parallel economic analysis, are due to publish in 2018. Details of both have been passed to the NICE surveillance team, and there are processes by which a rapid, targeted update of that part of the guideline can be undertaken, should that new evidence imply the recommendations need to be reviewed. It should be noted that the decision to recommend FLACS only as part of a trial reflects the economic evidence which does not at the time of writing support FLACS as a cost-effective option for cataract surgery. ECL was not included as an outcome of interest because we did not find evidence, including in the trials in the Cochrane review that the differences in ECL between phacoemulsification and FLACS impacted on key outcomes such as acuity. Furthermore, the existing economic evidence does not suggest that the differences in ECL translate into tangible health economic benefits which would offset the costs of the device, disposables and estate costs associated.

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				PCS. The overall effect in phacoemulsification power favored FLACS (WMD: -6.57, 95% CI: -7.08 to -6.05, P < .001, I2 > 50%)." **Reference:** (93) VALERY, S., ISHCHENKO, V., USTIMENKO, S., VOLODYMIR, S., HETMAN, J., MAGDYCH, K. Advantages of femto-phaco. In: Proceedings from the European Society of Cataract & Refractive Surgeons; 13-17 September 2014, Excel, London, UK.	
Alcon Eye Care UK	Full	137	3207-3210	We would like to highlight that effective phacoemulsification time (EPT) is an important metric since it is associated with safety outcomes but has not been considered in this evidence review. Several studies have shown that EPT is significantly reduced with FLACS and two meta-analyses which synthesized the evidence from individual studies (Chen 2015 and Chen 2016) found that EPT was significantly lower for FLACS versus PCS. **Reference:** (94) CHEN, X., XIAO, W., YE, S., CHEN, W., LIU, Y. 2015. Efficacy and safety of femtosecond laser-assisted cataract surgery versus conventional phacoemulsification for cataract: a meta-analysis of randomized controlled trials. Sci Rep., 13; 5, 13123.	The currently available randomised controlled trials, including a recent Cochrane Review, do not support these conclusions. Whilst we agree that some cohort studies have reported reduced endothelial cell loss and reduced phacoemulsification energies, the study type searched and included as the most appropriate, in this case RCTs (so as to avoid potential selection bias), within the review question was determined and ratified by the guideline committee prior to its commencement. We are aware that 2 large RCTs (FACT and FEMCAT), at least 1 of which will include a parallel economic analysis, are due to publish in 2018. Details of both have been passed to the NICE surveillance team, and there are processes by which a rapid, targeted update of that part of the guideline can be undertaken, should

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					that new evidence imply the recommendations need to be reviewed. It should be noted that the decision to recommend FLACS only as part of a trial reflects the economic evidence which does not at the time of writing support FLACS as a cost-effective option for cataract surgery. ECL was not included as an outcome of interest because we did not find evidence, including in the trials in the Cochrane review that the differences in ECL between phacoemulsification and FLACS impacted on key outcomes such as acuity. Furthermore, the existing economic evidence does not suggest that the differences in ECL translate into tangible health economic benefits which would offset the costs of the device, disposables and estate costs associated.
Alcon Eye Care UK	Full	137	3211-3214	We would like to bring to the Committee's attention that a cost-effectiveness study comparing FLACS vs. PCS has not been included in the review of evidence (Lee et. al., 2016). This study was conducted to assess the cost-effectiveness of FLACS compared to PCS for medically necessary cataract removal in a publicly funded hospital in Canada. Incremental QALY gain was observed in FLACS group over time and over lifetime FLACS resulted in incremental cost-effectiveness ratio (ICER) of Canadian $18,099 over PCS. This ICER is well within the acceptable thresholds recommended by NICE and it	Thank you for your comment. The reference you refer to is an abstract and has not been published as a complete paper in a peer reviewed journal. It cannot therefore be critically appraised and evaluated with sufficient rigour to be included as evidence in a Clinical Guideline.

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				demonstrates FLACS are a cost-effective treatment option with incremental QALY gain. **Reference:** (95) LEE, A., et al. Economic evaluations of medical devices in Canada: LenSx® Femtosecond laser-assisted cataract surgery. Value in Health 19.3 (2016): A304-A305.	
Alcon Eye Care UK	Full	137	3203-306	We believe that FLACS has the potential to improve the post-operative visual outcomes of cataract surgery, as indicated in the independently conducted meta-analysis (Chen 2016) which synthesized the evidence from individual studies and found that "the uncorrected distant visual acuity at the end of the follow-up period with FLACS was significantly better than PCS (WMD: -0.07, 95% CI: -0.14 to 0.00, P = .05) based on a random-effects model". We fully recognize that as noted by the authors there was a very high heterogeneity between the studies which limits the validity of the argument. Nevertheless it indicates the potential advantages of the technology over PCS.	Thank you for your comment. The currently available randomised controlled trials, including a recent Cochrane Review, do not support these conclusions. The study type searched and included as the most appropriate, in this case RCTs, within the review question was determined and ratified by the guideline committee prior to its commencement. We are aware that 2 large RCTs (FACT and FEMCAT), at least 1 of which will include a parallel economic analysis, are due to publish in 2018. Details of both have been passed to the NICE surveillance team, and there are processes by which a rapid, targeted update of that part of the guideline can be undertaken, should that new evidence imply the recommendations need to be reviewed.

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					It should be noted that the decision to recommend FLACS only as part of a trial reflects the economic evidence which does not at the time of writing support FLACS as a cost-effective option for cataract surgery.
Alcon Eye Care UK	Full	137	3216	We do not believe that the assumption stated (underpinning these recommendations) "that the evidence is in line with current clinical opinion" is valid. Innovative technology will be associated with a learning curve and the published data and RCT results will, by definition, lag behind current clinical practice and outcomes (Robert 2016). We would like to draw the Committee's attention to the findings from independently conducted meta-analyses (Chen 2015; Chen 2016; Kohnen 2016), which we believe indicates that FLACS technology offers clinical and safety advantages over PCS, particularly in cataract cases at risk of corneal endothelial loss. In addition, FLACS may bring efficiencies to cataract clinics in performing cataract surgeries (Keith et al., 2016) and in long term could pay for their higher acquisition costs. **Reference:** (96) KEITH, M. S., G. BECKER, AND S. BAYER. Efficiency in Use of LenSx Vs Phacoemulsification Surgery for Cataract Treatment: Results from a Global Observational Study. Value in Health 19.7 (2016): A707.	Thank you for your comment. The currently available randomised controlled trials, including a recent Cochrane Review, do not support these conclusions. Whilst we agree that some cohort studies have reported reduced endothelial cell loss and reduced phacoemulsification energies, the study type searched and included as the most appropriate, in this case RCTs, within the review question was determined and ratified by the guideline committee prior to its commencement. We are aware that 2 large RCTs (FACT and FEMCAT), at least 1 of which will include a parallel economic analysis, are due to publish in 2018. Details of both have been passed to the NICE surveillance team, and there are processes by which a rapid, targeted update of that part of the guideline can be undertaken, should that new evidence imply the recommendations need to be reviewed. It should be noted that the decision to recommend FLACS only as part of a trial reflects the economic evidence which does not at the time of writing support FLACS as a cost-effective option for cataract surgery.

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					ECL was not included as an outcome of interest because we did not find evidence, including in the trials in the Cochrane review that the differences in ECL between phacoemulsification and FLACS impacted on key outcomes such as acuity. Furthermore, the existing economic evidence does not suggest that the differences in ECL translate into tangible health economic benefits which would offset the costs of the device, disposables and estate costs associated.
Alcon Eye Care UK	General	General	General	Inclusion/ Exclusion Criteria On another point of consistency, we consider that the Committee acted unreasonably by including non-OECD countries in its review for some questions but not for others. We note that for RQ20 the Committee did not exclude non-OECD countries from the scope of reviewed studies, while it did for other review questions. This inclusion/exclusion criterion appears to be implemented in a non-systematic way. We are not entirely clear on the rationale for this distinction. The Manual notes: *"Search filters should, however, be used with caution because concepts such as study design, age, setting and geography may not be adequately described in the title or abstract of a database record, and may not be captured by the indexing."*[18] The Committee should have applied the same standard across all review questions.	Thank you for your comment. The review question protocols, including both inclusion and exclusion criteria, were developed and agreed by the guideline committee, based on their estimates of the volume of literature in the area, and the likely additional benefits of including non-OECD studies. The inclusion/exclusion of OECD countries was determined on the review questions context with regards to UK settings and structures. Please note: the recommendations around lens design and material have been removed to allow for further consideration.

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				Specifically, it is our view Recommendation 22 is heavily influenced by the results from one study, Zhu et al. (2012). This paper and 4 studies contained within were conducted in non-OECD countries: • Rocha et al. (2007) Brazil • Pandita et al. (2007) India • Barisic et al. (2007) Croatia • Wang et al. (2010) China If the same criterion was applied to this review question as was to the review questions on astigmatism or femto-second laser, data attained from the above studies would not have been deemed sufficient to inform this draft guidance. This has particular significance with respect to the Wang et al. (2010) study; results from which play the largest role on the overall result from the meta-analysis on colour vision in mesopic conditions in Zhu et al. (2012). **Clarification Question:** We would like to understand why for this review question studies from non-OECD countries were included but for the other review questions were excluded? **Reference:** [18] Manual, page 85.	

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Alcon Eye Care UK	General	General	General	We would like to bring to the Committee's attention that the following eligible RCT studies should have been included in the evidence review: 1. Maxwell et al. (2017) a. An RCT (n=155) that compared post-operative clinical outcomes and safety of multifocal IOLs and monofocal IOLs implantation in cataract patients b. Significant improvement in corrected near vision and intermediate vision was reported in patients with multifocal IOL group vs. monofocal IOL group (P<0.0001). c. Significantly greater improvement in spectacle independence in multifocal group (p<0.01) d. Comparable adverse event rates 2. Shah et al. (2015) a. An RCT that compared treatment outcomes in cataract patients implanted with monofocal (non-toric only, n=100) or	Thank you for your comment and providing us with information regarding the evidence base for multifocal lenses. The Maxwell study has now been incorporated in to the review and all the results updated accordingly, Its inclusion does not alter the conclusions of the review, that multifocal lenses provide improvements in uncorrected visual acuity and spectacle independence, but increase rates of glare and halos. The committee also agreed that this evidence did not alter their conclusion that multifocal lenses did not appear to represent a cost-effective use of NHS resources. The study by Shah was identified as part of the original evidence review, but then excluded. The participants were randomised to receive either a monofocal IOL or multifocal IOL (mixture of toric and non-toric). However, results were not reported separately for the toric and non-toric multifocal groups, and therefore it was not possible to isolate the results for the comparison of interest – non-toric monofocal versus non-toric multifocal. As a result of this, it was necessary to exclude this study from the review.

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				multifocal (nontoric or toric, as needed, n=108) IOLs. b. Significantly more patients in multifocal group achieved UDVA and UNVA of logMar of 0.1 or better (p<0.0001). c. Significantly higher spectacle independence at 6 months in the multifocal IOL group than in the monofocal IOL group (p < .0001). These two RCT studies were conducted more recently than the majority of studies included in the evidence review, represent the currently available multifocal technology better and demonstrate that multifocal IOLs improve post-operative visual outcomes: in particular, patients achieve significantly higher spectacle independence vs. monofocal IOLs. We believe that this evidence should further strengthen the findings of the meta-analysis in favor of multifocal IOLs. **References:** (60) MAXWELL, A., HOLLAND, E., CIBIK, L., FAKADEJ, A., FOSTER, G., GROSINGER, L., MOYES, A., NIELSEN, S., SILVERSTEIN, S. & TOYOS, M. 2017. Clinical and patient-reported outcomes of bilateral	

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				implantation of a+ 2.5 diopter multifocal intraocular lens. Journal of Cataract & Refractive Surgery, 43, 29-41. (61) SHAH, S., PERIS-MARTINEZ, C., REINHARD, T. & VINCIGUERRA, P. 2015. Visual outcomes after cataract surgery: multifocal versus monofocal intraocular lenses. *Journal of Refractive Surgery,* 31**,** 658-666.	
Alcon Eye Care UK	General	General	General	We are surprised to see that observational studies were not considered by the Committee while making recommendations on the multifocal IOLs. We recognize the fact that observational studies are conducted in less controlled environment however they provide supportive evidence reflecting the real world scenario and compliment/confirm RCT findings. We have identified the following comparative prospective observational studies on multifocal IOLs vs. monofocal IOLs and key findings are summarized below: 1. Berdeaux et al. (2008) a. Patients with multifocal IOLs reported significant improvement in spectacle independence, visual functioning and patient satisfaction vs. those with monofocal IOLs. 2. Wang et al. (2012) a. In cataract patients with high myopia, multifocal IOLs provided improvements in functional vision range from near to	Thank you for your comment. The Committee prioritised RCTs as the highest standard of evidence available to answer this question, and sufficient evidence was available from RCTs that the Committee did not believe additional evidence from lower quality observational studies would have been useful for decision making. However notwithstanding this fact, the evidence identified here from observational studies, whilst adding further weight to the conclusions already made about benefits from multifocal lenses, do not address the central issue that led the committee to make a 'do not' recommendation for multifocal lenses, namely the increased costs, and lack of evidence they represent a cost-effective use of NHS resources.

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				distance and a high level of spectacle independence and satisfaction. 3. Alio et al. (2011) a. Patients with full diffractive multifocal IOLs performed better in several daily tasks at near and intermediate distances, with less night-driving limitation than with apodized multifocal and monofocal IOLs. It is clear from these observational studies that the benefits of multifocal IOLs observed in RCTs are replicated in real world clinical practice, that they improve the post-operative visual outcomes and enable patients to achieve significantly higher spectacle independence. Therefore, we would ask the Committee to acknowledge this evidence and modify evidence statements accordingly. **References**: (62) BERDEAUX, G., VIALA, M., ROBOREL DE CLIMENS, A. & ARNOULD, B. 2008. Patient-reported benefit of ReSTOR multi-focal intraocular lenses after cataract surgery: results of principal component analysis on clinical trial data. Health Qual Life Outcomes, 6, 10. (63) WANG, Q., ZHAO, G., WANG, Q. & JIA, W. 2012. Visual quality after AcrySof IQ ReSTOR intraocular lens	

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				implantation in eyes with high myopia. Eur J Ophthalmol, 22, 168-74. (64) ALIO, J. L., PLAZA-PUCHE, A. B., PINERO, D. P., AMPARO, F., RODRIGUEZ-PRATS, J. L. & AYALA, M. J. 2011. Quality of life evaluation after implantation of 2 multifocal intraocular lens models and a monofocal model. J Cataract Refract Surg, 37, 638-48.	
Association of British Healthcare Industries	Full	General	General	As the UK's leading medical technology industry association, the ABHI are pleased that NICE have thought it imperative to develop guidelines on the management of cataracts. While we very much welcome the recommendation that cataract surgery should not be restricted on the basis of visual acuity, we feel that overall tone of this guideline is regressive in nature, as throughout, recommendations are made which will act to restrict patients from accessing innovative technologies, such as the following: • Toric intraocular lenses (IOLs) • Femtosecond laser-assisted cataract surgery • Multifocal IOLs. As part of its Mandate, NHS England highlight that innovation is critical in enabling delivery of better outcomes for patients across the NHS. Furthermore, in Lord Darzi's report, *High quality care for all* - it is asserted	Thank you for your comments and recognition of the value of this guidance. Whilst supporting innovation is important, NICE has a statutory duty under the Health and Social Care Act to '… have regard to the broad balance between the benefits and costs of the provision of health services or of social care in England' Consequently, NICE considers cost-effectiveness alongside effectiveness in all recommendations it makes, as to make positive recommendations for interventions that are not cost-effective would result in people elsewhere in the system being denied access to more effective interventions. The Committee agreed that patient choice is a key feature of the cataract pathway, and it is for this reason that a number of recommendations around patient information (section 1.1 of the recommendations) and discussions (recommendations 1.2.1 and 1.6.4) were

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				that innovation also must be supported to foster a pioneering NHS (Darzi, 2008). We believe that the NICE guidance with respect to the technologies outlined above, may act to stifle the very same innovation that the NHS have made their intention to foster. Patient choice - There should be a vehicle of measurement to ensure that patients are explained the options available to them in terms of new innovation, which would allow them to make informed choices jointly with their Healthcare provider. A tool/metric would be extremely valuable, as part of executing the NICE Cataract Surgery Pathway guidance. This would address our concerns of patient awareness of new/current technologies i.e. Toric intraocular lenses (IOLs), Femtosecond laser-assisted cataract surgery and Multifocal IOL's. **Reference 1: DARZI, A. 2008. High quality care for all: NHS next stage review final report, The Stationery Office.**	made. However, the importance of these discussions does not take away NICE's responsibility to only recommend interventions that will represent a cost-effective use of NICE resources.
Association of British Healthcar	Full	25	581 - 582	It is of considerable concern that the implementation of these surgery guidelines in the NHS would prevent astigmatic cataract patients from accessing the best available astigmatism correction treatment (Toric IOLs)	Thank for your comment. Recommendations to address pre-existing astigmatism were determined by the guideline committee following analysis of the existing relevant efficacy and cost effectiveness

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e Industries				and consequently, resign patients to surgical interventions which are infrequently used, and which are likely to result in poorer outcomes This clear clinical superiority is perhaps best illustrated by the Meta-analysis of 13 RCTs initiated by the Danish Health and Medicines Authorities in 2016, where the authors conclude that toric IOLs are superior to non-toric IOLs even in combination with a relaxing incision, in lowering postoperative astigmatism, improving postoperative uncorrected visual acuity and greater spectacle independence (Kessel., 2016) This proven clinical superiority (as is also detailed in this guideline) has offered sufficient grounds for highly respected clinical societies/national health authorities in other OECD countries, to recommend the use of Toric IOLs for cataract patients with pre-operative corneal astigmatism The 2016 American Academy of Ophthalmologists (AAO) Preferred Practice Pattern (PPP) guidelines recommends Toric IOLs should be offered to cataract patients with ≥1D of pre-operative corneal astigmatism. (Olson et al., 2016) Similarly, the 2014 Danish Health and Medicines Agency (DHMA) recommend Toric IOLs for the correction of ≥2D pre-operative corneal astigmatism in cataract patients.	evidence. NICE is required to consider cost-effectiveness alongside effectiveness in all the guidelines it produces, and therefore it is not sufficient to only demonstrate that toric lenses are effective in reducing astigmatism, but also that they are a cost-effective use of NHS resources. The committee agreed that the evidence demonstrated their were benefits from toric lenses in terms of reduced post-operative astigmatism, but also agreed there were considerable additional pathway costs associated with their use (over and above the costs of the lenses themselves). Therefore, the committee were not convinced that toric lenses represented a cost-effective use of NHS resources, and therefore agreed the appropriate recommendation to make was a research recommendation looking at the cost-effectiveness of toric IOLs in the NHS.

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	Full	38	General	Due to the clear clinical benefits associated with toric IOLs (as is detailed extensively in this guidance), we are of the considered view that individual NHS trusts assess affordability of toric IOLs based on their own pathway and negotiated toric pricing agreements in place with their IOL supplier, ultimately affording cataract patients with astigmatism the right to choose the best available astigmatism correction treatment Reference X: KESSEL, L., ANDRESEN, J., TENDAL, B., ERNGAARD, D., FLESNER, P. & HJORTDAL, J. 2016. Toric Intraocular Lenses in the Correction of Astigmatism during Cataract Surgery A Systematic Review and Meta-analysis. Ophthalmology, 123, 275-286 Reference X: OLSON, R. J., BRAGA-MELE, R., CHEN, S. H., MILLER, K. M., PINEDA, R., II, TWEETEN, J. P. & MUSCH, D. C. Cataract in the Adult Eye Preferred Practice Pattern 2016 *Ophthalmology,* 124**,** P1-P119 Reference X: KESSEL, L., ANDRESEN, J., TENDAL, B., ERNGAARD, D., FLESNER, P. & HJORTDAL, J. 2016. Toric intraocular lenses in the correction of astigmatism during cataract surgery: a systematic review and meta-analysis. Ophthalmology, 123, 275-286.	

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				Reference 5: OLSON, R. J., BRAGA-MELE, R., CHEN, S. H., MILLER, K. M., PINEDA, R., II, TWEETEN, J. P. & MUSCH, D. C. Cataract in the Adult Eye Preferred Practice Pattern. Ophthalmology, 124, P1-P119 The referral pathway should be clearly defined through the Optometrist to diagnose the cataract to speed up the referral and ensure appropriate referrals are made to the hospital.	
Association of British Healthcare Industries	Full	27	36	In reference to the recommendation, "consider bilateral simultaneous cataract surgery for people who are at low risk of complications during and after surgery" It is our considered view, that in recommending the above, the committee have underestimated the impact of the following: • As this procedure is currently infrequently performed, it is our considered opinion that very few centres have the structures in place (in terms of procurement and materials handling) to facilitate bilateral simultaneous cataract surgery. Consequently, this may jeopardize the safeguarding of patients having both eyes operated on in one session. • From a supply side, the situation is similar with very few suppliers set up to sufficiently facilitate this procedure	Thank you for your comment. The committee agreed that not all centres may have the systems in place to be able to deliver bilateral simultaneous surgery. However, they emphasised that the recommendation was only made at the 'consider' level, and therefore the expectation is not that the guideline lead to simultaneous surgery becoming commonplace at all the centres in the near future. The committee agreed there was the risk of particularly serious post-operative complications with bilateral simultaneous surgery (in particular harm to both eyes). This was included in the evidence base, formed part of the committee discussion (as detailed in the evidence to recommendations section) and was reflected in the recommendations made, as bilateral simultaneous surgery was only recommended for people at a low risk of ocular complications.

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				Finally, we would like to make the point that post-operative complications and associated costs should be detailed comprehensively in the guideline. These costs should not be underestimated.	
Association of British Healthcare Industries	Full	34	648 - 650	We are concerned that innovative femto-laser assisted cataract surgery (FLACS) has not been recommended by NICE for use in the NHS. FLACS brings multiple advances to conventional phacoemulsification surgery with improved outcomes of cataract surgery. FLACS technology is continuously evolving and appears to be the standard of cataract surgery in future (Ranka and Donnenfeld, 2015) The 2016 American Academy of Ophthalmology (AAO) preferred practice pattern guidelines have acknowledged "Femtosecond laser technology has the potential to improve safety, accuracy, and clinical outcomes" (Olson et al.). A number of studies demonstrate the relative benefits of femtosecond laser, in particular in the case of refractive-cataract surgery and typically these studies provide evidence that in comparison to standard ultrasound phacoemulsification, FLACS is a safe procedure (Abell et al., 2015, Donaldson et al., 2013, Chen & Swinney., 2015) It is also the case that numerous studies report that capsulotomies made with a femtosecond laser are significantly more precise in reproducibility than manual continuous curvilinear capsulorrhexis (CCC). This is likely	Thank you for your comment. The currently available randomised controlled trials, including a Cochrane Review on the topic, do not support the conclusion that there are significant clinical or productivity gains with FLACS. Whilst we agree that some cohort studies have reported reduced endothelial cell loss and reduced phacoemulsification energies, the study type searched and included as the most appropriate, in this case RCTs, within the review question was determined and ratified by the guideline committee prior to its commencement. We are aware that 2 large RCTs (FACT and FEMCAT), at least 1 of which will include a parallel economic analysis, are due to publish in 2018. Details of both have been passed to the NICE surveillance team, and there are processes by which a rapid, targeted update of that part of the guideline can be undertaken, should that new evidence imply the recommendations need to be reviewed. It should be noted that the decision to recommend FLACS only as part of a randomised trial reflects the economic evidence, which does not at the time of

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				to result in more stable refractive results with less decentration and IOL tilt in comparison to manual CCC and consequently may play a role in both refractive IOL centration and outcomes. (Kranitz et al., 2011, Kranitz et al., 2012, Nagy et al., 2011, Filkorn et al., 2012, Conrad-Hengerer., 2015) We would also like inquire why 'endothelial cell loss' (ECL), an important complication of PCS, has not been included as an outcome of interest in this review? Evidence suggests that patients undergoing femto-laser surgery experience significantly lower mean ECL compared with those having standard ultrasound phacoemulsification surgery (Chen et al, 2016, Valery., 2012, Schargus et al., 2015) Furthermore, there is evidence to suggest that less effective phacoemulsification time and cumulative dissipated energy is required in order to emulsify the lens when lens fragmentation is performed by a femtosecond laser. (Abell et al., 2013, Packer et al., 2014) Outputs from the FEMCAT study led by Dr Cedric Schweitzer from Bordeaux (https://clinicaltrials.gov/ct2/show/NCT01982006?term=FEMCAT&rank=1) , which will be presented at ESCRCS 2017 in Lisbon (7-11th October 2017). As this is the world's largest study being conducted globally with 1700	writing support FLACS as a cost-effective option for cataract surgery. Endothelial Cell Loss (ECL) was not included as an outcome of interest because we did not find evidence, including in the trials in the Cochrane review, that the differences in ECL between phacoemulsification and FLACS impacted on key outcomes such as acuity. Furthermore, the existing economic evidence does not suggest that the differences in ECL translate into tangible health economic benefits which would offset the costs of the device, disposables and estate costs associated. With regard to your final assertion that FLACS has "…potential to improve safety, accuracy, and clinical outcomes in comparison to standard ultrasound phacoemulsification surgery" we hope that the recommendation to use this technology only within a trial will provide opportunity for researchers to develop high quality trials to support these assertions, which are not currently supported by the findings of existing trials.

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				patients and five centres across France reporting on the safety and efficacy of FLACS along with its cost effectiveness. So there should be an opportunity to have a revision based on this study reporting so close to the NICE Guidance being finalised in the same period. We are deeply concerned that this 'do not do' recommendation will play a role in preventing patients in the NHS from accessing this innovative technology which as is reflected by the above evidence, has the potential to improve safety, accuracy, and clinical outcomes in comparison to standard ultrasound phacoemulsification surgery. **Reference 3: RANKA, M. & DONNENFELD, E. D. 2015. Femtosecond laser will be the standard method for cataract extraction ten years from now. Surv Ophthalmol, 60, 356-60.** **Reference 4: OLSON, R. J., BRAGA-MELE, R., CHEN, S. H., MILLER, K. M., PINEDA, R., II, TWEETEN, J. P. & MUSCH, D. C. Cataract in the Adult Eye Preferred Practice Pattern. *Ophthalmology,* 124, P1-P119** **Reference 5: Abell RG, Darian-Smith E, Kan JB, et al. Femtosecond laser-assisted cataract surgery versus standard phacoemulsification cataract surgery: outcomes and safety in more than 4000 cases at a single center. J Cataract Refract Surg 2015;41:47-52.**	

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				Reference X: Donaldson KE, Braga-Mele R, Cabot F, et al. Femtosecond laser-assisted cataract surgery. J Cataract Refract Surg 2013;39:1753-63. 511. **Reference X: Chen M, Swinney C. Comparing the intraoperative complication rate of femtosecond laser-assisted cataract surgery to traditional phacoemulsification. Int J Ophthalmol 2015;8:201-3.** **Reference X: Kranitz K, Takacs A, Mihaltz K, et al. Femtosecond laser capsulotomy and manual continuouscurvilinear capsulorrhexis parameters and their effects on intraocular lens centration. J Refract Surg 2011;27:558-63.** **Reference X: Kranitz K, Mihaltz K, Sandor GL, et al. Intraocular lens tilt and decentration measured by Scheimpflug camera following manual or femtosecond laser-created continuous circular capsulotomy. J Refract Surg 2012;28:259-63.** **Reference X: Nagy ZZ, Kranitz K, Takacs Al, et al. Comparison of intraocular lens decentration parameters after femtosecond and manual capsulotomies. J Refract Surg 2011;27:564-9. 515.**	

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				Reference X: Filkorn T, Kovacs I, Takacs A, et al. Comparison of IOL power calculation and refractive outcome after laser refractive cataract surgery with a femtosecond laser versus conventional phacoemulsification. J Refract Surg 2012;28:540-4. **Reference X: Conrad-Hengerer I, Al Sheikh M, Hengerer FH, et al. Comparison of visual recovery and refractive stability between femtosecond laser-assisted cataract surgery and standard phacoemulsification: six-month follow-up. J Cataract Refract Surg 2015;41:1356-64.** **Reference X: Hatch KM, Schultz T, Talamo JH, Dick HB. Femtosecond laser-assisted compared with standard cataract surgery for removal of advanced cataracts. J Cataract Refract Surg 2015;41:1833-8.** **Reference X: Abell RG, Kerr NM, Vote BJ. Femtosecond laser-assisted cataract surgery compared with conventional cataract surgery. Clin Experiment Ophthalmol 2013;41:455-62. 519.** **Reference X: Packer M, Solomon JD. Impact of crystalline lens opacification on effective phacoemulsification time in femtosecond laser-assisted cataract surgery. Am J Ophthalmol 2014;157:1323-4.**	

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				Chen X, Xiao W, Ye S, Chen W, Liu Y. Efficacy and safety of femtosecond laser-assisted cataract surgery versus conventional phacoemulsification for cataract: a meta-analysis of randomized controlled trials. Sci Rep. 2015;5:13123. **Reference X: Valery S, Ishchenko V, Ustimenko S, Volodymir S, Hetman J, Magdych K. Advantages of femto-phaco. In: Proceedings from the European Society of Cataract & Refractive Surgeons; 13-17 September 2014, Excel, London, UK.** **Reference X: Schargus M, Suckert N, Schultz T, Kakkassery V, Dick HB. Femtosecond laser-assisted cataract surgery without OVD: a prospective intraindividual comparison. J Refract Surg. 2015;31(3):146-152.**	
Association of British Healthcare Industries	Full	100 - 126	General	**On the issue of lens restrictions (Page 100-126)** Firstly from a clinical perspective, the obvious problem that could occur is that when a patient comes back after an extended period for surgery on the second eye then a lens may not be available as it is outside the recommendations, and could have been removed from the market in the most extreme scenario or prohibited from use or purchase by a hospital manager. In addition a clinician may be discouraged from using a specific type of	Thank you for your comment. The committee agreed that the recommendations being made were for the most appropriate choice of lens design going forwards, and it was the responsibility of service providers to ensure that individuals were not disadvantaged due to a change in the type of lens used.

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				lens technology that may be of particular benefit to a patient with special needs because it is either removed from the market or not on the purchase list.	
Association of British Healthcare Industries	Full	100 - 126	General	Secondly and not unrelated to the above comment, is that an individual trust could be faced with significantly increasing costs, caused by changing from their presently contracted lens or supplier to a different one. The reason for this is, that a highly competitive open market has resulted in many trusts having negotiated volume based contracts on a particular lens type. A change to this contract is more likely to mean an increased item price than a reduction. Also there is likely to be a general drifting up of prices, as in our experience, restrictions of this type tend to act as a barrier to and consequently stifle competition	Thank you for your comment. The committee agreed it was appropriate to recommend the most appropriate lens design for individuals, and that the commercial arrangements behind purchasing lenses currently available at equivalent prices were the responsibility of individual providers. The committee noted that the guideline providers comment on the timescale for implantation of its recommendations: "Putting recommendations into practice can take time. How long may vary from guideline to guideline, and depends on how much change in practice or services is needed. Implementing change is most effective when aligned with local priorities" The committee agreed that if a provider had a long-term contract in place for a particular lens and there would be high costs from altering that contract, then it may well be appropriate to wait until that contract expires before making decisions about future lens suppliers.
Association of British	Full	100 - 126	General	A further point related to the cost of changing lenses concerns the required additional training of both doctors and nurses. When a team has been used to using one	Thank you for your comment. The committee noted that the types of lenses used in the NHS had changed many times over the history of cataract surgery in the

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Healthcare Industries				type of lens system over time (often many years) the training burden is quite high and there is also inevitably a period of compromised outcomes and increased wastage when wholesale changes are made.	NHS, and there was no reason to suppose that any changes arising from these recommendations would be more complex or expensive to implement than those previous changes.
Association of British Healthcare Industries	Full	116	2732	While we are cognizant of the association between Multifocal IOLs and the increased risk of glare & halos, we would like to make the committee aware that there are Multifocal IOLs available with a lower add for near vision that can help minimize these issues (Madrid-Costa et al., 2013, Hayashi et al. 2009)	Thank you for your comment and bringing this to our attention. After reconsidering the evidence, the committee continued to conclude that the additional costs of multifocal lenses (both lens costs and pathway costs) were not currently justified by any robust evidence of cost-effectiveness, and therefore it was appropriate to recommend that multifocal lenses not be routinely offered in the NHS.
Association of British Healthcare Industries	Full	118	2748	We are concerned with the assertion that there is 10% chance of needing a lens explantation with multifocal lenses. As the source of this rate has not been documented by the committee, we believe this is assertion to be anecdotal. There is evidence to show a much lower rate: a large real-world study (1438 eyes conducted between 2009-2014) reported an explanation rate of just 0.83% with multifocal IOLs (Kermani & Gerten., (2016). Kermani O., Gerten G. Klinische Monatsblatter fur Augenheilkunde (2016) 233:8 (928-932).	Thank you for your comment. The committee has agreed it was appropriate to remove the reference to explantation rates with multifocal lenses, as it was agreed the reported number were unlikely to be accurate for modern lens designs.
Association of British Healthcar	Full	118	2750	It is our considered opinion that the recommendation to "Do not offer multifocal intraocular lenses for people having cataract surgery" will act to restrict patients in the NHS from the best possible treatment to be spectacle-	Thank you for your comment. The committee agreed that multifocal lenses are effective at improving levels of unaided visual acuity and reducing rates of spectacle dependence (as shown in both the evidence in the

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e Industries				free following cataract surgery. Therefore, requiring patients to invest in purchasing glasses out of their own pocket in order to correct their far or near-sightedness. A Cochrane systematic review and meta-analyses of 16 RCTs conducted in 2012, demonstrated that multifocal IOLs were effective at improving near vision when compared with monofocal IOLs and that unaided distance visual acuity was similar in the two groups. Total freedom from use of glasses was achieved more frequently with multifocal than monofocal IOLs (Calladine et al., 2012) Due to the clear benefits associated with multifocal IOLs we are of the considered view that individual NHS trusts assess affordability of multifocal IOLs based on their own pathway and negotiated pricing agreements in place with their IOL supplier, ultimately affording cataract patients the right to choose the best available treatment in order be spectacle-free following cataract surgery. Reference X: Calladine D, Evans JR, Shah S, Leyland M. Multifocal versus monofocal intraocular lenses after cataract extraction. Cochrane Database Syst Rev 2012, Issue 9. Art. No.: CD003169. DOI: 10.1002/14651858.CD003169.pub3.	guideline and the published Cochrane review), and that if there were no additional costs associated with their use, then they would represent a relevant treatment alternative. However, NICE guideline are required to consider the cost-effectiveness as well as the effectiveness of the interventions under consideration, and given the substantial additional costs associated with multifocal lenses (both lens and pathway costs) the committee agreed that they could not be recommended as a cost-effective use of NHS resources.

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				Reference X: Madrid-Costa D, Ruiz-Alcocer J, Ferrer-Blasco T, et al. Optical quality differences between three multifocal intraocular lenses: bifocal low add, bifocal moderate add, and trifocal. J Refract Surg 2013;29:749-54. Reference X: Hayashi K, Manabe S, Hayashi H. Visual acuity from far to near and contrast sensitivity in eyes with a diffractive multifocal intraocular lens with a low addition power. J Cataract Refract Surg 2009;35:2070-6.	
Association of British Healthcare Industries	Review Protocols	General	General	While we are cognisant of the pursuit of the best quality evidence to include in this guideline, we were concerned with the lack of consistency applied to inclusion/exclusion criteria throughout. For some review questions, observational studies are included to inform the guidance, while for other review questions, Randomised controlled trials only, are included. It is our view that a more holistic approach should be taken when considering the evidence, as in the case of medical devices, traditional clinical trials may be challenging or impractical to conduct. This is true due to the realities of medical device innovation and development cycles, ethical issues that may arise with treatment assignment, and other similar challenges in	Thank you for your comment. The choice of study design to include for each review question were decided by the guideline committee at the outset of the process, guided by their judgement as to which questions would most benefit from the inclusion of non-RCT evidence. The committee agreed to prioritise the focus on non-RCT evidence to those question it was felt to provide most value to. The committee also noted that across a wide range of areas around cataract surgery, randomised controlled trials are not only feasible, but also easier to undertake than in many other clinical areas due to the large patient populations eligible for inclusion. This assertion is supported by the considerable number of

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				executing traditional trials (Food and Administration, 2016). Analyses of RWD, using appropriate methods, may in some cases provide similar information with comparable or even superior characteristics to information collected through a traditional clinical trial (Food and Administration, 2016). **Reference 2: FOOD & ADMINISTRATION, D. 2016. Use of real-world evidence to support regulatory decision-making for medical devices: draft guidance for industry and Food and Drug Administration staff. September 16, 2016.** It is our view that, excluding all non-RCTs from certain review questions, narrows the evidence base considerably and acts to undervalue observational data, which as outlined above (and in particular in the case of medical devices) may provide comparable or superior information compared with RCTs. A balanced approached is required in light of the challenges with MedTech and the technologies being fast paced. This would mean that a criteria which goes beyond looking at RCTs should be considered and discussed with the decision making panel.	randomised trials identified for a number of the questions included within the guideline.
Association of British	Review Protocols	General	General	On another point of consistency, we would like to understand why for some review questions studies from non-OECD countries were included but for others were	Thank you for your comment. Decisions around whether to include non-OECD evidence for each question were made by the guideline committee at the

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Healthcare Industries				excluded? This inclusion/exclusion criteria appears to be implemented in a non-systematic way.	start of the reviewing process, based on their judgement of the available literature in the area, and whether non-OECD studies were likely to provide additional relevant evidence. However, in order to improve the transparency and consistency of the results, we have now added some additional analyses and results to the guideline where, for every question in which non-OECD evidence was included alongside OECD evidence, a sensitivity analysis is reported restricting that analysis to OECD evidence only. No qualitatively different conclusions were identified from this restricted analysis for any questions.
Association of British Healthcare Industries	Short	17	General	Quality of Life questionnaire being used is the VF14 and could you also explain why the CATQUEST9SF (Lundstrom) was not used? As this is a widely validated questionnaire and efficient with use of time.	Thank you for your comment. This comment was not meant to suggest that the VF-14 was the appropriate instrument to use, merely as an example of one that has been used previously.
Bausch + Lomb	Full	137 - 139	3216 - 3220	**Evidence to Recommendations** The committee's 'do not use' recommendation unless part of an RCT, we believe does not take in to account potential outcome and efficiency benefits associated with femtosecond lasers in an NHS setting. The exclusion criteria limiting studies to RCTs only does not take in to	Thank you for your comment and providing us with information regarding the evidence base in FLACS. The study type searched and included within each review question was determined and ratified by the guideline committee prior to its commencement. The committee agreed that RCTs represented the highest standard of evidence available, and that in situations where there were a sufficient number of RCTs

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				account real world data such as the peer review paper by Chee et al [56]. This paper describes a non-randomised comparison between 1,105 laser surgeries, performed by 18 surgeons, and a standard phaco control group, following an audit of the outcomes at the Singapore National Eye Centre. This is a public institution receiving a wide variety of challenging cataract cases. Data worthy of note from the study reported: - Posterior capsule rupture rate of 0.3% compared favourably with their conventional rate of 1.4%. - 794 laser surgeries with the femtosecond laser were matched with 420 historical controls to compare uncorrected visual outcomes. At 6 weeks post op, 38% of eyes in the femto group (242 eyes) were 20/20 or better vs 28.2% of the control group (101) eyes. 68.9% (439 eyes) were 20/25 or better in the femto group vs 56.4% (202 eyes) in the manual control group. - Mean refractive spherical equivalent (MRSE) was significantly better in the femto group at 6 weeks postop, equalling -0.08+/- 0.36D in the femto group vs - 0.13+/- 0.41D in the control group. 56 SOON-PHAIK CHEE, YOUNIAN YANG, AND SENG-EI TI, (2015). Clinical Outcomes in the First Two Years of Femtosecond Laser–Assisted Cataract Surgery	available, it would not be appropriate to include lower quality study designs such as cohort or non-comparative studies, as this would increase the risk of bias in the conclusions being made. The "only in research" recommendation made reflects the clinical and health economic evidence considered by the committee, which does not support the use of the technology in an NHS context. We are aware that 2 large RCTs (FACT and FEMCAT), at least 1 of which will include a parallel economic analysis, are due to publish in 2018. Details of both have been passed to the NICE surveillance team, and there are processes by which a rapid, targeted update of that part of the guideline can be undertaken, should that new evidence imply the recommendations need to be reviewed. For more information about how NICE formulates the wording of recommendations, please see https://www.nice.org.uk/process/pmg6/chapter/developing-and-wording-guideline-recommendations

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Bausch + Lomb	Full	15	218 - 233	**Committee guidance on IOL material** We are pleased that the committee is agreed that the primary focus for IOLs should be primarily on measures such as visual function, quality of life and patient satisfaction. We would therefore like to draw your attention to a multicentre RCT comparing a hydrophilic acrylic IOL and a silicone IOL demonstrating patient satisfaction to be higher with a hydrophilic acrylic IOL vs a silicone IOL in terms of subjective visual quality and dysphotopsia. "Twenty-eight percent of patients reported better subjective visual quality in the Akreos AO eye and 14%, in the Tecnis Z9000 eye (P<.0001). Accordingly, 33% perceived more visual disturbances in the Tecnis Z9000 eye and 11%, in the Akreos AO eye (P<.0001)" [1] We therefore believe it is important, given a study such as this, that hydrophilic acrylic IOLs should carry equal weighting as an IOL choice to hydrophobic acrylic or silicone IOLs and consultants should be given free choice of a particular IOL material based on what they understand would most benefit their patients within the cost restraints of the NHS Trust. Furthermore there are some clear benefits of hydrophilic acrylic over other materials as outlined below: **Biocompatibility**	Please note: the recommendations around lens design and material have been removed to allow for further consideration.

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				Biocompatibility of IOL material is now assessed in terms of uveal biocompatibility (inflammatory response after IOL implantation, with non-specific foreign-body reaction to the lens) and capsular biocompatibility (Lens Epithelial Cells (LEC) reaction to the IOL that play an important role in the pathogenesis of the posterior capsular opacification. Used for many years in ophthalmology, (contact lenses, intracorneal lenses, indentation materials, etc.) hydrophilic acrylics are known for their good uveal biocompatibility, due to their hydrophilic nature and low surface energy. As reported by Schauersberger et al [2], hydrophilic material has less susceptibility to bio contamination. In an in vitro study, nine different types of IOLs were exposed to standardized suspensions of Staphylococcus epidermidis for 5 minutes, then rinsed and tested them for the presence of bacteria. PMMA and hydrophobic IOLs had bacterial densities two or more times higher than hydrophilic IOLs. The authors concluded that hydrophilicity of IOL material was inversely related to adhesion and bacterial density on the IOL surface. In addition, the hydrophilic properties of these hydrophilic acrylic, including low surface energy, cause minimal adherence to silicone oil in patients requiring vitreoretinal surgery[3, 4].	

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				Hydrophilic IOLs seem to have a higher uveal biocompatibility than other type of material in normal and high risk eyes (with uveitis or pseudo exfoliation syndrome) [5-9, 10-12], although it has to be noticed that flare values showed no clinically relevant differences [6, 11]. Conversely, hydrophilic acrylics IOLs seem to have lower capsular biocompatibility as compared to other biomaterials, resulting in more LEC outgrowth, and PCO formation following adult cataract surgery [5-9, 10-12]. However, although LEC outgrowth is material dependant, some authors [8, 11, 12] showed lower LEC outgrowth with modern sharp edges hydrophilic compared to round edges. This is fully coherent with our actual knowledge on PCO development where the lens geometry, especially the square edge design is the main important factor preventing PCO. 1 JOHANSSON, B. (2007) VISUAL AND OPTICAL PERFORMANCE OF THE AKREOS ADAPT ADVANCED OPTICS AND TECNIS Z9000 INTRAOCULAR LENSES. J CATARACT REFRACT SURGERY.33,1565–1572 2 SCHAUERSBERGER J, AMON M, AICHINGER D, GEORGOPOULOS A	

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				Bacterial adhesion to rigid and foldable posterior chamber intraocular lenses – In vitro study J Cataract Refract Surg 2003, 29: 361-6 3 APPLE DJ, ISAACS R, KENT DG ET AL Silicone oil adhesion to intraocular lenses : an experimental study comparing various biomaterials J Cataract Refract Surg 1997, 23: 536-44 4 ARTHUR SN, PENG Q, APPLE DJ, ET AL. Effect of heparin surface modification in reducing silicone oil adherence to various intraocular lenses J Cataract Refract Surg 2001; 27: 1662-9 5 Mullner-Eidenbock A, Amon M, Schauerberger J, et Al Cellular reaction on the anterior surface of 4 types of intraocular lenses J. Cataract. Refract. Surg 2001; 27: 734-40 6 Abela-Formanek C, Amon M, Schild G, et Al Uveal and capsular biocompatibility of hydrophilic acrylic, hydrophobic acrylic, and silicone intraocular lenses J. Cataract. Refract. Surg 2002; 28: 50-61	

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				7 Tognetto D, Toto L, Ballone E, Ravalico G Biocompatibility of hydrophilic intraocular lenses J. Cataract. Refract. Surg 2002; 28: 644-51 8 Schild G, Schauersberger J, Amon M, et Al Lens epithelial cell ongrowth: comparison of 6 types of hydrophilic intraocular lens models J. Cataract. Refract. Surg 2005; 31: 2375-8 9 Abela-Formanek C, Amon M, Schauerberger J, et Al Results of hydrophilic acrylic, hydrophobic acrylic, and silicone intraocular lenses in uveitic eyes with cataract J. Cataract. Refract. Surg 2002; 28: 1141-52 10 Abela-Formanek C, Amon M, Schauerberger J, et Al Uveal and capsular biocompatibility of 2 foldable acrylic intraocular lenses in patients with uveitis or pseudoexfoliation syndrome J. Cataract. Refract. Surg 2002; 28: 1160-72 11 Richter-Mueksch S, Kahraman G, Amon M, et Al Uveal and capsular biocompatibility after implantation of sharp-edged hydrophilic acrylic, hydrophobic acrylic and silicone	

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				intraocular lenses in eyes with pseufoexfoliation syndrome J. Cataract. Refract. Surg 2007; 33: 1414-8 12 Abela-Formanek C, Amon M, Kahraman G, et Al Biocompatibility of hydrophilic acrylic, hydrophobic acrylic, and silicone intraocular lenses in eyes with uveitis having cataract surgery: Long-term follow-up J. Cataract. Refract. Surg 2011; 37: 104-12 **Dysphotopsia and Visual Quality** Dysphotopsia is the primary source of patient dissatisfaction after cataract surgery.[13] The term *dysphotopsia* is used to describe a variety of visual symptoms that result from light reflecting off the intraocular lens (IOL) onto the retina. Dysphotopsia are generally divided into two categories: positive and negative. Positive visual changes involve symptoms of bright artifacts, while negative dysphotopsia are perceived as shadows or dark areas in the visual field.[14] Studies reported a range from as low as 1.5% to as high as 67% for positive dysphotopsia, (with most data showing more moderate numbers of 12% to 35%).[15-16] Negative	

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				dysphotopsia are less prevalent and are thought to occur in only 0.5% to 2.4% of patients.[16,18] **Positive dysphotopsia** are caused by stray light projecting onto the retina, which worsens if that stray light is concentrated in one particular area[19]. Materials with high refractive indices, like Hydrophobic IOLs, help to concentrate a larger amount of light onto a smaller area of retina, resulting in symptoms. Moreover, the increased surface reflectivity of hydrophobic acrylic lenses causes more symptoms compared with hydrophilic acrylic or silicone lenses.[15-20] **Negative dysphotopsia** are a much less studied and understood visual complication than positive dysphotopsia. Patients usually complain of a dark shadow in the temporal visual field. Numerous theories attempt to identify a cause for negative dysphotopsia; suspects include IOL parameters and optics, corneal incision scars, anterior capsulotomy edge involvement, and distance of IOL from the iris.[18,20,21, 22,23] 13. Kinard K, Jarstad A, Olson R. Correlation of visual quality with satisfaction and function in a normal cohort of pseudophakic patients. J Cataract Refract Surg. 2013;39:590-7.	

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				14. Hood CT, Sugar A. Subjective complaints after cataract surgery: common causes and management strategies. Curr Opin Ophthalmol. 2015;26:45-9. 15. Ellis MF. Sharp-edged intraocular lens design as a cause of permanent glare. J Cataract Refract Surg. 2001;27:1061-4. 16. Meacock WR, Spalton DJ, Khan S. The effect of texturing the intraocular lens edge on postoperative glare symptoms: a randomized prospective, double-masked study. Arch Ophthalol. 2002;120:1294-8. 17. Tester R, Pace NL, Samore M, Olson RJ. Dysphotopsia in phakic and pseudophakic patients: incidence and relation to intraocular lens type. J Cataract Refract Surg. 2000;26:810-6. 18. Osher RH. Negative dysphotopsia: long-term study and possible explanation for transient symptoms. J Cataract Refract Surg. 2008;34:1699-1707. 19. Erie JC, Bandhauer MH, McLaren JW. Analysis of postoperative glare and intraocular lens design. J Cataract Refract Surg. 2001;27:614-21. 20. Davison JA. Positive and negative dysphotopsia in patients with acrylic intraocular lenses. J Cataract Refract Surg. 2000;26:1346-55.	

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				21. Peng Q, Visessook N, Apple DJ, et al. Surgical prevention of posterior capsule opacification. Part 3: Intraocular lens optic barrier effect as a second line of defense. J Cataract Refract Surg. 2000;26:198-213. 22. Holladay JT, Zhao H, Reisin CR. Negative dysphotopsia: The enigmatic penumbra. J Cataract Refract Surg. 2012;38:1251-65. 23. Vamosi P, Csakany B, Nemeth J. Intraocular lens exchange in patients with negative dysphotopsia symptoms. J Cataract Refract Surg. 2010;36:418-	
Bausch + Lomb	Full	25	571 - 573	**PCO** We appreciate and agree that PCO is an important consideration for cataract surgery outcomes and therefore efforts should be made to minimise it. However we think that the committee using the word 'offer' and thus implying a 'strong' recommendation to use Hydrophobic acrylic or Silicone IOLs to prevent PCO is not taking into account a number of factors: In accordance with the experimental works of Nishi[24-26] on physiopathology and mechanisms of PCO, square edge design is the most important feature for mid-term PCO prevention.	Please note: the recommendations around lens design and material have been removed to allow for further consideration.

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				The role of square edge design has been clinically confirmed in a recent Meta analysis[27] including only prospective controlled randomised trials with a 12 months minimum follow-up. This review is part of a Cochrane review, available in the Cochrane library[28], which analysed the roles of the geometry of the lenses, the IOL material, surgical technique and pharmacology therapy on the PCO development. The authors concluded that the PCO score was significantly lower with sharp-edge design IOLs, and did not show evidence of the role of the optic material. It should be mentioned that the large variation in the PCO score systems and the limited number of trials with a long term follow-up lead to some difficulties pooling the data. Two experimental studies [29-31] have evaluated the square edge profile of a variety of square-edge design IOLs available on the market using Scanning Electron Microscopy (SEM). Although these in vitro studies used a different quantification method (deviation from a perfect square[29, 30], or mean radius curvature[31], their conclusions are comparable: hydrophilic acrylic IOLs appear to have relatively rounder edges than silicone and hydrophobic IOLs. This variation in PCO incidences seems however to reflect differences in manufacturing process, rather than a material effect. Hydrophilic lenses are usually lathe-cut and then polished. During the polishing process, there is some degree of abrasion of the square edges. Thus the level of	

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				the edge sharpness varies according to the polishing process used by different manufacturers. As a result of new manufacturing processes, the square edge design of recent hydrophilic acrylic has been improved, with sharper edges compared with hydrophobic acrylic IOLs. An experimental study, conducted by Prof D. Spalton[32], using the same method as Nanavaty et al[31] reported a radius of curvature of the edge profile of 3 microns. Moreover, a presentation of Dr Werner[33] reported a large variation of the edge sharpness with the hydrophobic IOLs as well. This large variation is observed not only among different designs, but also between different powers of the same design. In addition, when Nd: YAG capsulotomy is necessary, hydrophilic material tends to have better resistance to Nd: YAG laser as demonstrated in in-vitro studies: greater capacity to act a shock absorber rather than to crack under stress than PMMA[34], greater damage (like crack and central defects) observed with PMMA than with polyHEMA material[35-36]. We don't feel that new manufacturing techniques have been fully explored by the committee and taken into account with these guidelines. Since some of the RCTs cited in the guidelines comparing IOL material are up to 15	

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Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				years old we believe the committee should not offer at this time a specific recommendation on IOL material. 24 NISHI O, NISHI K Preventing posterior capsule opacification by creating a discontinuous sharp bend in the capsule J. Cataract. Refract. Surg 1999; 25: 521-6 25 NISHI O, NISHI K, SAKANISHI K Inhibition of migrating lens epithelial cells at the capsular bend created by the rectangular optic edge of a posterior chamber intraocular lens Ophthalmic Surg Lasers 1998; 29: 587-94 26 NISHI O, NISHI K, OSAKABE Y Effect of intraocular lenses on preventing posterior capsule opacification : Design versus material J. Cataract. Refract. Surg 2004; 30: 2170-76 27 BUEHL W, FINDL O Effect of Intraocular lens design on posterior capsule opacification J. Cataract. Refract. Surg 2008; 34: 1976-85 28 FINDL O, BUEHL W, BAUER P, SYCHA T	

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				Interventions for preventing posterior capsule opacification The Cochrane collaboration 2010: 1-81 29 WERNER L, MÜELLER M, TETZ M EVALUATING AND DEFINING THE SHARPNESS OF INTRAOCULAR LENSES ; MICROEDGE STRUCTURE OF COMMERCIALLY AVAILABLE SUARE-EDGED HYDROPHOBIC LENSES J. CATARACT. REFRACT. SURG 2008; 34: 310-7 30 WERNER L, TETZ M, FELDMANN I, ET AL EVALUATING AND DEFINING THE SHARPNESS OF INTRAOCULAR LENSES: MICROEDGE STRUCTURE OF COMMERCIALLY AVAILABLE SQUARE-EDGED HYDROPHILIC INTRAOCULAR LENSES J. CATARACT. REFRACT. SURG 2009; 35: 556-66 31 NANAVATY MA, SPALTON DJ, BOYCE J, ET AL EDGE PROFILE OF COMMERCIALLY AVAILABLE SQUARE-EDGED INTRAOCULAR LENSES J. CATARACT. REFRACT. SURG 2008; 34: 677-86 32 DHITAL A, SPALTON D, BOYCE J: IMAGING & EVALUATION OF 1.4 IOL 33 MULLER M. , WENER L. AND TETZ M.	

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				EVALUATING AND DEFINING THE SHARPNESS OF IOLS: *MICROEDGE STRUCTURE OF COMMERCIALLY AVAILABLE SQUARE-EDGE HYDROPHOBIC IOLS*" ASCRS 2010 PRESENTATION 34 SKELNIK DL, LINDSTRÖM R, ALLARAKHIA L ET AL NEODYMIUM :YAG LASER INTERACTION WITH ALCON IOGEL HYDROGEL INTRAOCULAR LENSES : AN IN VITRO TOXICITY ASSAY J CATARACT REFRACT SURG 1987, 13: 662-8 35 KEATES RH, SALL KN, KRETER JK EFFECT OF THE ND :YAG LASER ON POLYMETHYLMETHACRYLATE, HEMA COPOLYMER, AND SILICONE INTRAOCULAR MATERIALS J CATARACT REFRACT SURG 1987; 13: 401-9 36 JOO CK, KIM JH EFFECT OF NEODYMIUM :YAG LASER PHOTODISRUPTION ON INTRAOCULAR LENSES IN VITRO J CATARACT REFRACT SURG 1992; 18: 562-6	
Bausch + Lomb	Full	25	581 - 582	**Committee guidance on Toric IOLs**	Thank for your comment. Recommendations to address pre-existing astigmatism were determined by the guideline committee following analysis of the

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		124 123	2884 2867 - 2870	With the advent of predictable and relatively astigmatically neutral incisions in cataract surgery, astigmatism correction by toric IOLs is a successful alternative in the pre-existing astigmatism surgical correction strategy. Toric IOLs may be even the optimal choice in in high level of astigmatism. Literature has shown Toric IOLs to provide effective correction of the regular pre-existing astigmatism (UCVA, postoperative residual astigmatism), with low incidence of its major complication of more than 10° postoperative rotation and without compromising the integrity of the cornea[47,48] Toric IOLs can correct up to 8.00D of corneal astigmatism as opposed to on axis incision (0.50 to 0.75 D if additional incision 180° apart) and LRI (up to 1.50 -3.00D). [47,48] Beside pain and dry eye syndrome, the use of Toric IOLs also mitigates some of the disadvantages and side effects of incisional astigmatic correction, such as varied wound healing, corneal denervation, corneal perforation, infection, and wound gape, and decreased best spectacle corrected vision due to irregular astigmatism.[49-52] Similarly, it obviates some limitations and side effects of excimer laser correction of astigmatism via surface treatment, such as corneal haze, dry eyes, regression and diffuse lamellar keratitis.[53]	existing relevant efficacy and cost effectiveness evidence. NICE is required to consider cost-effectiveness alongside effectiveness in all the guidelines it produces, and therefore it is not sufficient to only demonstrate that toric lenses are effective in reducing astigmatism, but also that they are a cost-effective use of NHS resources. The committee agreed that toric lenses have been demonstrated to be an effective method of reducing post-operative astigmatism. However, the committee also agreed that in the absence of robust evidence on either cost-effectiveness of, or quality of life gains with, toric lenses, it was not possible to recommend their routine use within the NHS. The committee also agreed it would not be appropriate to extrapolate other evidence on the impact of spectacle independence to the population of people using toric lenses, but rather that future studies on toric lenses should include patient quality of life as an outcome measure, to ensure it is possible to estimate the quality of life benefits people may get with toric lenses, and therefore their cost-effectiveness in the NHS.

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				Although a progressive diminution of prevalence occurs with increasing magnitude of astigmatism, an increasing burden of disability also occurs with increasing magnitude, thereby making the correction of higher degrees of astigmatism more clinically meaningful and personally relevant to those patients who suffer from dependence on thick, distorting complex spectacle lenses or rigid contact lenses as their only options. Spectacle correction of astigmatism creates meridional magnification, which when coupled with the associated back vertex distance produces retinal images that are asymmetrically magnified and distorted. Such images have been reported to reduce spatial perception and adaptation to them is particularly challenging for elderly individuals, in whom cataracts are more prevalent. If contact lenses do not lead to similar disadvantages, their rigidity is often badly tolerated by older patients. A study (Pesudovsk et al)[54] using 20-item QIRC questionnaire and performed in a UK pre-presbyopic population has shown that in the absence of postoperative complications, post-refractive surgery patients have better quality of life than spectacle or contact lens wearing patients. Quality of life was lowest in spectacle wearers, particularly those with higher corrections. Contact lens wearers had significantly better QIRC score than spectacle wearers.	

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				Refractive surgery patients scored significantly better than both. Although we know that these study outcomes cannot be directly extrapolated to the Toric IOL population, the study shows that convenience seems to be the key difference. Refractive surgery patients typically have little or no trouble using non-prescription sunglasses, seeing when waking, seeing when swimming or on the beach, or while exercising, and have the convenience of not thinking about spectacles or contact lenses before traveling, etc. The committee itself has evidenced high quality data which shows that visual acuity is better, residual astigmatism is lower and spectacle independence is higher using Toric IOLs. **Impact on the department and team's organisation** Compared to LRI, using a Toric IOL should not significantly disturb the team organisations. Whatever the technique used, preoperative characterisation of the pre-existing astigmatism is the same, with accurate biometry and corneal topography. Similarly, in both strategies, the surgeon should use markers in pre-op and post-op to denote the axis of the astigmatism ensuring perfect centration, negating the perceived additional cost of markers for use with Toric IOLs.	

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				Surgeons should be trained whatever the techniques used. It's also important to note that for LRI, it's recommended to perform a pre-operative pachymetry. Moreover there is a requirement to use diamond knives. It is felt that the committee's rationale for this recommendation is therefore more subjective than evidence based. The committee could for example take evidence from Trusts already implementing Toric IOLs successfully into their practice. In some Trusts, members of staff performing the biometry are trained to look at differences in K values, suggest a Toric IOL and pass this on to a surgeon who is skilled and happy to implant it. If an astigmatic threshold is agreed by a Trust to be the point at which they treat with a Toric IOL then the workload can be managed by the Trust to within their capabilities. e.g. 2D cyl threshold for Toric IOL implantation represents around 9% of the total volume. We therefore would like to suggest to the committee that they review this guidance to allow the use of Toric IOLs where possible within the cost restraints of the NHS. 47. Burkhurst P. et al, Clin Exp. Optom 2010;93 :6 :409-418	

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				48. Gills james P.: A complete guide for correcting Astigmatism– An Ophthalmic manifesto – SLACK Inc. 2003 pp227 49. Horn JD. Status of toric intraocular lenses. Curr Opin Ophthalmol. 2007;18:58-61. 50. Bayramlar HH, Daglioglu MC, Borazan M. Limbal relaxing incisions for primary mixed astigmatism and mixed astigmatism after cataract surgery. J Cataract Refract Surg. 2003;29:723-8. 51. Amesburry EC, Miller KM. Correction of astigmatism at the time of cataract surgery. Curr Opinion Ophthalmol. 2009;20(1):19-24. 52. Nichamin LD. Astigmatism Control. Ophthalmol Clin N Am. 2006;19(4):485-93. 53. Netto MV, Mohan RR, Ambrosio R Jr, et al. Wound healing in the cornea: a review of refractive surgery complications and new prospects for therapy. Cornea. 2005;24:509 -22. 54. Pesudovs et al: A Quality of Life Comparison of People Wearing Spectacles or Contact Lenses or Having Undergone Refractive Surgery Refract Surg. 2006;22:19-27.]	

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Bausch + Lomb	Full	29 104	741 - 742 2507	**Glistenings and Visual Quality** If the glistening formation (fluid-filled microvacuoles that may form within the optic when the IOL is in an aqueous environment), could be observed with all IOL materials, it has been mainly associated with hydrophobic acrylic intraocular lenses. As described in an extensive review realised by Dr. Werner[37], similarly to optic opacification, the causes of glistenings are multi-factorial, involving IOL material composition, manufacturing technique, packaging and associated patient's conditions leading to a breakdown of the blood-aqueous barrier. These vacuoles create refractive heterogeneities within the lens material and increase over time[38-42]. Severe glistenings may negatively impact visual acuity[43] and/or contrast sensitivity[44,45], and may lead although rare to explantation[46]. Given the research recommendation into the long term outcomes of different choice IOL material, it would seem that there are some unknowns in terms of long term outcomes with different IOL materials. The committee has acknowledged that glistenings in particular are more	Please note: the recommendations around lens design and material have been removed to allow for further consideration.

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				prevalent in hydrophobic acrylic IOLs and it is also acknowledged that there is no known method to treat them. We therefore believe that the committee should not issue a strong recommendation on IOL material. 37 WERNER L Glistenings and surface light scattering in intraocular lenses J. Cataract. Refract. Surg 2010; 36: 1398-420 38 TOGNETTO D. ET AL GLISTENINGS IN FOLDABLE INTRAOCULAR LENSES 39 *J CATARACT REFRACT SURG 2002; 28:1211–1216* MORENO MONTANES X. ET AL CLINICAL FACTORS RELATED TO THE 40 FREQUENCY AND INTENSITY OF GLISTENINGS IN ACRYSOF INTRAOCULAR LENSES *J CATARACT REFRACT SURG 2003; 29:1980–1984* 41 WAITE A., FAULKNER N. AND OLSON R.Y GLISTENINGS IN THE SINGLE-PIECE, HYDROPHOBIC, ACRYLIC INTRAOCULAR LENSES AM J OPHTHALMOL 2007;144:143–144	

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				42 BENHDIG A. AND MONESTAM E. QUANTIFICATION OF GLISTENINGS IN INTRAOCULAR LENSES USING SCHEIMPFLUG PHOTOGRAPHY 43 J Cataract Refract Surg 2009; 35:14–17 Colin et al Incidence of glistenings with the latest generation of yellow-tinted hydrophobic 44 acrylic intraocular lenses J Cataract Refract Surg 2012; 38:1140–1146 Christiansen G. et al 45 Glistenings in the AcrySof intraocular lens: Pilot study *J Cataract Refract Surg 2001; 27:728–733* Oshika T, Shiokawa Y, Amano S, and Mitomo K. 46 Influence of glistening on the optical quality of acrylic foldable intraocular lens. Br J Ophthalmol 2001; 85:1034–1037. Matsushima H, Mukai K, Nagata M, Gotoh N, Matsui E, Senoo T. Analysis of surface whitening of extracted hydrophobic acrylic intraocular lenses.	

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				J Cataract Refract Surg 2009; 35:1927–1934 Werner L et al Unusual pattern of glistening formation on a 3-piece hydrophobic acrylic intraocular lens J Cataract Refract Surg 2008; 34:1604–1609	
Bausch + Lomb	Full	29 25 109 - 110	747 - 748 574 - 575 2597	**Committee guidance on IOL tint** Given the research recommendation here, we feel that there is insufficient evidence for the committee to have made the decision to recommend "do not use blue light filtering intra-ocular lenses in cataract surgery, unless as part of a research study." and that this is too strong a recommendation, especially in light of the committee's concerns that many studies have relied upon using the Farnsworth-Munsell hue test for measuring colour vision which may not be applicable.	Please note: the recommendations around lens design and material have been removed to allow for further consideration.
Bausch + Lomb	Full	135	3121 - 3123	**Laser Assisted Cataract Surgery** We agree with the committee's opinion that the potential patient benefits with femtosecond laser assisted cataract surgery need to be balanced with the costs associated with purchasing and operating the equipment. We do however disagree that the duration of the procedure is increased.	Thank you for your comment. The committee made no argument that the duration of the procedure will necessarily increase, merely that there is currently no evidence from randomised trials that there are productivity gains from the use of laser assisted surgery – a commonly cited argument from its proponents.

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				Operational efficiencies have been demonstrated in an NHS setting through modifications to the surgical pathway in Frimley Health Foundation Trust and Leeds teaching Hospitals NHS Trust, with further work ongoing within Cambridge University Hospitals NHS Foundation Trust. We believe that the committee would be well served in visiting Frimley Park Hospital which has been using a femtosecond laser as a standard of care for all suitable NHS patients since July 2016. Tom Poole, consultant ophthalmologist at Frimley Park Hospital, whom was clinical lead during the implementation of the femtosecond laser service in Frimley Park, has provided his own insight of his experiences and that of his team since using the technology: "The recommendation 'do not use' is too prescriptive for a technology that has several theoretical advantages in an NHS setting. Clearly NICE need to decide whether a new technology is cost-effective or not, but NHS Trusts will set out their own business plans, and will not buy or lease a femtosecond laser that they cannot afford. The committee noted that the current health-economic evidence for or against femtosecond laser was weak. Femtosecond laser may yet provide an innovative way of providing highly efficient cataract surgery for the NHS, and further developments in this field should not be limited by a recommendation not to use femtosecond laser unless part of a RCT. Furthermore, Femtosecond laser astigmatic	We are aware that 2 large RCTs (FACT and FEMCAT), at least 1 of which will include a parallel economic analysis, are due to publish in 2018. Details of both have been passed to the NICE surveillance team, and there are processes by which a rapid, targeted update of that part of the guideline can be undertaken, should that new evidence imply the recommendations need to be reviewed. It should be noted that the decision to recommend FLACS only as part of a randomised trial reflects the economic evidence, which does not at the time of writing support FLACS as a cost-effective option for cataract surgery.

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				keratotomies were not mentioned. This is disappointing as the opportunity exists to offer NHS cataract patients the best possible outcomes by correcting pre-existing astigmatism, based on cost assumptions the committee have made without any evidence shown in the health benefits and resource use section."	
Bausch + Lomb	Full	135 - 136	3125 - 3160	**Effectiveness of laser-assisted phacoemulsification cataract surgery** We disagree with the committee's view on sole inclusion of RCTs. It is our view that excluding all non-RCTs, in particular with reference to new technology, significantly restricts the available data on which to make a balanced and informed decision. A report by the Food & Drug Administration in 2016 highlighted the benefits in considering real world data which may prove to be superior to a traditional clinical trial [55]. It is stated clearly by the committee that their judgement is based solely on the Cochrane Eyes and Vision data review. The 16 papers that Cochrane deemed eligible for inclusion are dated, with most of the patients having been treated between 2010 and 2013, prior to the significant improvements all of the femtosecond laser systems have undergone since then, (which the Cochrane Review acknowledges). As a minimum we at least feel any	Thank you for your comment. The committee agreed from the outset that randomised controlled trials were the most appropriate source of data to address this question. In particular, because of the high additional costs associated with laser assisted surgery, the committee agreed that robust clinical data (the type that only RCTs can commonly provide) would be necessary in order to make recommendations. We are aware that 2 large RCTs (FACT and FEMCAT), at least 1 of which will include a parallel economic analysis, are due to publish in 2018. Details of both have been passed to the NICE surveillance team, and there are processes by which a rapid, targeted update of that part of the guideline can be undertaken, should that new evidence imply the recommendations need to be reviewed.

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				judgement pertaining to femtosecond laser use in the NHS could have been delayed until the publication of both the FACT and FEMCAT studies being conducted in the UK and France respectively. 55 FOOD & DRUG ADMINISTRATION, D. 2016. Use of real-world evidence to support regulatory decision-making for medical devices: draft guidance for industry and Food and Drug Administration staff. September 16, 2016.	
Bausch + Lomb	Full	136 - 137	3161 - 3193	**Health Economic Evidence** We do not believe that the Abell et al study (2014), referenced in the committee's health economics assessment, is representative of the challenges faced by the modern NHS, as it takes no account of potential efficiency improvements through utilisation of femtosecond technology within the NHS. Femtosecond lasers have successfully been implemented within an NHS setting (Frimley Park Hospital & Addenbrookes Hospital) with approved financial models supporting the use of this technology. The report takes no account of innovative funding models available nor the reduced cost to acquire this technology since the report was published in 2014.	Thank you for your comment. The study was appropriately downgraded to reflect the non-NHS setting, and some methodological concerns. We are aware that femtosecond lasers have been implemented in certain trusts, and we are aware that the recent Cochrane review, included in the evidence for this Clinical Guideline, along with other evidence, does not support the technology as improving efficiency. We are aware that 2 large RCTs (FACT and FEMCAT), at least 1 of which will include a parallel economic analysis, are due to publish in 2018. Details of both have been passed to the NICE surveillance team, and there are processes by which a rapid, targeted update of that part of the guideline can be undertaken, should that new evidence imply the recommendations need to be reviewed. We are not aware of any other cost-utility analyses in the NHS setting or elsewhere which accounted for the

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					innovative funding models referred to in your comment so it is difficult to comment further on that issue,
Carl Zeiss Ltd	Full	General	General	The term "Do not use" throughout the document needlessly and callously restricts patient choice for devices and features.	Thank you for your comment. The use of "do not use" is standard terminology used by NICE within Thank you for your comment. The use of "do not use" is standard terminology used by NICE within recommendations to determine their strength, in situations either where interventions are unlikely to be effective (and may cause harm), or unlikely to be cost-effective. NICE considers cost-effectiveness as part of all the recommendations it makes, and therefore even if an intervention may be effective, if it does not represent a cost-effective use of NHS resources it is appropriate for NICE to make recommendations that such an intervention not be used, as the net result of using it would be that a more effective intervention is not funded. The recommendations produced as part of a guideline are only intended as guidelines for the majority of individuals with a condition, and therefore this does not preclude an individual clinician from continuing to use them in particular individuals, if they believe doing so is clinically appropriate.
Carl Zeiss Ltd	Full	General	General	The methodology for the review is flawed: • The presented meta-analysis only included RCTs comparing different treatment methods or features in the search. However, the vast majority of publications	Thank you for your comment. The study type searched and included within each review question was determined and ratified by the guideline committee prior to its commencement. The committee agreed that

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				on cataract surgery are not comparative and/or randomised; RCTs represent a minor portion of the available scientific literature. • Many of the selected publications are outdated and do not necessarily represent current practices and/or devices. • Despite crafting key guidance based on visual symptoms, the assessment of patient reported outcome parameters is inadequate. By not including and reviewing the full scope of available scientific material, the guidance provided is biased and should not be relied upon for pivotal patient care conclusions.	RCTs represented the highest standard of evidence available, and that on situations where there were a sufficient number of RCTs available, it would not be appropriate to include lower quality study designs such as cohort or non-comparative studies, as this would increase the risk of bias in the conclusions being made. The committee agreed that in some areas of the guideline, some of the available RCTs were not 100% representative of current practice. However, they agreed they still represented the highest standard of evidence available, and if claims were to be made that new generations of technologies were to be more effective, it would be necessary to demonstrate these improvements by conducting randomised trials of these newer alternatives. The committee agreed there are limitations in the way patient outcomes are captured in people with cataracts, and indeed made specific research recommendations about validating quality of life instruments in people undergoing cataract surgery. However, when writing recommendations as part of this guideline, the committee was constrained by the outcomes measures used in the trials identified, and the limitations associated with them.
Carl Zeiss Ltd	Full	General	General	While we understand the financial pressures the NHS faces, any restriction in cataract surgery made through	Thank you for your comment. Recommendations are determined from the evidence base available. The quality of such evidence is then critically appraised and

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				commissioning decisions will not likely produce the efficiencies or cost savings expected. Of particular concern is the proposition that only monovision or monofocal IOLs are provided to patients. The technical evolution of IOLs (multifocals, toric, trifocal toric, anti-PCO techniques) and the related clinical benefits for the patients over the last 15 years were given inadequate consideration[i]. Conclusions stating that quality of life and patient satisfaction are similar between multifocal and monofocal IOLs are not valid. Recommendations should not be based only on 'very-low to low-quality evidence'. We recommend for ethical reasons and patient transparency that all appropriate and reasonable lens types be discussed with the patient. This is an important aspect of fully informing the patient in order for them to provide their informed consent for cataract surgery.	evaluated according to the GRADE criteria. The committee agreed that the quality of the evidence identified was not sufficient to be able to detect any differences in quality of life or patient satisfaction between monofocal and multifocal lenses. The committee also agreed that the quality of evidence was not sufficient to rule out the possibility that multifocal lenses provide benefits in quality of life. They agreed that to recommend an expensive intervention would require robust evidence of benefits, not simply be a situation where it is not possible to rule out that those benefits may exist. Overall, the committee agreed that multifocal lenses are unlikely to represent a cost-effective use of NHS resources, and therefore it was appropriate to recommend they not be used after cataract surgery.
Carl Zeiss Ltd	Full	13	167	The statement "Do not offer" is more than a strong recommendation and is, in fact, an order rather than a request. While the intention by the NHS is to provide guidance for surgeons, patients and the public, "Do not offer" may incorrectly be perceived as a safety or health risk in the numerous instances throughout the document where it is applied to technology that is both approved and well	Thank you for your comment. The use of 'do not use' is standard terminology used by NICE within recommendations to determine their strength, in situations either where interventions are unlikely to be effective, or unlikely to be cost-effective. The recommendations produced as part of a guideline are solely that, guidelines, and therefore this does not preclude an individual clinician from continuing to use

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				established as safe and effective in scientific literature. The negative impact this would have on patients treated in private practice is a major concern. A precedence for such as concern is the dramatic decline in private practice laser eye surgery after the 2003/2004 NICE guidelines were published.	them in particular individuals, if they believe doing so is clinically appropriate.
Carl Zeiss Ltd	Full	25	571	Silicone lenses have declined in use with the advent of modern cataract surgery techniques. In particular, silicone cannot be used for the production of a single piece open-loop lens, and cannot be used for micro-incision cataract surgery. There is also evidence that silicone IOLs are at increased risk of posterior capsule rupture. Smith[ii] states that if there is doubt about the integrity of the zonules, anterior capsule, or posterior capsule, a plate-haptic silicone IOL should not be injected.	Please note: the recommendations around lens design and material have been removed to allow for further consideration.
Carl Zeiss Ltd	Full	25	576	The recommendation "Do not offer multifocal IOLs" needlessly and callously reduces patient choice and interferes with the patient – surgeon relationship.	Thank you for your comment. The use of 'do not use' is standard terminology used by NICE within recommendations to determine their strength, in situations either where interventions are unlikely to be effective, or unlikely to be cost-effective. The committee agreed that there are established additional costs associated with multifocal lenses (both the costs of the lenses themselves, and additional pathway costs). The clinical evidence does demonstrate some benefits with multifocal lenses (e.g. increased spectacle independence) but also some harms such as an increase in glare and halos. In the absence of robust evidence on outcomes such as

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					quality of life, that would enable the trade-offs between these benefits and harms to be quantified, the committee agreed that the current evidence base did not support multifocal lenses as being a cost-effective use of NHS resources.
Carl Zeiss Ltd	Full	25	581	The recommendation "consider on-axis surgery or limbal-relaxing incisions (LRI) to reduce post-operative astigmatism" implies that no patient could benefit from a toric IOL. This implication contradicts literature, including several publications found in the guideline draft: • Gangwani[iii] cited in Table 30 (page 121, line 2797) numerates the advantages of toric IOL implantation compared to peripheral corneal relaxing incision (PCRI). Astigmatism reduction is more pronounced with toric IOLs (this is particularly true for high corneal astigmatism >2.0D), the difference between expected and achieved postop cylinder is smaller in the toric group and therefore toric IOLs are more predictable. The side effects of PCRI such as transient foreign body sensation shortly after surgery, decreased corneal sensitivity, risk for corneal infection, and potentially more pronounced dry eye syndrome. • Hirnshall[iv] also cited in Table 30 (page 121, line 2797), confirmed these results and, in addition, demonstrated that toric IOLs were better at reducing low to moderate astigmatism and that PCRI showed regression within the first 6 months.	Thank you for your comment. The committee emphasised that the lack of a positive recommendation for toric lenses does not imply there are no clinical benefits from their use. The committee agreed that the evidence demonstrated there were benefits from toric lenses in terms of reduced post-operative astigmatism, but also agreed there were considerable additional pathway costs associated with their use (over and above the costs of the lenses themselves). Therefore, the committee were not convinced that toric lenses represented a cost-effective use of NHS resources, and agreed the appropriate recommendation to make was a research recommendation looking at the cost-effectiveness of toric IOLs in the NHS.

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				• Several comparative trials [v,vi,vii,viii] demonstrated that toric IOL implantation was more effective and predictable compared to the limbal relaxing incision • Over- correction of astigmatism cannot be corrected in the case of PCRI and that under-correction involves greater invasion compared to a re-alignment of a toric IOL. • Ouchi[viii] demonstrated that total ocular High Order Aberrations (HOA) and ocular coma aberration were greater in the LRI+toric group compared to toric only group even at 6 months. HOA are directly related to Modulation Transfer Function (MTF): high levels of HOA negatively impact contrast sensitivity. • The stability of the LRI correction is controversial[ix,x]. For these reasons we recommend the following statement for optimal patient care: "Depending on the amount of corneal astigmatism, consider toric lenses, on-axis surgery or limbal-relaxing incisions to reduce post-operative astigmatism"	
Carl Zeiss Ltd	Full	30	791	We are concerned that "a realistic discussion between the surgical team and the patient preoperatively" that does not include appropriate and beneficial treatment options, including microincision cataract surgery with hydrophilic IOLs, multifocal lenses and/or toric lens implantation options, will not allow a complete and informed patient consent. We strongly recommend the inclusion of the above elements in this "realistic discussion".	Thank you for your comment. NICE is required to consider the cost-effectiveness as well as the effectiveness of interventions when making recommendations for their use in the NHS, and therefore some interventions, though they may be effective, may not represent a cost-effective use of NHS resources and therefore it would not be appropriate for NICE to recommend their use.

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Carl Zeiss Ltd	Full	96	2313	The development and use of techniques that improve safety and efficacy, as well as avoiding costly postoperative surprises, were not discussed. One major advance is a decrease in the invasiveness of cataract surgery. The development of hydrophilic acrylic lenses that can be inserted through an incision size of 1.8mm substantially reduce the size of the corneal wound. The positive effects of micro incision cataract surgery (MICS) is not discussed. Published data[xi,xii] demonstrates that MICS can minimize surgically induced astigmatism. Recovery times for the patient can also be reduced with less postoperative inflammation.	Thank you for your comment. Unfortunately, the effectiveness of micro incision surgery was not part of the scope of this guideline, and therefore no recommendations could be made on this topic.
Carl Zeiss Ltd	Full	96	2313	The development of preloaded injectors for hydrophilic acrylic lenses was not discussed and apparently not considered. This development limits the manipulation of the lens and reduces the incision size. The benefits include shorter duration of wound healing and recovery, less wound-induced post-operative astigmatism and lower risk of infection through reduction of micro-organism contamination in the early post-operative period[xiii,xiv]. From an economical point of view, compared to a manual IOL delivery process, use of a preloaded IOL delivery system for cataract surgery reduced total case time, total surgeon lens time, surgeon delays, and eliminated IOL touches. Authors calculated a potential increase in cataract throughput without increasing surgeon and staff	Thank you for your comment. Unfortunately, preloaded injectors were not part of the scope of this guideline, and therefore no recommendations could be made on this topic.

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				capacity of minimum 1 case per day, annual throughput ranging from 36 to 48 cases per operating room[xv].	
Carl Zeiss Ltd	Full	98 25	2396 571	We challenge the methodology used to convert the PCO scores to a 0-100 scale prior to analysis of the published data on PCO levels. No protocol is given for this conversion. We do, however, agree that due to the different measurement methods and the absence of standardized assessment methods, analysis is difficult. The multifactorial nature of PCO impedes a direct comparison of different study results and makes it difficult to relate the varying reported outcomes to distinct aspects of IOL design. PCO can be influenced by various factors or combinations of different factors such as patients' age, concomitant pathologies, surgical technique, different design aspects (including 360° square edge) and the follow-up period in addition to IOL material [xvi],[xvii]. Indeed a metaanalysis (Cochrane review16[xviii]) showed no significant differences between different IOL optic materials (hydrophilic acrylic, hydrophobic acrylic, PMMA, silicone). Another aspect linked to safety is not included in the analysis. Extracellular matrix proteins, inflammatory cells and lens epithelial cells (LECs) can easily adhere to hydrophobic surfaces, leading to a high incidence of iris posterior synechiae (IPS) and anterior capsule opacification (ACO) especially in patients with blood-aqueous barrier damage. Serious ACO may cause	Please note: the recommendations around lens design and material have been removed to allow for further consideration.

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				anterior capsule shrinkage, IOL decentration, and may hinder the examination of peripheral fundus. These problems limit the application of hydrophobic acrylic IOL in patients with uveitis, glaucoma or diabetes. This finding leads to recent research aiming at increasing hydrophilicity of hydrophobic IOLs in order to improve hydrophobic IOL biocompatibility[xix]. We recommend that "offer square-edged hydrophobic acrylic or silicone intraocular lenses to people having cataract surgery, to reduce the risk of posterior capsule opacification" be altered to: "consider square-edged hydrophobic or hydrophilic intraocular lenses and lenses with anti-PCO features for people having cataract surgery, to reduce the risk of posterior capsule opacification".	
Carl Zeiss Ltd	Full	113 114	2652	We are concerned about the conclusion of monovision compared to multifocal IOLs. Only 2 papers with a total of 262 assessable patients were analysed. One of the papers has significant bias as described in appendix E line 209. Nevertheless, the committee recommends to offer monovision, apparently drawing the conclusion from a single paper. Not considered in the guideline is that multifocal IOLs are preferred by many patients due to their unique advantages, such as improved binocularity and success in achieving satisfactory distance, intermediate and near vision.	Thank you for your comment. The committee agreed that the evidence base for monovision as a technique was limited, and therefore did not make a recommendation for the widespread use of monovision as a technique. However, they noted there was a specific subset of people, those who had either pre-operative anisometropia or monovision pre-operatively, in whom it would not be appropriate not to offer them the opportunity to remain this way after surgery.

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Carl Zeiss Ltd	Full	115	2677	The health economic evidence publication from Dolders[xx] on 1,218 patients was rejected for methodological reasons. We would like to point out an important finding: "the use of multifocal IOLs in cataract surgery resulted in a significant reduction in costs for patient's postoperative spectacles". We recommend a re-assessment of this paper	Thank you for your comment. We remain of the opinion that this study be excluded because of methodological concerns with the way in which patient preferences data (the relevant metric of effect for our decision-making regarding cost-effectiveness in this case) are presented and analysed. We agree that the paper contains the finding you have quoted. However, a more complete analysis would consider the resource impact on the NHS and PSS budgets, which are the preferred cost-perspective according to the NICE Reference Case detailed in the Guidelines Manual. https://www.nice.org.uk/process/pmg6/chapter/assessing-cost-effectiveness
Carl Zeiss Ltd	Full	117	2748	In the table section related to "Consideration of health benefits and resource use", the statement "highlighting the current 10% chance of needing a lens explantation with multifocal lens" has no basis in literature. Most reported explantation rates were between 0.0% to 4.0% after cataract surgery[i].	Thank you for your comment. This comment has now been deleted, as the committee agreed it was not an accurate number to retain.
Carl Zeiss Ltd	Full	118	2748	The recommendation "do not offer" multifocal intraocular lenses for people having cataract surgery" will present a significant challenge in practice because it needlessly interferes with the surgeon/patient relationship and decision making process. In the table, section related to "Consideration of health benefits and resource use", the committee discusses the reasons for not recommending multifocal IOL because	Thank you for your comment. When making recommendations, NICE is requited to consider the cost-effectiveness as well as the effectiveness of the interventions being considered, and the committee agreed that in this case the additional costs of multifocal lenses could not be justified, given the available evidence.

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				"The committee agreed that it was not only the individual cost of the lens that was the issue, but rather the cost of the care pathway within the NHS." The recommendation of the committee is to offer monovision instead. However, the time and related costs for a monovision contact lens trial before surgery (as recommended by the guidance) as well as the failure rate of such tests are completely neglected, rendering the cost assessment incomplete and inaccurate.	The committee has also reconsidered the recommendation made around monovision, and agreed that the reference to a contact lens trial should be removed. With this removal, the committee is keen to emphasise that monovision is not being suggested as an alternative to multifocal lenses, but rather that for people who already have anisometropia or monovision pre-operatively, they should be offered the option to remain this way after surgery. The committee noted that in this group of people a contact lens trial would not be necessary, and therefore the concerns around additional costs would not apply.
Carl Zeiss Ltd	Full	118	2750	The recommendation to "not offer" multifocal IOLs contradicts the conclusions drawn from the in-depth analysis presented in 8.3.5.1. Expected goal of multifocal IOLs, e.g. to reach spectacle independence by providing uncorrected visual acuities (VA) at far, near and intermediate distance is clearly achievable in comparison with monofocal IOLs. There was a lack of appropriate methodology in the analysis of patient-reported-outcomes. Questionnaire validation, analysis techniques, disparities between studies and other important limitations were not discussed. Patients should be presented with the benefit/risk/cost balance of all appropriate types of lenses, including multifocal IOLs, to maintain transparency and trust	Thank you for your comment. The committee agreed that multifocal lenses are effective in reducing rates of spectacle dependence, and that if there were no additional costs associated with their use, then they would represent a relevant treatment alternative. However, given the substantial additional costs associated with multifocal lenses (both lens and pathway costs) the committee agreed that they could not be recommended as a cost-effective use of NHS resources. The quality of evidence from all the studies included in the review was assessed, and quality ratings associated with each of the outcomes in the review are presented in the GRADE tables in appendix G.

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				between the doctor and patient and to enable the patient to make an informed choice.	
Carl Zeiss Ltd	Full	125	2894	We support the statement that "there is clear evidence that toric lenses are effective at reducing levels of postoperative astigmatism" and consider toric lens implantation as the optimal technique for treating significant pre-operative corneal astigmatism which, in addition, improves QALY. The article by Pineda[xxi] used in the guideline (page 121, line 2799) as "health economic evidence" concludes that "toric IOLs reduce lifetime economic costs by reducing the need for glasses or contact lenses". In addition the authors claim that toric IOLs provide an additional 10.20 QALY compared with conventional IOLs with or without intraoperative refractive correction	Thank you for your comment. Pineda et al. note that "When utility weights were estimated based on patients' UCVA for each treatment arm, the resulting cumulative lifetime QALYs with toric IOLs were 10.20 and with conventional IOLs with and without IRC were 10.14 and 10.10 per patient, respectively". Care should be taken interpreting these figures, which do not equate to an additional 10.20 QALY compared to conventional IOLs with or without IRC. However, the data do equate to an additional 0.06 and 0.10 cumulative QALYs for toric lenses compared to conventional IOLs with or without IRC, respectively. The committee were presented with these data as part of their decision making process and these figures are included in the health economic profiles in the Guideline Appendices.
Carl Zeiss Ltd	Full	125	2897	We agree with the statement "acquisition of toric lenses are unlikely to exceed those of standard monofocal lenses". Indeed, from an economical perspective, results suggest that incremental cost differences in treatment terms are small, and that over a lifetime the use of toric IOLs generates a small saving in terms of patient and provider borne costs. This finding should be consolidated with spectacle independence requested now by most patients as highlighted in the guidance draft.	Thank you for this comment. The costs of spectacles to patients does not fit within the NICE reference case for economic evidence (which only considers costs to the NHS and personal social services), and therefore reduced costs to individuals over a lifetime was not something the committee was able to take in to account when coming to its conclusions.

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				We strongly recommend that toric lenses be part of a cost-effective strategy to address pre-existing astigmatism, taking into account the whole care pathway cost implications. Multifocal toric IOLs are another option that was not addressed in section 8.3 or 8.4	
Carl Zeiss Ltd	Full	137	3216	Femtosecond laser-assisted cataract surgery (FLACS) is recommended only within randomized clinical trials. In your evidence to recommendations (long version, line 3216, page 137) you state that there was no meaningful improvement of results with FLACS (trade-off between benefits and harms, page 138) compared to the increased costs (considerations of health benefits and resource use, page 138). As large trials are underway looking into this details (FACT, FEMCAT) and that other femtosecond laser systems might enter the market with improved workflow (and therefore costs), we are concerned that this NICE recommendation will remain even in the presence of newer information. The advantages of femtosecond laser cataract surgery in some complicated cases such as white intumescent cataracts, zonular dehiscence, Marfan's syndrome, some pediatric cases[xxii,xxiii], etc., have not been given consideration. Indeed, the limited cases are inadequate to demonstrate a clinical benefit with statistical confidence. However, ample non RCT data strongly suggest that further investigation may prove beneficial for patients.	Thank you for your comment. The currently available randomised controlled trials, including a recent Cochrane Review, do not support these conclusions. Whilst we agree that some cohort studies have reported reduced endothelial cell loss and reduced phacoemulsification energies, the study type searched and included as the most appropriate, in this case RCTs, within the review question was determined and ratified by the guideline committee prior to its commencement. We are aware that 2 large RCTs (FACT and FEMCAT), at least 1 of which will include a parallel economic analysis, are due to publish in 2018. Details of both have been passed to the NICE surveillance team, and there are processes by which a rapid, targeted update of that part of the guideline can be undertaken, should that new evidence imply the recommendations need to be reviewed. It should be noted that the decision to recommend FLACS only as part of a trial reflects the economic

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				We therefore recommend deleting the FLACS related recommendation.	evidence which does not at the time of writing support FLACS as a cost-effective option for cataract surgery.
City Hospitals Sunderland NHS Foundation Trust	Full	General	General	We welcome this draft guideline which we see as having many important points and recommendations.	Thank you for your comments and recognition of the value of this guidance.
City Hospitals Sunderland NHS Foundation Trust	Full	78	1876	We are concerned that recommending different formulas for different ranges of axial length may lead to confusion and increase the possibility of errors. The range of values for 'within 0.5D of target' is quite small for eyes with 'normal' axial lengths (22-26 mm) and we feel that the Haigis formula has an acceptable result for these axial lengths. This would allow a recommendation to use the Haigis for all eyes and so avoid potential confusion for clinic staff. This has been the standard in our unit for some time. Outcome audits of random samples in 2 consecutive years by one of us showed refraction within 0.5 D in 73% and 75% respectively.	Thank you for your comment. The committee agreed that the identified evidence implied that different formulas were optimal to use in people with different axial lengths, and therefore the best outcomes for patients would be achieved by using the most accurate formula for their axial length. They also noted that the use of differing formulae for different axial lengths is current practice in many centres. Service providers should ensure there are measures in place to guarantee the device is appropriately reset and minimise the risk of the wrong formula being used.
City Hospitals Sunderland NHS Foundation Trust	Full	78	1879	We are surprised that you have not included anything about the Wang-Koch correction of axial length in the >26mm group. While it is mentioned in the 'Evidence to Recommendation' on page 76, we would also have expected at the least a suggestion in the recommendations that users should consider using this correction.	Thank you for your comment. Unfortunately, no evidence was identified that the Wang-Koch correction provides an improvement to the accuracy of biometry measurements, and therefore it was not possible to make any recommendation on this topic.

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City Hospitals Sunderland NHS Foundation Trust	Full	78	1880	While you recommend for future research evaluation of other formulas, given that most users will consult the short version of this guideline (which does not include research suggestions) we would suggest that another recommendation would be for users to consider newer formulas (including the very new Hill RBF method) when more information is available about their accuracy.	Thank you for your comment. NICE does not make recommendations based on research whose outcomes are not yet known. NICE undertakes surveillance of its guidelines and if data on the Hill RBF method becomes available that would make a substantial difference to the guideline an update of the relevant part of the guideline would be considered.
City Hospitals Sunderland NHS Foundation Trust	Full	107	2542	We believe the use of the phrase 'tinted IOLs' to be misleading. At some points in the text you refer to UV-light-filtering IOLs and blue-light-filtering IOLs and we believe that this is a much better description.	Thank you for your comment; where possible the text has been updated to match this suggestion.
City Hospitals Sunderland NHS Foundation Trust	Full	111	2599	We are very concerned about this recommendation. The only evidence against the use of blue-light-filtering IOLs that the committee has found is that in mesopic lighting conditions colour discrimination in the blue part of the spectrum is altered. We would question the clinical relevance of this for the majority of patients. While there may be a very small number of people who require accurate blue discrimination in mesopic conditions for occupational or hobby/pastime reasons, for the vast majority of patients this has no relevance. In our experience over the past 10 years (in the whole unit at least 40,000 eyes) there has not been any serious issue - even in patients who have had a non-blue-light-blocking lens in their first eye. The committee acknowledges that there are sound theoretical reasons to feel that blocking potentially	Please note: the recommendations around lens design and material have been removed to allow for further consideration.

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				harmful short wavelength blue light might protect macular pigment. There are studies with laboratory models that show protection of RPE and there are clinical studies (which do not meet the evidence requirements of the committee) that suggest protection of macular pigment density and improved contrast sensitivity with the use of such lenses. In the absence of evidence of serious harm we feel the committee should consider allowing surgeons/units to argue the 'precautionary principle' and say that while there is no good evidence of benefit there is also no good evidence of harm and therefore in the light of the theoretical benefit, such lenses can be used.	
City Hospitals Sunderland NHS Foundation Trust	Full	124	2884	We feel there may be unconscious bias in this section dealing with the benefits of toric IOLs for reduction of astigmatism. In a private setting (where most of these IOLs are currently used) it is certainly the case that additional visits may be needed to assess the accuracy of placement and the refractive outcome because of the likely unhappiness of paying patients if they are not left spectacle-free. In an NHS setting however, with no direct payment by the patient additional visits are not required Sufficient data about efficacy and accuracy of alignment can be obtained at routine follow-up. Additional pre-operative examinations (corneal topography) to confirm the amount and axis of corneal astigmatism is surely needed for both toric IOLs and limbal relaxing incisions. We agree that a small additional amount of surgical time is needed, but if use of toric IOLs is limited to larger	Thank you for your comment. The committee discussed this issue and remained of the opinion that there are significant additional pathway costs associated with toric lenses, as detailed in the evidence to recommendations section of that chapter, and therefore toric lenses could not be currently recommended. However, the guideline does also contain a research recommendation on the cost-effectiveness of toric lenses, and the committee agreed it would be appropriate to revise the recommendations made if either it can be demonstrated that toric lenses can be routinely used without additional costs, or that sufficient gains in quality of life are made to justify those additional costs. The committee noted that any further

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				amounts of astigmatism, rather than used in all patients above say 1D of astigmatism (as would be the case in private settings), then this would not be a significant additional burden. Similarly only a small number of toric markers would be needed if the number of toric IOLs used on any surgical session is low. We feel that offering toric IOLs to patients with greater than 2.5 or 3D of astigmatism could be justified, and even if such patients are not going to be spectacle free because of their need for reading, their overall visual quality without spectacles will be sufficiently improved to justify this.	amendments to the recommendations would be subject to NICE's surveillance and commissioning procedures for clinical guidelines.
City Hospitals Sunderland NHS Foundation Trust	Full	132	3041	We fully support the clear and practical guidance on avoiding wrong implant errors which are similar to the guidelines we follow at our own hospital, and which we feel if followed universally would significantly reduce the risk of these events occurring.	Thank you for your comment and support for the proposed guidance.
Guy's and St. Thomas' NHS Foundation Trust	Full	27 139	648 - 650 10.1.7	We are disappointed that Femto-second laser assisted cataract surgery (FLACS) has not been recommended by NICE for use in the NHS. FLACS brings potential advances to conventional phacoemulsification surgery with multiple studies supporting improved outcomes in terms of post-operative endothelial cell loss with FLACS. FLACS technology is continuously evolving and has the potential to improve the outcomes of cataract surgery especially in complex cases such as dense cataracts (Chen JCRS 2017).	Thank you for your comment. The currently available randomised controlled trials, including a thorough Cochrane Review, do not support the conclusions that laser assisted surgery provides either meaningful clinical or productivity benefits. Whilst we agree that some cohort studies have reported reduced endothelial cell loss and reduced phacoemulsification energies, the study type searched and included as the most appropriate, in this case RCTs, within the review question was determined and ratified by the guideline committee prior to its commencement.

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				We are therefore seriously concerned that this 'do not do' recommendation does not foster innovation in the NHS. We would therefore suggest that "do not do" is far too strong a negative recommendation and not supported by the current published evidence, as current meta-analyses support reduced total phakoemulsification energies with FLACS and less endothelial cell loss. We therefore feel that the recommendation might be better phased by stating "that while at present published evidence does not support the widespread implementation of Femtosecond laser cataract surgery into the NHS, especially as there are associated financial costs with its usage, it does offer potential surgical advantages especially in complex cases, with reduced endothelial cell loss and/or dense cataracts, and further randomized controlled studies are indicated and its usage for research purposes is supported".	We are aware that 2 large RCTs (FACT and FEMCAT), at least 1 of which will include a parallel economic analysis, are due to publish in 2018. Details of both have been passed to the NICE surveillance team, and there are processes by which a rapid, targeted update of that part of the guideline can be undertaken, should that new evidence imply the recommendations need to be reviewed. The decision to recommend FLACS only as part of a trial reflects the economic evidence which does not at the time of writing support FLACS as a cost-effective option for cataract surgery.
Guy's and St. Thomas' NHS Foundation Trust	Full	135	10.1.1	We feel the evidence review conducted to evaluate laser assisted cataract surgery in its current form in this review does not capture all relevant outcomes to compare FLACS vs. conventional phacoemulsification surgery (CPS). We believe that the review question should have included comparative assessment between laser assisted cataract surgery devices and PCS on efficiency parameters (effective phacoemulsification time) as well as safety parameters (phaco or ultrasound energy) and reduced	Thank you for your comment. The review question, and all its relevant outcomes was developed and agreed by the guideline committee at the start of the guideline development process, and the committee agreed at this time that it was important to prioritise clinical outcomes over proxy measures. The currently available randomised controlled trials, including a recent Cochrane Review, do not demonstrate significant improvements in surgical time/throughput compared to standard

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				endothelial cell loss. It is well documented in the published evidence that phacoemulsification time and ultrasound (or phaco) energy used during cataract surgery are known to directly cause endothelial cell loss (Chen et. al, 2016; Cho et al, 2010; Hayashi et al, 1996) which may impact corneal endothelium and that in FLACS these energies are reduced as is endothelial cell loss Chen et. al, 2016; Schargus et al. (2015)	phacoemulsification. Whilst we agree that some cohort studies have reported reduced endothelial cell loss and reduced phacoemulsification energies, the study type searched and included as the most appropriate, in this case RCTs, within the review question was determined and ratified by the guideline committee prior to its commencement. We are aware that 2 large RCTs (FACT and FEMCAT), at least 1 of which will include a parallel economic analysis, are due to publish in 2018. Details of both have been passed to the NICE surveillance team, and there are processes by which a rapid, targeted update of that part of the guideline can be undertaken, should that new evidence imply the recommendations need to be reviewed. It should be noted that the decision to recommend FLACS only as part of a trial reflects the economic evidence which does not at the time of writing support FLACS as a cost-effective option for cataract surgery.
Guy's and St. Thomas' NHS Foundation Trust	Full	137	10.1.5.2	It appears that 'endothelial cell loss' (ECL), an important complication of PCS, has not been evaluated in this review while several studies have reported this outcome: 4. An independently conducted SLR and meta-analysis (Chen et al, 2016) concluded that the mean ECL was significantly lower for patients undergoing FLACS	Thank you for your comment. The currently available randomised controlled trials, including a recent Cochrane Review, do not support these conclusions. Whilst we agree that some cohort studies have reported reduced endothelial cell loss and reduced phacoemulsification energies, the study type searched and included as the most appropriate, in this case RCTs, within the review question was determined and

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				versus PCS at 1 week, 1 month and 3 months after surgery. 5. Schargus et al. (2015) found that ECC significantly decreased in both the FLACS group vs. PCS by 6 months (P=0.046 and P=0.002, respectively). Phacoemulsification power is an important determinant of intra-and post-operative complications associated with phacoemulsification cataract surgery. An independently conducted meta-analysis (Chen 2016) synthesized evidence from studies reporting mean phacoemulsification power (MP) and findings show that "the mean phacoemulsification power in the FLACS group was significantly lower than in the PCS group (WMD: -7.09, 95% CI: -7.64 to -6.55, $P < .001$, $I^2 > 50\%$). Therefore, the overall effect in phacoemulsification power favored FLACS (WMD: -6.57, 95% CI: -7.08 to -6.05, $P < .001$, $I^2 > 50\%$)."	ratified by the guideline committee prior to its commencement. We are aware that 2 large RCTs (FACT and FEMCAT), at least 1 of which will include a parallel economic analysis, are due to publish in 2018. Details of both have been passed to the NICE surveillance team, and there are processes by which a rapid, targeted update of that part of the guideline can be undertaken, should that new evidence imply the recommendations need to be reviewed. It should be noted that the decision to recommend FLACS only as part of a trial reflects the economic evidence which does not at the time of writing support FLACS as a cost-effective option for cataract surgery. ECL was not included as an outcome of interest because we did not find evidence, including in the trials in the Cochrane review that the differences in ECL between phacoemulsification and FLACS impacted on key outcomes such as acuity. Furthermore, the existing economic evidence does not suggest that the differences in ECL translate into tangible health economic benefits which would offset the costs of the device, disposables and estate costs associated.
Guy's and St. Thomas'	Full	137	10.1.5.4	We would like to highlight that effective phacoemulsification time (EPT) is an important metric	Thank you for your comment. The currently available randomised controlled trials, including a recent Cochrane Review, do not support these conclusions.

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NHS Foundation Trust				since it is associated with safety outcomes but has not been considered in this evidence review. Several studies have shown that EPT is significantly reduced with FLACS and two meta-analyses which synthesized the evidence from individual studies (Chen 2015 and Chen 2016) found that EPT was significantly lower for FLACS versus PCS.	Whilst we agree that some cohort studies have reported reduced endothelial cell loss and reduced phacoemulsification energies, the study type searched and included as the most appropriate, in this case RCTs, within the review question was determined and ratified by the guideline committee prior to its commencement. We are aware that 2 large RCTs (FACT and FEMCAT), at least 1 of which will include a parallel economic analysis, are due to publish in 2018. Details of both have been passed to the NICE surveillance team, and there are processes by which a rapid, targeted update of that part of the guideline can be undertaken, should that new evidence imply the recommendations need to be reviewed. It should be noted that the decision to recommend FLACS only as part of a trial reflects the economic evidence which does not at the time of writing support FLACS as a cost-effective option for cataract surgery. ECL was not included as an outcome of interest because we did not find evidence, including in the trials in the Cochrane review that the differences in ECL between phacoemulsification and FLACS impacted on key outcomes such as acuity. Furthermore, the existing economic evidence does not suggest that the differences in ECL translate into tangible health

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					economic benefits which would offset the costs of the device, disposables and estate costs associated.
Guy's and St. Thomas' NHS Foundation Trust	Full	137	10.1.5.5	We would like to bring to the committee's attention that a cost-effectiveness study comparing FLACS vs. PCS has not been included in the review of evidence (Lee et. al., 2016). This study was conducted to assess the cost-effectiveness of FLACS compared to PCS for medically necessary cataract removal in a publicly funded hospital in Canada. Incremental QALY gain was observed in FLACS group over time and over lifetime FLACS resulted in incremental cost-effectiveness ratio (ICER) of Canadian $18,099 over PCS. This ICER is well within the acceptable thresholds recommended by NICE and it demonstrates FLACS are a cost-effective treatment option with incremental QALY gain.	Thank you for your comment. The reference you refer to is an abstract and has not been published as a complete paper in a peer reviewed journal. It cannot therefore be critically appraised and evaluated with sufficient rigour to be included as evidence in a Clinical Guideline.
Guy's and St. Thomas' NHS Foundation Trust	Full	139	10.1.7	Therefore, we request to the guideline committee to consider modifying recommendations on laser assisted cataract surgery to recommend that while at present published evidence does not support the widespread implementation of Femtosecond laser cataract surgery into the NHS, especially as there are associated financial costs with its usage, it does offer potential surgical advantages especially in complex cases, with reduced endothelial cell loss and/or dense cataracts, and further randomized controlled studies are indicated and its usage for research purposes is supported".	Thank you for your comment. The committee reconsidered the evidence for laser assisted cataract surgery and remains of the opinion that the current evidence does not support the use of laser assisted cataract surgery outside of randomised trials. We are aware that 2 large RCTs (FACT and FEMCAT), at least 1 of which will include a parallel economic analysis, are due to publish in 2018. Details of both have been passed to the NICE surveillance team, and there are processes by which a rapid, targeted update of that part of the guideline can be undertaken, should that new evidence imply the recommendations need to be reviewed.

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IND	Full	General	General	Nearly all recommendations are to be hugely welcomed to reduce inequalities of access and increase clarity in practice and will significantly benefit patients and services.	Thank you for your comment and recognition of the value of this guidance.
IND	Full	General	General	There are a number of missing references, and the appendix needs to be cross checked against the document.	Thank you for your comment. Corrections have been made where errors have been identified.
IND	Full	55	1438	It is not enough to know the length of the eye and the power of the cornea. You also need to know where the lens will sit in the eye as that controls its effective power. The further forward it is, the higher the effective power.	Thank you for your comments; this section has now been updated to include reference to where the lens will sit in the eye.
IND	Full	55	1457	This is incorrect. The time taken for light to travel through the eye is measured in femtoseconds and is this too small to be measurable. That is why interferometry is used instead. Only ultrasound uses a time/distance calculation.	Thank you for your comments; this section has now been updated to remove this inaccuracy.
IND	Full	55	1473	Risk stratification needs to be applied to biometry too, for example eyes that are very short may result in a lens power that is outside the range available in theatre, and this needs to be flagged. A very long eye may result in a minus powered IOL, and we had a case where that was not noticed, and the corresponding plus power was used instead. Eyes that have had previous refractive surgery should be highlighted for the person doing the biometry.	Thank you for your comment. The scope of this guideline only included risk stratification for complication rates, and therefore risk stratification as part of biometry is not part of the guideline scope and we are unable to make recommendations on this topic.

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IND	Full	61	7.1.6 trade off…	The third paragraph is incorrect, though it is a common myth. Although ultrasound instruments measure to the inner limiting membrane while optical instruments measure to the RPE, no allowance needs to be made for this. The reason is that optical instruments do not directly measure the eye length, but rather optical path difference. This is then used in a look-up table calibrated against high-resolution ultrasound *immersion* biometry. The key word there is immersion: because there is no corneal compression with immersion ultrasound, the measured axial length will typically be 0.2 – 0.3mm longer than with contact ultrasound, hence the need to make an adjustment for optical or immersion ultrasound biometry compared with contact ultrasound. This is normally done by adjusting the a-constant from the value quoted on the IOL packet which is commonly for contact ultrasound.	Thank you for your comment. The relevant text has been amended to focus on the fact that the results of optical and ultrasound biometry may be different, and it is necessary to adjust for this.
IND	Full	62	Top of page	Agreed that corneal topography can be a useful adjunct, but that is no help unless guidance is given as to how to use that data, especially when the corneal power varies significantly across the cornea, such as in keratoconus for example.	Thank you for your comment. Unfortunately, the evidence available to the Committee was not sufficient to enable them to be any more specific with recommendations made around corneal topography.
IND	Full	64	Top of page	Users are not able to calibrate instruments, only the factory or service engineer can do that, but they should carry out calibration *checks* as per manufacturer's recommendations.	Thank you for your comment. The relevant sentence has been updated to reflect this comment.
IND	Full	64	1671	Again, recommending corneal topography is only helpful if people know what to do with the data. The role of manual keratometry should also be acknowledged in these difficult cases.	Thank you for your comment. Unfortunately, the evidence available to the Committee was not sufficient to enable them to be any more specific with recommendations made around corneal topography.

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IND	Full	65	1687	I would suggest that this is impractical, because there are too few patients for an RCT at any single centre. A multi-centre trial would be an alternative, but given the variation in instrumentation across practices/hospitals that would be difficult too. Happily RCTs are not needed to establish the best methods, because back-calculation can be done. This is acknowledged (and arguably contradicted) in line 1761 onwards. The method is to carry out surgery and implant a lens of known power. The patient is then refracted to establish the final outcome. You can then use any combination of data and formula to see what the *predicted* outcome is for that combination and the lens power used, and compare it with the *actual* outcome. This gives the prediction error, and the combination with the consistently smallest prediction error is the best one to use. Randomising patients in that scenario would not add to the power of the study as all combinations can be tested on all subjects.	Thank you for your comment. This research recommendation has been amended to clarify that within person studies are also a relevant study design.
IND	Full	66	1715	This is true for myopes, but incorrect for hypermetropes who have the opposite effect.	Thank you for your comment; this has been amended to clarify this point was referring to myopic individuals.
IND	Full	67	1762	As above, RCTs are not required in these studies. In fact using a combination this known to be less effective would be unethical.	Thank you for your comment. This research recommendation has been amended to clarify that within person studies are also a relevant study design.

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IND	Full	78	1873	I believe this to be dangerous advice, particularly for users of the IOL Master and IOLM 500 instruments (certainly to version 5.x software), and possibly the newer ones too. The problem is that the IOLM 'remembers' the setting for the last patient. We have had two occasions where, following the old RCOphth guidance, Hoffer Q was used for a short-eyed patient , and the instrument was left on that formula for the rest of the session. It only came to light weeks later after some patients with normal or long eyes had been operated on. The LenStar by comparison always returns to a default setting. For that reason, we now use Haigis as a 'universal' formula for all our non-refractive surgery patients. The committee noted that Haigis performed well in three out of the four axial length categories, and I believe the gains from using an alternative formula for average eyes are minimal, and are outweighed by the risks outlined above.	Thank you for your comment. The committee noted that the use of differing formulae for different axial lengths is current practice in many centres. Service providers should ensure there are measures in place to guarantee the device is appropriately reset and minimise the risk of the wrong formula being used.
IND	Full	78	1898	As above re RCTs	Thank you for your comment; the same alteration has been made to this research recommendation.
IND	Full	81	7.3.6 Trade-off…	The committee is right to acknowledge the difficulty of collecting post-operative refractive data, but I am unclear why 'automated biometry with electronic storage of results' should make this easier. Online entry by community (or hospital) optometrists of refractive data	Thank you for your comments. The comment about automated biometry was merely one example of the

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				which feeds directly into the hospital database would certainly help, but that is not the same thing. The committee might also consider a recommendation around the use, or not, of auto-refractors in IOL constant optimization. Such instruments may not be sufficiently reliable, and may have a systematic error which is absolutely not what is wanted.	way such data could be collected, and was not meant to imply this was the only method this could be done. Unfortunately, the use of auto-refractors was outside of the scope of this guideline, and therefore it was not possible to make any recommendations on this topic.
IND	full	82	7.3.6 Trade-off…	Much is made of the improvement in prediction error obtained in the study by Aristodemou et al, but I believe the gains from optimization are over estimated in this study. They compared the outcomes of using the manufacturer's a-constant using *optical biometry* (which we know to be incorrect for the reasons outlined above) with an optimized a-constant. The gains will be proportional to the error you start with! If you have sensible starting point, such as using data from the ULIB website, our experience is that the gains are tiny.	Thank you for your comment. The committee agreed that the gains from optimisation were likely to differ based on the baseline levels of error (which in turn depend on the techniques used by an individual surgeon/practice). This informed the decision to recommend that surgeons should 'think about' modifying constant, rather than a recommendation they should do so. If an individual surgeon is achieving good results without optimisation, then the result of this is likely to be that modification of lens constants is not necessary.
IND	full	84	2028	One question that often arises when I am teaching biometry is 'How long is biometry valid for?'. I am not aware of any studies looking at this, and that might make a useful research recommendation. The guidance I give is one year, unless the cataract has become so dense that contact ultrasound biometry has to be used, in which case the older optical biometry is likely to be more reliable. This is not based on any evidence however…	Thank you for your comment. Unfortunately, the issues you raise were not within the scope of the guideline, and therefore it was not possible to make any recommendations (or research recommendations) on this topic.

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IND	Full	96	2347	Typographical error: plane instead of plain	Thank you for your comment; this has now been corrected.
IND	Full	132	General	I feel it is unfortunate to state that an 'incorrect lens that is implanted in good faith' should not be classed as a 'never event'. It depends on the definition of 'imperfect biometry'. Biometry will never be an exact science, but if an error has been made that could and should have been picked up, either by the person doing the biometry, or the surgeon, then that should be a never event. One example might be ultrasound biometry where the scan misses the retinal peak, or an oil-filled eye, both of which will give falsely long readings.	Thank you for your comment. The text has been amended to clarify the meaning around this point, namely that something should not be classed as a never event if it does not result from an error by an individual or group of individuals.
IND	Full	133	3077 - 3081	Having been an author of one of the wrong IOL papers (steeples et al 2016) and also having done a great deal of work as CD for Safety at Moorfields in light of investigation and auctioning several wrong IOL Never events, I would challenge the practicality of the suggestion that more than 1 person will be in theatre who can check this level of detail without significant implications for training theatre staff which may be unachievable. What theatre staff can do is check the IOL is for the correct refractive target, is the correct eye and is the correct IOl type. I suspect this is what you mean when you say check the A constant is correct but this should be more explicitly stated the correct A constant *and lens type* e.g. MA60 etc. I do not think theatre staff will understand checking the calculations and formulae.	Thank you for your comment. The committee agree this recommendation was originally phrased in a way that was open to misinterpretation. It was not the intention that two people should necessarily check these details on the day itself, but rather that on the day they should be checked and that it is ensured that at least two people have previously undertaken the checks. The recommendation has been amended to make this point clear.

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IND	Full	149	3478 - 3487	The way these two recommendations are phrased suggests that all low risk patients should potentially be offered simultaneous bilateral surgery routinely but the RCTs are all fairly small numbers and may fail to pick up the rare but devastating problems when both eyes have an issue. Most surgeons remain highly concerned about offering this lightly as it only takes 1 rare disaster to put one off for life. It might be better phrased to say "Bilateral simultaneous cataract surgery may be appropriate for selected low risk patients" or some equivalent to make it sound less like one ought to offer it to everyone but that *occasionally* it can be appropriate.	Thank you for your comment. The committee was aware of the concerns you raise (as discussed in the evidence to recommendations section of this chapter), and it was for this reason that the recommendation was kept at the weaker 'consider' level. However, they were keen to emphasise that there are specific groups of people in whom it may be an appropriate option, for example people requiring general anaesthesia in whom there may be additional risks in having to undergo that anaesthesia twice.
IND	Full	193-4	4322 - 4328	You have not mentioned the recent evidence, and previous studies, regarding the risk of using topical NSAIDs which is unexpected corneal melting. Consideration of their use should take this risk into account.	Thank you for your comment. Whilst we understand that this event has occurred in the past, the committee agreed that due to its rarity no amendment to the recommendations regarding NSAIDs was warranted at this time, due to the clear evidence of benefits provided by NSAIDs.
IND	full	198	2750	I do not think this advice is safe. We have received two complaints from patients who were not informed about the availability of multifocal lenses prior to cataract surgery, and later complained that they might well have chosen them had they been told about them. Any arrangement of IOL that allows simultaneous distance and near focus will compromise the quality of vision whether it is facilitated by monovision or a multifocal implant. As someone so nicely put it, 'blur is blur however it is produced', and there will always be a	Thank you for your comment. When NICE makes recommendations for the NHS on the use of particular technologies, it is required to consider both the effectiveness and cost-effectiveness of those options. In this case, whilst the committee agreed that there were clear benefits identified for multifocal lenses (in particular in reducing spectacle dependence), there was not robust evidence available on the cost-effectiveness of these lenses, and therefore the additional costs (both of the lenses and the pathway) could not be justified.

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				background image that reduces contrast and produces haloes. It seems perverse to strongly recommend not offering multifocal IOLs, but then to suggest offering monovision to some patients, especially when there are (probably) millions of very happy people with multifocal IOLs and even more happy with multifocal contact lenses. We do use multifocal IOLs for a small number of our private patients, and have had great success. However we counsel them very carefully as to what to expect, emphasizing the limitations, and give them a four-page A4 leaflet to take away. I feel strongly that the recommendation should be to discuss the limitations of multifocals thoroughly before making the decision to use them, rather than effectively imposing a blanket ban. The problem with the draft recommendation is that it could and would be used against any surgeon who uses multifocal IOLs with a patient who turns out to be dissatisfied. Guidelines are a very useful tool for lawyers!	The committee has also reconsidered the recommendation made around monovision, and agreed that the reference to a contact lens trial should be removed. With this removal, the committee is keen to emphasise that monovision is not being suggested as an alternative to multifocal lenses, but rather that for people who already have anisometropia or monovision pre-operatively, they should be offered the option to remain this way after surgery.
IND	Full	211	4671	You have mentioned collection of *postop* data but not made clear that all surgery providers should collect and audit *all* the minimum national cataract dataset and submit data to the NOD College HQIP national ophthalmic cataract audit which is a shame.	Thank you for your comment. NICE guidelines do not routinely refer to external sources of data collection or audits. However, the committee were confident that all providers should be aware of these datasets, and therefore it was unlikely to be necessary for the guideline to raise awareness on this issue.

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Kestrel Ophthalmics Ltd	Full	General	General	We acknowledge the importance of providing a clinical practice guideline aimed to provide reliable and up-to-date information to help ophthalmic professionals make the best possible clinical decisions for the patient benefit. However, we are deeply concerned that most recommendations in the NICE guideline are based on incomplete, biased and/or out-of-date information (see other comments below). Furthermore, there is a lack of transparency in the evidence statements (e.g. "moderate-quality evidence from up to 8 RCTs") since the reference studies are not mentioned in the text. Finally, and in many ways, this guideline seems to look backward offering little perspectives for patients in terms of advanced technologies and treatments such as toric IOLs, multifocal and trifocal IOLs, extended depth of focus IOLs, customized IOLs and laser-assisted cataract surgery.	Thank you for taking the time to comment on this guideline. Individual comments have been responded to where they appear. The individual studies going in to each analysis are given in both the GRADE tables (appendix G) and the meta-analysis graphs (appendix H). NICE is conscious of the need to always be up to date in its guidance, but also that new technologies need to demonstrate both effectiveness and cost-effectiveness before it is appropriate for NICE to recommend they be adopted for widespread use in the NHS.
Kestrel Ophthalmics Ltd.	Full	General	General	We are surprised that the different chapters of the guidelines do not all have the same level of patient's focus clinical expectations. As for example, 4 chapters are dedicated to strategies to improve postoperative refractive outcomes with biometry techniques, intraocular lens formulas, lens constant optimization and other considerations in biometry (pages 55 to 87), whereas the optimal strategy to address pre-existing astigmatism does not include toric intraocular lenses as patients would still require reading glasses.	Thank you for your comment. Toric lenses were considered as one of the relevant interventions in the section on addressing astigmatism, and spectacle independence was one of the outcomes considered as part of that question. NICE is required to consider cost-effectiveness alongside effectiveness in all the guidelines it produces, and therefore it is not sufficient to demonstrate that toric lenses are effective in reducing astigmatism, but also that they are a cost-effective use

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				We believe that recommendations should be centered on patient's needs and outcomes. Practice management should be included in this guideline to reduce resource burden and the cost associated rather than reducing access to new technologies.	of NHS resources. The committee were not convinced that robust evidence currently exists that toric lenses are a cost-effective intervention, and therefore did not feel it was appropriate to make a recommendation for their use.
Kestrel Ophthalmics Ltd.	Full	106	2515 - 22	**Long term stability of different lens materials** Long-term stability of IOL materials is a concern, particularly for children and other young cataract patients who will undergo long-term IOL implantation. As highlighted by the NICE committee, there is currently a lack of *in vivo* evidence for long-term outcomes with different IOL materials. However, the appearance of lens materials tested in *in vitro* tests simulating 20 years of material deterioration would presumably be very similar to that seen in patients as reported by Kawai et al. in 2012. The severe accelerated deterioration tests were performed on 7 types of hydrophobic and hydrophilic acrylic IOLs (from 6 manufacturers). The results showed that all hydrophobic IOLs, except one, displayed glistening-like opacities with differences in the degree of opacity among manufacturers. The hydrophilic acrylic IOL showed no opacity at any of the time points examined. The experiment showed that the higher the water content, the better transparency was maintained. This study provides a good reference when considering which IOL to choose for cataract patients necessitating long-term IOL implantation. It also strengthens the results reported by Werner in 2010 showing that hydrophilic	Thank you for your comment. In vitro studies were not considered by the Committee to be relevant evidence for addressing this question (see the study protocol in appendix C), and therefore studies of this type were not considered within the evidence base used in this guideline. In general, such data would be regarded as representing a much lower standard of evidence, and not one that would be relied upon to make recommendations.

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				materials are more stable over time while hydrophobic materials might lose transparency with age with the formation of glistenings. **References :** **Kawai et al. Simulation of 20-year deterioration of acrylic IOLs using severe accelerated deterioration tests. Tokai J Exp Clin Med. 2012 Sep 20;37(3):62-5.** **Werner L. Glistenings and surface light scattering in intraocular lenses. J Cataract Refract Surg. 2010 Aug;36(8):1398-420.**	
Kestrel Ophthalmics Ltd.	Full	106	2509	**"Offer square-edged hydrophobic acrylic or silicone intraocular lenses to people having cataract, to reduce the risk of PCO".** According to the committee, this recommendation is based on clinical data showing clear benefit of hydrophobic acrylic and silicone over hydrophilic acrylic for reducing PCO and the evidence that square edge designs prevent PCO. On the other hand, the committee also acknowledges that hydrophilic acrylic lenses may have less square edges than their hydrophobic counterparts, which may introduce an element of confusion (in other words, the distinction between the effect of IOL material and the optic edge on PCO could not be clearly established).	Please note: the recommendations around lens design and material have been removed to allow for further consideration.

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				We are concerned that in the above recommendations, several critical points should have been considered by the committee before making finale recommendations: **<u>PCO prevention/Capsular biocompatibility</u>** 1- Hydrophobic and hydrophilic acrylic lenses cannot be categorized under 2 simple denominations. Not all hydrophobic lenses are the same and not all hydrophilic lenses are the same. This is due to variations in the chemical and physical characteristics of the polymers and the methods for manufacturing them that can significantly affect performance outcomes. In the literature review from the guidance, the denomination "hydrophobic acrylic" refers to mostly one material only (Acrysof) and only 2 manufacturers are cited (Alcon/AMO) whereas more and more formulations are widely available with strong differences particularly in terms of monomers, manufacturing processes and mechanical and optical properties. 2- There are serious flaws in the NICE review that may have led to inaccurate conclusions : a. All hydrophilic acrylic lenses evaluated here are not commercially available anymore (BL27, Hydroview, Memorylens) and/or belong to the older generations (C-Flex 570, Akreos Adapt) with rounder edges than the newest generation. In this context, we'd like to emphasize that	

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				nowadays, with innovative manufacturing processes, latest generation hydrophilic lenses have sharper edges than the former generations. Moreover, it has been shown that certain models of hydrophilic lenses have even sharper edges than hydrophobic lenses (Nanavaty et al. 2008; Werner et al. 2009). b. As highlighted in the Cochrane review by Findl et al., 2010 (page 98, line 2402, first reference of Table 23), there is bias in the design of several studies. Two studies out of six investigating PCO incidence and YAG rate compared sharp edge acrylic lenses *versus* round edge hydrogel lenses preventing a clear distinction between the effect of IOL material and the optic edge on PCO. However, and interestingly, in the four studies comparing a sharp edge hydrophobic acrylic *versus* a sharp edge hydrogel IOL, one study favoured the hydrophobic acrylic IOL while three favoured the hydrogel IOL. Based on these outcomes, it was concluded that there was no clear difference between optic materials. 3- The only method so far that seems effective in preventing PCO formation is the implantation of an intraocular lens with sharp edged optics (Review: Nibourg et al. 2015) **<u>ACO prevention/Uveal Biocompatibility</u>**	

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				Uveal and capsular biocompatibility of lens materials is critical to reduce post-operative complications. Therefore, we are surprised that uveal biocompatibility (i.e. anterior chamber opacification (ACO) and inflammation) has not been considered in this review since intraocular lens material may influence the severity of postoperative inflammation. a- In particular, hydrophobic materials have been shown to cause more inflammatory responses and more rapid ACO than hydrophilic materials (Mullner-Eidenbock et al. 2001; Abela-Formanek et al. 2002; Richter- Mueksch et al. 2007; Abela-Formanek et al. 2011). This is because inflammatory cells adhere more easily on hydrophobic surfaces leading to higher incidence of iris posterior synechiae and ACO, especially in patients with blood-aqueous barrier damage. Serious ACO can, in turn, cause anterior capsule shrinkage, IOL decentration and may hinder the examination of peripheral fundus (Macky et al. 2001). Thus, these problems limit the application of hydrophobic acrylic IOLs in compromised eyes i.e in patients with uveitis, glaucoma or diabetes. b- There is also evidence that the higher the hydrophilicity, the lower the early adhesion and bacterial density on the lens surface (Schauersberger et al. 2003; Kodjikian et al. 2003). These studies suggest that hydrophilic	

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				lenses may help reduce the rate of postoperative endophtalmitis. c- Finally, the current research in terms of materials is focusing on the treatment of the anterior surface of hydrophobic acrylic lenses to render their surface hydrophilic in order to enhance the surface biocompatibility, thereby reducing inflammation (Huang et al. 2017). **<u>Optical properties of different materials</u>** Optical properties of hydrophilic materials are closer to those of the natural lens than hydrophobic materials because of their lower refractive index and higher Abbe number (the higher the Abbe number, the lower the chromatic aberrations). Since chromatic aberrations impact negatively on vision and in particular on contrast sensitivity, it is important to consider these parameters for the patient benefit. a- A recent study has shown that eyes with hydrophobic IOLs had consistently higher longitudinal chromatic aberration than eyes with hydrophilic IOLs of the same design (Vinas M et al. 2015). b- High refractive index might be a risk factor for negative dysphotopsia (Henderson et al. 2015). **References :**	

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				Nanavaty et al. Edge profile of commercially available square-edged intraocular lenses. J Cataract Refract Surg. 2008 Apr;34(4):677-86 **Werner et al. Evaluating and defining the sharpness of intraocular lenses: Microedge structure of commercially available square-edged hydrophilic intraocular lenses. J Cataract Refract Surg 2009; 35:556–566** **Nibourg et al. Prevention of posterior capsular opacification. Exp Eye Res. 2015 Jul;136:100-15 http:// dx.doi.org/10.1016/j.exer.2015.03.011** **Mullner-Eidenbock et al. Cellular reaction on the anterior surface of 4 types of intraocular lenses. J Cataract Refract Surg 2001; 27, 734–740 ;** **Abela-Formanek et al. Results of hydrophilic acrylic, hydrophobic acrylic, and silicone intraocular lenses in uveitic eyes with cataract : Comparison to a control group. J Cataract Refract Surg 2002; 28, 50–61;** **Richter- Mueksch et al. Uveal and capsular biocompatibility after implantation of sharp-edged hydrophilic acrylic, hydrophobic acrylic, and silicone intraocular lenses in eyes with pseudoexfoliation**	

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				syndrome. J Cataract Refract Surg. 2007 Aug;33(8):1414-8 **Abela-Formanek et al. Biocompatibility of hydrophilic acrylic, hydrophobic acrylic, and silicone intraocular lenses in eyes with uveitis having cataract surgery: Long-term follow-up. J Cataract Refract Surg 2011; 37, 104–112;** **Macky et al. Anterior capsule opacification. Int Ophthalmol Clin. 2001 Summer;41(3):17-31.** **Schauersberger et al. Bacterial adhesion to rigid and foldable posterior chamber intraocular lenses: In vitro study. J Cataract Refract Surg 2003; 29:361–366** **Kodjikian et al. Bacterial Adherence of *Staphylococcus Epidermidis* to Intraocular Lenses: A Bioluminescence and Scanning Electron Microscopy Study. IOVS. 2003 Oct; 44(10):4388-4394** **Huang et al. UV-assisted treatment on hydrophobic acrylic IOLs anterior surface with methacryloyloxyethyl phosphorylcholine: Reducing inflammation and maintaining low posterior capsular opacification properties. Mater Sci Eng C Mater Biol Appl. 2017 Jun 1;75:1289-1298**	

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				Vinas M et al. In vivo subjective and objective longitudinal chromatic aberration after bilateral implantation of the same design of hydrophobic and hydrophilic intraocular lenses. J Cataract Refract Surg. 2015 Oct;41(10):2115-24 **Henderson et al. Negative dysphotopsia: A perfect storm. J Cataract Refract Surg. 2015 Oct;41(10):2291-312**	
Kestrel Ophthalmics Ltd.	Full	120	2767 - 2887	**"Consider on-axis surgery or limbal-relaxing incisions to reduce postoperative astigmatism"** Although we appreciate that you used "consider" not as a strong recommendation, we would like to emphase the long-term economic and quality of life benefits for the use of toric IOLs under public health systems: 1. Toric IOLs decrease spectacle dependence. Rate of spectacle independence when reaching for emmetropia for distance vision can be twice higher than in a control group with monofocal lens only (Lane et al. 2009; Mingo-Botin et al. 2010). 2. Toric IOLs reduce lifetime economic costs by reducing the need for glasses or contact lenses. It should be noted that on the reference retained for this matter from Pineda et al. 2010 (line 2804 page 121), the study may have underestimates	Thank you for your comment. The committee agreed that toric lenses were an effective method for reducing postoperative astigmatism, and are likely to be more clinically effective for some individuals than the surgical techniques which were given a 'consider' recommendation. However, NICE is required to consider cost-effectiveness alongside effectiveness in all the decisions it makes and, given the additional pathway costs associated with toric lenses, the committee agreed that there was no robust evidence on their cost-effectiveness that enabled them to make a positive recommendation. The committee also noted that the NICE reference case only considers costs to the NHS and social services, and not costs to individuals themselves. Therefore, the costs of spectacles to individual patients are not relevant for inclusion within the analysis.

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				the cost difference between treatments as actual cost of wearing glasses and contact lenses was not incorporated after the first year postoperatively. As cataract surgery becomes increasingly safer and more effective, surgery could be performed for younger patients. Together with increasing life expectancy, this would trend for even greater lifetime benefit for toric IOLs. 3. Patients have a better objective optical and retinal image quality which resulted in better subjective quality of life (Mencucci et al. 2013) We would like to propose to the national health services to reimburse premium IOL including toric lenses the same way as they currently do for monofocal IOLs with a shift of costs to patients. Extra costs, lying entirely outside NHS budgets which reimbursed cataract surgery but not the cost of extra refraction visits would be paid by the patient. This system led to savings in 4 European countries as reported by Laurendeau et al. in 2009. **References :** **Lane et al. Comparison of clinical and patient-reported outcomes with bilateral Acrysof toric or spherical control intraocular lenses. J Refract Surg 2009; 25:899-901e**	Finally, issues around price sharing arrangements or co-payments are outside the scope of NICE guidelines, and therefore it was not possible for the committee to make recommendations along these lines.

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				Mingo-Botin et al. Comparison of toric intraocular lenses and peripheral corneal relaxing incisions to treat astigmatism during cataract surgery. J Cataract Refract Surg. 2010 Oct; 36(10):1700-1708 **Mencucci et al. Astigmatism correction with with toric intraocular lenses: wavefront aberrometry and quality of life. Br J Ophthalmol. 2013 May; 97(5):578-582** **Laurendeau et al. Modelling lifetime cost consuquences of toric compared with standard IOLs in cataract surgery of astigmatic patients in four European countries. J Med Econ. 2009 Sep; 12(3):230-237**	
Maidstone and Tunbridge Wells NHS Trust	Full	General	General	Are there any recommendations about anticoagulant usage in cataract surgery? What is a safe level of INR for cataract surgery in a patient on warfarin? Should drugs like apixiban, rivaroxaban, clopidogrel be stopped prior to surgery and for what duration?	Thank you for your comment. Unfortunately, the effects of anticoagulant use on cataract surgery was not part of the scope developed for this guideline, and therefore it is not possible to make any recommendations in this area.
Maidstone and Tunbridge Wells NHS Trust	Full	General	General	What is a safe level of blood pressure and blood glucose before proceeding with cataract surgery?	Thank you for your comment. Unfortunately, the effects of blood pressure and blood glucose on cataract surgery were not part of the scope developed for this guideline, and therefore it is not possible to make any recommendations in this area.
Maidstone and Tunbridg	Full	General	General	Is it safe to proceed with surgery if the patient is being treated for a urinary tract infection?	Thank you for your comment. Unfortunately, the effects of urinary tract infections on cataract surgery was not part of the scope developed for this guideline, and

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e Wells NHS Trust					therefore it is not possible to make any recommendations in this area.
NHS Northern, Eastern and Western Devon CCG	Short	5	4	1.2.2. Do not restrict access to cataract surgery on the basis of visual acuity. We are concerned that recommendation 1.2.2 does not reflect the evidence. The Guideline Development Group state that the economic model provides good evidence to support a commissioning strategy that is not based on visual acuity thresholds alone (page 51, full version). Recommendation 1.2.2 also conflicts with 1.2.1 which advises that the decision to refer a patient with cataract for surgery should be based on a discussion which includes how the cataract affects the person's vision and quality of life. Rewording recommendation 1.2.2 to advise that access to surgery should not be based on visual acuity alone would clarify the position.	Thank you for your comment. The committee agreed that the evidence presented was sufficient to demonstrate that visual acuity thresholds should not be used as part of the decision whether to refer someone for cataract surgery. Whilst visual acuity may form part of the discussion with a patient on how a cataract is affecting their quality of life, this should always be based around the impact that acuity loses are having on their quality life, not purely the extent of the acuity loss itself. The committee agreed there were currently issues with people being denied access to cataract surgery on the basis of arbitrary visual acuity thresholds, and agreed it was appropriate to keep the strongest possible wording in this recommendation, to try and minimise the extent to which this happens in the future.
NICE	Short	9	17	For rec 1.5.8 could also include here the importance of applying and sharing learning with peers/MDT, including feedback to support continuing professional development.	Thank you for your comment. The committee agreed that due to the importance of preventing wrong lens errors, this recommendation should be kept as brief and focused as possible, to ensure the key steps necessary to prevent a repeat of previous mistakes are undertaken.
NICE	Short	18	22	Diamox is a brand name, better to use its generic name here which is acetazolamide	Thank you for your comment; this correction has been made.

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NICE	Short	18	22	For 'steroidal anti-inflammatory drugs' I'm assuming you mean steroid drugs in which case better to use 'steroid based anti-inflammatory drugs' rather than referring to them as 'SAIDs' as this may get confused with NSAIDs which is a term more commonly used in practice.	Thank you for your comment; this correction has been made.
Optegra Eye HealthCare	Full Short	7 25	1 571 - 5	The recommendation appears to advise against the use of all hydrophilic lenses and blue light filtering lenses, both of which are still being widely used. We are concerned that this recommendation may be challenging to implement in practice. Manufacturers may challenge these recommendations, perhaps citing the lack of long-term evidence. In some other areas of the guidance, widespread usage appears to be offered as a rationale to recommend approaches that are not supported by the published literature e.g. the common use of older IOL formulae.	Please note: the recommendations around lens design and material have been removed to allow for further consideration.
Optegra Eye HealthCare	Full Short	7 25	5 576	It is recommended that multifocal intraocular lenses should not be offered for people having cataract surgery. It seems ill advised to make such a strong recommendation and somewhat illogical to suggest that the benefits of MFIOLs shown in RCTs can be dismissed based on the fact some groups e.g. professional drivers would not have been included in such trials. Whilst we appreciate that this is somewhat of a sub-speciality within cataract surgery, as are toric and limbal relaxing incisions, and that there is a cost / resource consideration, we believe this recommendation is likely to be challenged. Not least since there is a body of evidence to support the fact modern multifocal/extended depth of	Thank you for your comment. The recommendation regarding multifocal lenses was determined by the Committee following review of the efficacy and cost effectiveness evidence. Whilst we agree that multifocal lenses improve aspects of vision, the "care pathway" is considerably more expensive than monofocal lenses without the major gains in improved vision needed to justify them as a cost effective use of NHS resources. The committee emphasised that the 'do not offer' recommendation made did not imply there were not potential benefits from multifocal lenses, but rather that

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				focus intraocular designs are effective in providing excellent distance, intermediate and near vision, and typically lead to high levels of patient satisfaction. Since this is clearly established in the literature, as well as in practice internationally, we contend that it is not correct to in any way insinuate that the use of multifocal lenses in cataract patients is in any way wrong. Calladine et al 2012, Cochener et al 201, Venter et al 2013; Rosen et al 2016. We would be happy to submit our experience with a range of advanced technology IOLs, supported by outcomes data. The reported explantation rate seems very high and appears to relate to older technologies and does not reflect our Organisation's clinical experience.	those benefits did not justify the additional cost of the lenses. The committee has agreed it was appropriate to remove the reference to explantation rates with multifocal lenses, as it was agreed the reported number were unlikely to be accurate for modern lens designs.
Optegra Eye HealthCare	Full	24	536 - 546	As above for this recommendation, common usage appears to be offered as a rationale to recommend older formulae that are not supported by the literature. We feel that Barrett formula has been shown to be effective for those with high axial lengths >26mm (Zhang et al 2016; Wang et al, 2011, Abulafia et al 2015). It has also been shown in the literature that Haigis is more effective if used with an adjustment factor if it is to be applied to axial lengths >26mm. Similarly there is evidence to support the use of the Barret formula which is built into the ASCRS post refractive calculator for post refractive surgery eyes (Abulafia et al 2016). The Barrett toric calculator is one of only two toric calculators that make adjustments for	Thank you for your comment. The committee were keen to note that common usage was not used as a reason to recommend any particular IOL formulas, and that recommendations were instead based on an evidence review looking at the different rates and levels of refractive error with alternative formulas. The only other criteria taken into consideration was that the most accurate formula appeared to be one that may not be available on all the biometry devices currently used in the NHS. Here the committee agreed it was appropriate to make a recommendation for a second choice formula, to ensure the results did not

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				posterior corneal astigmatism which can improve refractive outcomes (Abulafia et al 2015). Access to newer formulae is increasingly being made available either online or in instrumentation.	need to be transcribed by hand (an identified cause of wrong lens errors).
Optegra Eye HealthCare	Full	25	581	We are concerned that this recommendation is likely to be challenged and seems ill advised. On-axis surgery has been recently shown to be an inconsistent method of reducing astigmatism as the area of flattening will not necessarily occur on the incisional meridian. This also applies to LRIs. LRIs are a specialist technique and most cataract surgeons do not have this skillset. Toric IOLs are more accurate and are more forgiving in those patients in whom correction of astigmatism at the time of surgery is indicated (Kessel et al). Furthermore LRIs are not as adept as toric IOLs at correcting higher levels of astigmatism and therefore could end up costing more due to high retreat rates. The cost of a certain number of toric IOLs can often be included as part of an NHS Trust's monofocal contract and under these arrangements there is often no uplift for the use of an agreed proportion of toric IOLs.	Thank you for your comment. The committee emphasised that the lack of a positive recommendation for toric lenses does not imply there are no clinical benefits from their use. It agreed that the evidence demonstrated their were benefits from toric lenses in terms of reduced post-operative astigmatism, but also that there were considerable additional pathway costs associated with their use (over and above the costs of the lenses themselves). Therefore, the committee were not convinced that toric lenses represented a cost-effective use of NHS resources, and therefore agreed the appropriate recommendation to make was a research recommendation looking at the cost-effectiveness of toric IOLs in the NHS. The committee also agreed that the evidence suggested that on-axis surgery and LRIs may not be as clinically effective a method of reducing post-operative astigmatism as toric lenses, but the fact that they are not associated with the same high additional costs as toric lenses means they are likely to represent a more cost-effective use of NHS resources.
Optegra Eye	Full	28	684	We are concerned that this implies that capsular tension rings are somehow unproven when they can be useful to	Thank you for your comment. The evidence base identified for this guideline did not demonstrate any

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HealthCare				ensure a stable IOL with minimal disturbance from the shrinkage of the capsular bag around the IOL haptics. This may not be relevant for all IOLs but can be useful in some cases to allow for a more accurate predicted post-op refractive error.	advantage from the use of capsule tension rings in routing, uncomplicated cataract surgery, and therefore the Committee agreed it was appropriate to recommend they not be routinely used in these circumstances.
Optegra Eye HealthCare	Full	139	3218	It may be challenging for the sector if a document was produced that gave the impression that Femtosecond Laser-Assisted Cataract Surgery (FLACS) is purely an experimental technique whose safety and effectiveness has not been determined. The main reason for the conclusion appears to be the lack of demonstration of economic effectiveness and improved acuity outcomes, and the evidence presented was for these to be insignificant. Greater clarity is required in the wording, mindful of the fact that the procedure is i) perfectly valid and ii) performed regularly at some private hospitals in the UK and any implication that this is in some way against learned medical opinion.	Thank you for your comment. The "do not" recommendation does not refer to the safety of the technology, and we agree that there is no indication that there are significant differences in risks between FLACS and PCS on the basis of the evidence included in this Guideline. The "do not" recommendation reflects the clinical and health economic evidence which do not support the use of the technology in an NHS context. For more information about how NICE formulates the wording of recommendations, please see https://www.nice.org.uk/process/pmg6/chapter/developing-and-wording-guideline-recommendations
Optegra Eye HealthCare	Full	139	3218	There would be a potential impact if printed articles or similar media were to emerge quoting this report as being a general recommendation to avoid FLACS.	Thank you for your comment. As discussed above, NICE has specific rules about how it words recommendations, designed to avoid these sorts of confusions, which are given here: https://www.nice.org.uk/process/pmg6/chapter/developing-and-wording-guideline-recommendations
Optegra Eye HealthCare	Full	139	3218	We are concerned that the current wording of this recommendation may in some way imply that the use of FLACS is in some way intrinsically dangerous or detrimental to the patient, when the evidence presented does not demonstrate this. It would help to meet the	Thank you for your comment. The "do not" recommendation does not refer to the safety of the technology, and we agree that there is no indication that there are significant differences in risks between FLACS and PCS on the basis of the evidence included

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				potential challenges arising from this if there was a small wording change. We would seek a change to the wording which clarifies that the FLACS technique is a valid one and that the evidence shows that outcomes are at least equivalent to those obtained by conventional techniques. FLACS may not be recommended at the moment for use in the NHS but is provided as an option by some private providers, and we would look for assurances that the document does not contribute to denigration of the technique in passing by virtue of not recommending its use in the public sector environment.	in this Guideline. The "do not" recommendation reflects the clinical and health economic evidence which do not support the use of the technology in an NHS context. For more information about how NICE formulates the wording of recommendations, please see https://www.nice.org.uk/process/pmg6/chapter/developing-and-wording-guideline-recommendations
Optical Confederation and Local Optical Support Unit	Short	5	23 - 28 1 – 4	There is a time and hence cost implication for discussions with patients and their family members or carers. This requirement is beyond the requirements of a GOS sight test and should be part of a commissioned pre-referral service.1	Thank you for your comment. The commissioning and funding of services is outside the scope of this guideline, and therefore it was not possible to make recommendations on this topic. The committee agreed that for people already undertaking discussions with family members on carers, the points listed within the guideline should not lead to an increase in total contact time, and therefore should not lead to an increase in costs. This is discussed in the evidence to recommendations section for the patient information question in the full guideline.
Optical Confederation and Local Optical	Short	2 3	8 – 19 1 – 9	There is a time and cost implication to providing written and oral information. Information needs to be tailored to the individual person's needs and in addition to general information about cataracts and cataract surgery. We recommend that there should be information on local providers of surgery. This requirement is beyond the	Thank you for your comment. Unfortunately, the commissioning and funding of services is outside the scope of this guideline, and therefore it was not possible to make recommendations on this topic.

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Support Unit				requirements of a GOS sight test and should be part of a commissioned pre-referral service.1	The committee agreed that for people already undertaking discussions with family members on carers, the points listed within the guideline should not lead to an increase in total contact time, and therefore should not lead to an increase in costs. This is discussed in the evidence to recommendations section for the patient information question in the full guideline.
Optical Confederation and Local Optical Support Unit	Short	3	16 – 18	Individual's risk will be better informed if primary care optometrists are involved in the overall pathway through a commissioned pre-referral service.1	Thank you for your comment. Unfortunately, the commissioning and funding of services is outside the scope of this guideline, and therefore it was not possible to make recommendations on this topic.
Optical Confederation and Local Optical Support Unit	Short	4	18	'when it is appropriate to get new spectacles and how to do so' should be moved to 1.1.5 'on the day of surgery, after the operation,' because the first appointment after surgery will not necessarily be with the surgery provider; it may be in the community.3	Thank you for your comment. The Committee discussed this issue and remained of the opinion that the most appropriate time to discuss this issue for most people was the first postoperative appointment, rather than on the day of surgery itself.
Optical Confederation and Local Optical Support Unit	Short	5	4	We strongly support this statement. Currently many CCGs/commissioners are restricting access to cataract surgery on the basis of visual acuity alone, so we are very pleased that this NICE guideline states clearly that they should not be doing so.	Thank you for your comment and endorsement of recommendations regarding access to cataract surgery.

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Optical Confederation and Local Optical Support Unit	Short	10	2 – 3	We strongly support this statement. Currently some commissioners are applying more restrictive access criteria to second eye surgery.	Thank you for your comment and support of the recommendations regarding second eye cataract surgery.
Optical Confederation and Local Optical Support Unit	Short	12	18 - 19	Primary care optometrists are ideally situated to collect patient visual function and quality of life data as part of a commissioned cataract post-operative service community service pathway.1	Thank you for your comment. The commissioning and funding of services is outside the scope of this guideline, and therefore it was not possible to make recommendations on this topic.
Optical Confederation and Local Optical Support Unit	Short	12	12	"processes to ensure" should be changed to "a commissioned service to ensure" Providing electronic postoperative data for the UK Minimum Cataract Dataset for National Audit should be a requirement of a commissioned cataract post-operative service in primary care.1	Thank you for your comment. The commissioning and funding of services is outside the scope of this guideline, and therefore it was not possible to make recommendations on this topic.
Optical Confederation and Local Optical Support Unit	Short	13	8	• Patient choice – the process would be streamlined if primary care optometrists had access to the NHS e-referral service and hence up to date information on waiting times and capacity of service providers of cataract surgery. • Shared electronic patient records would facilitate full integration of primary and secondary care services.	Thank you for your comment. Unfortunately, these issues were not within the scope of this guideline, and therefore it was not possible to make recommendations on these topics.

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				• Direct referral by primary care optometrists to cataract services should be considered. Direct listing by community optometrists such as the service provided in Bedford should be considered.[6]	
Optical Confederation and Local Optical Support Unit	Short	13	16 – 17	"General Optical Council" should be added to emphasise that primary care optometrists play an essential role in the cataract pathway.	Thank you for your comment, and a reference to the General Optical Council has been added to this section.
Optical Confederation and Local Optical Support Unit	Short	14	9 – 10	Add "Local Optical Committee" after "health and social care organisations" as Local Optical Committees represent all local ophthalmic contractors and performers i.e. primary care optical practices and practitioners.	Thank you for your comment. This section is a standard piece of text that appears in all NICE guidelines, and therefore for consistency reasons we do not feel it is appropriate to make changes to this section.
Optical Confederation and Local Optical Support Unit	Short	15	17	As are some systemic medications such as cortico steroids.	Thank you for your comment. The factors mentioned here were not intended to be an exhaustive list of all the relevant risk factors, merely some illustrative examples.
Optical Confederation and	Short	16	12	Add "People should have a recent sight test and up-to-date spectacle prescription before referral for cataract extraction. A pre-referral service should be commissioned	Thank you for your comment. The commissioning and funding of services is outside the scope of this

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Local Optical Support Unit				to ensure further relevant social and clinical information is provided.	guideline, and therefore it was not possible to make recommendations on this topic.
Optical Express	Full	General	General	In general: □ The intended audience for the NICE Guidance, who it should apply to, and the objectives of the guidance should be stated more clearly. As we understand, the guidance is intended solely for NHS services and not for private practice, but this is not clear from the draft. □ It appears that much of the guidance is driven by the cost-effectiveness of interventions, supporting efficiencies in the NHS, and not based purely upon best patient care and outcomes. This raises serious ethical and moral concerns about the soundness of the recommendations. □ The NICE guideline has the potential to impact private cataract surgery and the identical Refractive Lens Exchange procedure, specifically the guidance: o does not promote best patient care o will needlessly reduce patient choice o interferes with the patient/surgeon relationship o may unnecessarily increase medico-legal risks to clinicians and insurance providers.	Thank you for your comment. NICE has a statutory duty under the Health and Social Care Act to '… have regard to the broad balance between the benefits and costs of the provision of health services or of social care in England' Consequently, NICE considers cost-effectiveness alongside effectiveness in all recommendations it makes, as to make positive recommendations for interventions that are not cost-effective would results in people elsewhere in the system being denied access to more effective interventions.
Optical Express	Full Short	28 12	713 – 714 20 - 21	Recommendation 13.2.7 – 55 (Full) and 1.9.3 (Short): □ It appears that the decision to not offer an in-person first-day review to all patients was made on cost saving grounds. Without strong evidence to support it, such a	Thank you for your comment. This recommendation was made on the basis of a number of randomised controlled trials which did not demonstrate any

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				proscriptive approach may impact the standard of care provided to patients.	worsening of outcomes in individuals where no first-day review was carried out. This recommendation was specifically restricted to uncomplicated cataract surgery, as the Committee agreed that first-day review would still be appropriate if any complications around surgery had occurred.
Optical Express	Full Short	106 7	2509 – 2510 2 - 4	Recommendation 8.1.7 - 21 (Full) and 1.4.1 (Short): □ The recommendation of lens design and material is overly proscriptive, unnecessarily limiting clinician choice. NICE provides inadequate evidence for such an important recommendation. □ The recommendation seems to be based on the delayed onset of Posterior Capsular Opacification (PCO) in hydrophobic lenses in comparison to hydrophilic lenses. There is an abundance of literature which demonstrates that PCO can develop with both hydrophobic and hydrophilic lenses. □ Surgeons and providers who follow the guidance will needlessly deny patients implants which are best suited to their individual needs, while surgeons and providers who do offer 'not recommended' procedures will do so against NICE guidance. In both cases, this recommendation presents surgeons and providers (to include the NHS) with a medico-legal risk	Please note: the recommendations around lens design and material have been removed to allow for further consideration.
Optical Express	Full	118	2750	Recommendation 8.3.7 – 23 (Full) and 1.4.2 (Short):	Thank you for your comment. The committee agreed that multifocal lenses are effective at improving levels of unaided visual acuity and reducing rates of spectacle

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	Short	7	5 - 6	□ The recommendation not to offer multifocal intraocular lenses for people having cataract surgery will significantly limit the range of outcomes and quality of life for patients. □ The NICE review carelessly disregards extensive research and numerous publications on multifocal IOLs which demonstrates high patient satisfaction, improved near vision, spectacle independence and enhanced quality of life. □ The committee recognises that the quality of evidence used to reach this decision was flawed, and the decision appears to have been reached based on the cost of lenses and the cost of the care pathway rather than the benefits to patients. Multifocal IOLs are significantly more expensive than monofocal IOLs. □ While basic monofocal IOLs may be deemed acceptable for NHS services solely due to cost constraints, the NICE recommendation will likely be taken out of context, restricting patients receiving independent services from having the best possible treatment tailored to their individual needs. □ Patients may erroneously perceive that multifocal IOLs represent a serious safety and / or efficacy concern. □ The NICE recommendation presents surgeons and providers (to include the NHS) with a medico-legal risk.	dependence, and that if there were no additional costs associated with their use, then they would represent a relevant treatment alternative. However, NICE guideline are required to consider the cost-effectiveness as well as the effectiveness of the interventions under consideration, and given the substantial additional costs associated with multifocal lenses (both lens and pathway costs) the committee agreed that they could not be recommended as a cost-effective use of NHS resources. NICE guidelines are produced for the public sector in England, and do not make recommendations based on the cost perspective of private healthcare services.
Optical Express	Full Short	119 7	2751-2753 7 - 9	Recommendation 8.3.7 – 24 (Full) and 1.4.3 (Short): □ This recommendation is employed in some practices, however the guidance fails to provide adequate evidence to support the universal usage of monovision over multifocal IOLs. It appears that the monovision	Thank you for your comment. The committee has reconsidered the evidence on multifocal lenses and remains of the opinion that they cannot currently be recommended as being a cost-effective use of NHS resources.

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				recommendation is based entirely on an effort to bolster its untenable position on multifocal lenses. Without the possibility of using multifocal IOLs, monovision is the only intraocular solution to achieve distant and near vision when implanting monofocal IOLs. • For many patients multifocal IOLs are a preferable option due to their unique advantages, such as enhanced binocularity or rejection of monovision	The committee has also reconsidered the recommendation made around monovision, and agreed that the reference to a contact lens trial should be removed. With this removal, the committee is keen to emphasise that monovision is not being suggested as an alternative to multifocal lenses, but rather that for people who already have anisometropia or monovision pre-operatively, they should be offered the option to remain this way after surgery.
Optical Express	Full Short	133 8	3055-3060 2 - 7	Recommendation 9.1.7 – 28 (Full) and 1.5.3 (Short): • The recommendation on intraocular lens selection and the focus on patient's chosen refractive outcome directly contradicts with the recommendation not to offer multifocal intraocular lenses. Clinicians are not able to fully base their choice of intraocular lens on the patient's chosen refractive outcome if they are not allowed to select multifocal IOLs. • For patients to provide an informed consent, they need to be fully informed of reasonable treatment alternatives, to include multifocal IOLs.	Thank you for your comment. The committee does not agree that this is a contradiction. When making the selection of an intraocular lens, the clinician will always be limited to the range of lenses available to be used (no surgery has access to every type of lens from every manufacturer), and this will remain the case whether or not multifocal lenses are available. As such, the lens chosen will always be the one that is most appropriate to the patient's preferred refractive outcome, from the selection of lenses available.
Optical Express	Full Short	139 9	3218-3220 25 - 27	Recommendation 10.1.7 – 34 (Full) and 1.6.1 (Short): • The recommendation that femtosecond laser technology should not be used appears to be based on cost considerations and may be detrimental to patient outcomes. • There are many peer review publications supporting the safety and efficacy of femtosecond laser assisted	Thank you for your comment. The currently available randomised controlled trials, including a recent Cochrane Review, do not support these conclusions. The study type searched and included as the most appropriate, in this case RCTs, within the review question was determined and ratified by the guideline committee prior to its commencement. Whilst we agree

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				cataract surgery which were apparently ignored in the review. □ The committee recognises that the evidence used to reach their conclusion is of poor quality, and further research is ongoing. □ There does not appear to have been adequate consideration to the safety benefits of femtosecond lasers – for example, a dense cataract in an elderly patient. □ Patients may erroneously believe that femtosecond cataract surgery is unsafe. □ Surgeons and providers who follow the guidance will be denying patients interventions which may be most suited to their clinical needs, while surgeons and providers who do offer femtosecond assisted cataract surgery will be doing so against NICE guidance. In both cases, this recommendation presents surgeons and providers (to include the NHS) with a medico-legal risk.	that the trial evidence shows no additional harm from FLACS over PCS, is does not suggest a clear safety or efficacy benefit of FLACS over PCS. We are aware that 2 large RCTs (FACT and FEMCAT), at least 1 of which will include a parallel economic analysis, are due to publish in 2018. Details of both have been passed to the NICE surveillance team, and there are processes by which a rapid, targeted update of that part of the guideline can be undertaken, should that new evidence imply the recommendations need to be reviewed. It should be noted that the decision to recommend FLACS only as part of a trial reflects the economic evidence which does not at the time of writing support FLACS as a cost-effective option for cataract surgery.
Optical Express	Full Short	181 11	4061 6 - 7	Recommendation 12.4.7 – 45 (Full) and 1.8.2 (Short): □ The recommendation not to use capsular tension rings appears to be based on the expense of capsular tension rings and does not adequately consider its potential safety and effectiveness advantages. □ The recommendation will likely lead to poorer outcomes for patients where a capsular tension is indicated. □ The recommendation may needlessly affect all providers, not just those offering NHS services.	Thank you for your comment. The evidence base identified for this guideline did not demonstrate any advantage from the use of capsule tension rings in routine, uncomplicated cataract surgery, and therefore the Committee agreed it was appropriate to recommend they not be routinely used in these circumstances.

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Optical Express	Short	16 - 18	19	Recommendation regarding toric IOLs: □ The recommendation for additional research regarding toric lenses disregards clear and compelling evidence on their clinical effectiveness and instead seems to be driven by the increased cost of these lenses. This dogmatic, cost driven approach puts the patients' interests and safety as a secondary consideration and raises ethical and moral concerns.	Thank you for your comment. NICE has a statutory duty under the Health and Social Care Act to '… have regard to the broad balance between the benefits and costs of the provision of health services or of social care in England' Consequently, NICE considers cost-effectiveness alongside effectiveness in all recommendations it makes, as to make positive recommendations for interventions that are not cost-effective would results in people elsewhere in the system being denied access to more effective interventions. The recommendation for research is based on the fact that toric lenses have shown themselves to be effective in reducing astigmatism – the outstanding question is whether they represent a cost-effective use of NHS resources.
Plymouth Hospitals NHS Trust	Full	125	2886	The recommendation to consider on axis surgery is not based on evidence. The one and only study of 71 patients quoted in the guideline (Kaufmann, 2005) was erroneously interpreted in lines 2876-2879 and in the evidence to recommendations section (line 2884) as showing no difference between on axis and LRI while in fact the study did show that LRIs were likely to be superior as they resulted in a significantly more flattening effect. Although the surgically induced astigmatism was not significantly different between the 2 groups, this was because of the lack of statistical power of the study even by the admission of the authors (Type 2 error).	Thank you for your comment. The committee agreed that the evidence base for on-axis surgery (and indeed that for limbal relaxing incisions) was not particularly strong. It was for this reason that the recommendation was made at the weaker 'consider' level. The committee agreed that the Kaufmann study could not be interpreted as proving there was no difference between the two procedures but rather that the study was unable to detect a difference between the two alternatives in terms of astigmatism.

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				In addition, the bespoke on axis cataract incision in the study using 600 micron groove with a micrometer knife and 3.5 mm wide incision resulted in a mere 0.35D flattening effect (at 6 months). Moreover, this bespoke incision doesn't reflect current practice where most incisions are 2.5mm or less without deep grooves and therefore on axis surgery using such smaller incisions is unlikely to have significant effect on reducing astigmatism. Another possible consequence of recommending on axis surgery (other than not achieving any meaningful astigmatic correction) is to make surgery more time consuming and difficult by having to mark the axis pre-operatively (which may necessitate performing corneal topography and sitting the patient to mark the limbus prior to introducing the anaesthetic) and more importantly by having to operate sometimes from an awkward position where the main incision might be located with the patient's nose in the way (such as if the axis of astigmatism is at 45 degrees in the right eye or at 135 degrees in the left eye). The evidence does not support on axis surgery to significantly or predictably reduce astigmatism and this recommendation should be changed to "Consider limbal-relaxing or other incisional methods to reduce postoperative astigmatism."	However, the committee agreed that it was important for the guideline to raise awareness of the surgical techniques that can be used to attempt to reduce postoperative astigmatism. It is for individual surgeons to decide whether they believe the use of such techniques is appropriate.
Plymouth Hospitals	Full	158	3648	This recommendation will demand a change in current practice that is not based on evidence. According to the last BOSU study of anaesthetic complications in 2015, it	Thank you for your comment. The committee agreed that there was no significant differences identified in effectiveness between peribulbar and sub-Tenon

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NHS Trust				is estimated that 8% (30000 per year) of all cataract surgery in the UK is performed using peribublar anaesthesia. There has been no reliable evidence sited in the draft guideline to show that sub-tenon injection is superior to peribulbar anaesthesia. The discussion on this page (158) and the previous page (157) seems to suggest an "opinion" by the committee rather than reasonable evidence (for example in the evidence to recommendations on page 157, there is a statement: "The committee …… felt that some of the serious complications seen in clinical practice, including globe perforation, were not captured in the studies presented, due to the relatively small sample sizes of the studies." - a presumption but not a fact). There is no doubt that in practice some patients are not suitable for topical anaesthesia (with or without intracameral) or some surgeons, especially those in training (supervised or unsupervised) feel uncomfortable to operate without significant akinesia. Therefore an injection form such as sub-tenon or peribulbar methods are required. The evidence doesn't support one over the other, so the recommendation should be changed to: "38. Offer topical (with or without intracameral) anaesthesia for people having cataract surgery. 39. If topical (with or without intracameral) anaesthesia is not preferred or suitable, consider sub-tenon or peribulbar anaesthesia unless contra-indicated where general anaesthesia may be required."	anaesthesia but, in addition to efficacy, they took into account the increased risks associated with peribulbar anaesthesia. The committee agreed that, in the absence of any identified benefits, the well-established risks of serious harm with peribulbar anaesthesia (even though these events may be rare) could not be justified. However, the committee agreed that peribulbar anaesthesia remained an option in situations where neither topical nor sub-Tenon's anaesthesia were appropriate alternatives.

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				In support of this change we would refer the committee to the current American Academy of Ophthalmologists 2016 Preferred Practice Pattern stating: " In summary, given the lack of evidence for a single optimal anesthesia strategy for cataract surgery, the type of anesthesia management should be determined according to the patient's needs, the preference of the patient, the anesthesia professionals, and the surgeon. (I+, good quality, strong recommendation) " (Page 22)	
Plymouth Hospitals NHS Trust	Full	168 General	3808 General	I am not sure where is best to record this comment because it seems that the draft guideline altogether omitted to discuss how to prevent an important complication of cataract surgery namely "corneal oedema / striae / Descemet's folds" or "corneal decompensation" which occurs as frequently as in 1.4% of cases following surgery according to the 2016 National Ophthalmology Audit (more common than cystoid macular oedema, 1.3% which was discussed in detail in the guideline). I would have thought such an important and in many cases preventable complication with serious consequences on vision should have been discussed. Recommendations on how to evaluate/investigate the state of the endothelium, case selection and how to protect the endothelium including intraocular solutions, viscoelastics, and ultrasound power should have been discussed. Current American Academy of Ophthalmologists 2016 Preferred Practice Pattern states on page 34: "Improper instrument entry into the anterior chamber can lead to Descemet membrane tears or detachment. A small tear	Thank you for your comment. Unfortunately, the management of corneal oedema was not a topic included in the scope of this guideline, and therefore it was not possible to make recommendations in this area.

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				may require no attention, since such tears often spontaneously resolve. Larger tears can be repaired by repositioning and tamponading the flap of Descemet membrane with an air bubble. The corneal endothelium is susceptible to damage from any mechanical injury and from prolonged ultrasonic power. It can also be damaged by intraocular solutions that have a nonphysiologic osmolarity or pH, or by chemical insult from toxic contaminants or improperly formulated intraocular solutions and medications. Prolonged elevated IOP can lead to further endothelial decompensation and corneal edema. The surgeon should avoid working close to the cornea and orient the irrigation port away from the corneal endothelium. (III, good quality, strong recommendation) Replenishing dispersive OVD during prolonged phacoemulsification or in the presence of several smaller shards of brunescent cataract can also help protect the corneal endothelium."	
Rayner Intraocular Lenses Limited	Full	General	General	Rayner Intraocular Lenses Limited ('**Rayner**') is a UK based manufacturer of intraocular lenses and proprietary injection devices for use in cataract surgery. Rayner was the first manufacturer of intraocular lenses ('**IOLs**') and remains the only manufacturer that is based in the UK. In 2016, Rayner was a significant supplier of IOLs to NHS hospitals and Rayner sells its IOLs to more than 79 countries around the world. At present all IOLs manufactured by Rayner are 360° square-edged hydrophilic acrylic lenses. Rayner works closely alongside a number of NHS Trusts in the UK for the purposes of	Thank you for your comments. Individual comments have been responded to where they appear.

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				research and development of both existing and future products.	
Rayner Intraocular Lenses Limited	Full	97	2367 - 2377	Whilst Rayner appreciates that the RCTs reviewed by the committee have been selected using criteria designed to ensure robust and unbiased analysis, this has severely limited the breadth of evidence they have been able to assess. The RCT criteria in Section 8.1.2, 2367 to 2377 is highly restrictive and does not take into account the predominant characteristics of studies conducted in this area i.e. commercially sponsored, product specific, designed to analyse the efficacy of a given platform, and unlikely to be comparative as between materials. This is exhibited by the fact that each of the RCTs reviewed have low participant numbers (out of all 48 RCTs assessed only 2 had a population sample greater than 1,000; the hydrophobic vs hydrophilic assessing PCO outcomes studies had no more than 60) and the majority were over 7 years old. Section 3.5 acknowledges that non-comparative data may be considered where it is the only data available (Section 3.5. 374-375). As there is an absence of data comparing like-with-like i.e. square-edged hydrophobic acrylic vs square-edged hydrophilic acrylic, it is Rayner's contention that assessment of non-comparative studies is justified. Even though this would be justification enough, the relative superiority of hydrophilic vs hydrophobic with regard to glistenings (see below) means widening the	Thank you for your comment. The study type searched and included within each review question was determined and ratified by the guideline committee prior to its commencement. The committee agreed that RCTs represented the highest standard of evidence available, and that in situations where there were a sufficient number of RCTs available, it would not be appropriate to include lower quality study designs such as cohort or non-comparative studies, as this would increase the risk of bias in the conclusions being made. The committee agreed that in some areas of the guideline, some of the available RCTs were not 100% representative of current practice. However, they agreed they still represented the highest standard of evidence available, and if claims were to be made that new generations of technologies were to be more effective, it would be necessary to demonstrate these improvements by conducting randomised trials of these newer alternatives.

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				scope of evidence is further vindicated. Rayner would therefore contend that the committee's review of statistically significant, scientifically robust data analysing rates of PCO in square-edged hydrophilic acrylic lenses is not only desirable but necessary. As such the Mathew / Coombes 2010 study entitled "Reduction of Nd:YAG Capsulotomy Rates After Implantation of a Single-Piece Acrylic Hydrophilic Intraocular Lens with 360° Squared Optic Edge: 24 Month Results" (Ophthalmic Surgery, Lasers & Imaging, Vol 41, No.6 2010) should be eligible for consideration. This study was carried out over 24 months across three sites – Moorfields Eye Hospital, Broomfield Hospital and St Bartholomew's Hospital – and involved 3,461 implantations. The rate of Nd:YAG capsulotomy observed on this study after 24 months was extremely low at 1.7%.	
Rayner Intraocular Lenses Limited	Full	102	2438 - 2455	Rayner believes that the committee has erred in excluding square-edged hydrophilic acrylic lenses from their recommendation in Section 8.1.7 of the Guidelines 'Lens Design'. Although Section 8.1.5.5 refers to 3 RCTs on the comparative rates of posterior capsule opacification ('**PCO**') in hydrophobic acrylic vs hydrophilic acrylic IOLs, these differed significantly in terms of quality and were for a very low number of eyes. Rayner is highly concerned that while lens material and design have been reviewed, each has been done in isolation. Rayner's position is that such an approach is limited and fails to	Please note: the recommendations around lens design and material have been removed to allow for further consideration.

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				highlight the prevailing influence of design over material in relation to rates of PCO.	
Rayner Intraocular Lenses Limited	Full	102	2438 - 2455	Finally, one of the principal drawbacks for patients in the use of hydrophobic acrylic lenses is the heightened probability of 'glistenings', a disadvantage that is not present in the use of hydrophilic acrylic lenses (see e.g. Chang 2015 study, referenced at Section 8.1.3.1). Whilst the RCTs reviewed by the committee did not evidence the resultant impact of glistenings on patient quality of life post-surgery, they acknowledged that the studies reviewed were not designed to pick this up (Section 8.1.6, Trade-Off Between Benefits and Harms). Where two of the principal objectives of the Guidelines and its recommendations are quality of life and patient satisfaction (Section 8.1.2, 2363 – 2365), it should not be the case that a product that removes the risk of post-operative glistenings (i.e. square-edged hydrophilic acrylic IOLs) should be excluded from recommendation by the Guidelines. Further to this, there is clearly a surgical justification for the use of hydrophilic acrylic IOLs as on conservative estimates, the current share of the UK IOL market for hydrophilic IOLs is > 30%. Ultimately, surgeons should be able to consider and consult with their patients on the use of an IOL that has a lower risk of glistenings, without contravening the recommendations in the Guidelines.	Please note: the recommendations around lens design and material have been removed to allow for further consideration.

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Rayner Intraocular Lenses Limited	Full	106	2508 - 2510	Rayner's strong contention is that due to the equivalent (or even improved rates of PCO and the absence of glistenings, the committee's recommendation in Section 8.1.7 should be expanded to include 'square-edged hydrophilic acrylic lenses'.	Please note: the recommendations around lens design and material have been removed to allow for further consideration.
Royal College of Anaesthetists	Full	149	3476 - 87	Discussion of the risks and benefits of simultaneous bilateral surgery ignores the benefit of this approach for patients who need general anaesthesia for cataract surgery but who have medical comorbidities that make general anaesthesia higher risk or learning difficulties that present logistical problems. There is a cogent argument for simultaneous bilateral surgery in some of these patients.	Thank you for your comment. The committee agreed that this was a specific, identifiable group of people in whom bilateral simultaneous surgery may be appropriate, and have amended the recommendation to specifically mention this group of people.
Royal College of Anaesthetists	Full	157	3646	It is perhaps surprising to see that "The group also highlighted that some surgeons do not allow enough time for the anaesthetic to penetrate the muscle, thus believing it less effective for akinesia", given that local anaesthetics have their action by working on nerves, not muscles.	Thank you for your comment. This error in the text has been amended to refer to surgeons not allowing time for the anaesthetic to take effect.
Royal College of Anaesthetists	Full	162	3704	The committee "agreed that if sedation is given, then an anaesthetist has to be present throughout the procedure. This is due to the risk of patients 'waking up' during the operation and needing additional sedation/anaesthesia". This shows a lack of understanding not only of sedation but also of the role of the anaesthetist in monitoring high	Thank you for this comment, and this inaccurate sentence has been deleted. It has been replaced by a hopefully clearer statement that an anaesthetist needs to be present at these times in order to monitor the patient.

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				risk patients during surgery. It also suggests that the committee believes that the role of sedation in this situation is to render the patient almost unconscious rather than to provide anxiolysis and conscious sedation when possible. This belief is erroneous.	
Royal College of Anaesthetists	General	General	General	The Royal College of Anaesthetists (RCoA) welcomes the development of NICE guidance on the management of cataracts in adults. However, it is concerned that the key roles of anaesthetists and of anaesthetist-led pre-assessment services in the care of this patient population are under-recognised in the current version of the guidance. It is disappointing to note that the RCoA's Guidelines for the Provision of Anaesthetic Services (GPAS) chapter on ophthalmic anaesthesia (http://www.rcoa.ac.uk/system/files/GPAS-2017-13-OPHTHAL.pdf), itself developed and produced using a NICE-approved, objective process, is not used or referred to in the draft guidance. Further, the recognised guidance on the safe delivery of local anaesthesia for eye surgery produced by the RCoA and the Royal College of Ophthalmologists appears not to feature in the development of the draft NICE guidance (https://www.rcophth.ac.uk/wp-content/uploads/2014/12/2012-SCI-247-Local-Anaesthesia-in-Ophthalmic-Surgery-2012.pdf).	Thank you for your comment. The committee agreed that anaesthetists have an important role to play within the cataract pathway, and were aware of the guidance published by both the Royal College of Anaesthetists and the Royal College of Ophthalmologists. They agreed that there was already high awareness of these guidelines, and consequently that there was little need to make specific recommendations around these guidelines merely to raise awareness of them. However, the committee did agree it was appropriate to make a reference to these guidelines within the evidence to recommendations section of the anaesthesia chapter. Unfortunately, issues around the organisation of pre-assessment services for anaesthesia were not within the scope of this guideline, and therefore the committee were not able to make recommendations on this topic. The committee re-discussed the recommendations made around peribulbar anaesthesia, in light of the comments received. They agreed that, in the absence

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				Anaesthetist-led pre-assessment services are well established in peri-operative care, and have been shown to improve patient satisfaction and outcome while minimising same-day procedure cancellation and thereby increasing efficiency. They are of particular value in the peri-operative care of an elderly patient population with multiple comorbidities, and can support decision making and consent processes, while providing a platform for multidisciplinary management of complex cases. Planning anaesthetic strategies for cataract patients is useful in determining the degree of anaesthetic support needed for operating lists, thereby maximising usage of anaesthetic services. Pre-assessment also allows planning of pre-operative fasting and the management of peri-operative drug administration for the many patients who take multiple medications. The lack of mention of pre-assessment services and pre-operative fasting before sedation and general anaesthesia in the guidance document are significant omissions. There is no mention of a "Stop Before You Block" check before performing local anaesthetic blocks for eye surgery, in line with national recommendations (http://www.rcoa.ac.uk/standards-of-clinical-practice/wrong-site-block) and as endorsed by NHS Improvement's National Safety Standards for Invasive Procedures (NatSSIPs) (https://improvement.nhs.uk/resources/national-safety-standards-invasive-procedures/).	of any meaningful benefits noted for peribulbar anaesthesia compared to sub-Tenon's and topical anaesthesia, the risks of rare but serious harm with peribulbar anaesthesia could not be justified for routine use, and that it was appropriate to restrict its use to situations where sub-Tenon's and topical anaesthesia were not available options. The committee agreed there were situations where general anaesthesia would be necessary for cataract surgery, and that it would not be appropriate to deny people access to cataract surgery solely because they would need general anaesthesia. However, in the absence of any evidence which enabled them to recommend which people should receive general anaesthesia, they agreed it was appropriate not to make any recommendations on the topic, and leave it to the judgement of individual clinicians. The committee have now added a reference to general anaesthesia under the section on bilateral simultaneous cataract surgery, as they noted that for people who require general anaesthesia and in whom there may be risks of harm (e.g. people with cognitive impairment), bilateral simultaneous surgery provides the advantage of the person only needing to undergo general anaesthesia once.

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				Some of the expert anaesthetists who responded to the RCoA's requests for comments were insistent that many units provide safe and effective peribulbar blocks for cataract surgery, and that there exist certain clinical situations in which peribulbar block may be preferable to topical or sub-Tenon's block even in the absence of contra-indications to the latter. They were concerned that the NICE guidance in its current form would lead to a decrease in the use of this technique overall, a decrease in its use in clinical situations in which it may be of value, and a decrease in experience with its use, which may in turn lead to an increase in the incidence of complications associated with its occasional use. The RCoA is concerned that, as no mention is made of general anaesthesia in the short version of the guidance, those reading only this version or an Executive Summary derived from it, may erroneously conclude that there is no place for general anaesthesia in the management of adults undergoing cataract surgery. The full version mentions general anaesthesia for patients not amenable to surgery under local anaesthesia with or without sedation, and this should be noted in any short or executive version of the guidance published. A small subsection of patients, such as those with learning difficulties or early dementia, can only enjoy the benefit of cataract surgery with the availability of general anaesthesia, and it would be wrong to deny them surgery	

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				by not including mention of the provision of general anaesthesia in published guidance documents.	
Royal College of Anaesthetists	Short	3	11 - 27	Mention is made of a pre-operative outpatient visit at which patients are given information about the types of anaesthesia. This would be an excellent opportunity to underline the importance of an anaesthetist-led pre-assessment service for ophthalmic surgery that would allow the assessment of this complex patient population, the delivery of information about anaesthesia and sedation, and review of patients with needs that would lead them to need more than topical or sub-Tenon's anaesthesia. The theme of effective pre-assessment should pervade the main document.	Thank you for your comment. The only topics included around pre-operative assessment in the scope of this guideline were patient information, biometry and risk assessment, and therefore it was not possible to make recommendations outside of these areas.
Royal College of Anaesthetists	Short	6	21 – 26	It is difficult to argue against an insistence that only consultants should perform this sort of surgery. Indeed, it is standard practice in several Trusts in England.	Thank you for your comment. Whilst the committee appreciated the argument that only consultant grade surgeons should undertake this surgery, they agreed that in order to facilitate the training of the next generation of staff it was appropriate that surgeons in training be allowed to undertake these operations, but only under close supervision.
Royal College of Anaesthetists	Short	8	24 - 28	It is highly likely that only surgeons will have the knowledge and training to check and confirm these calculations but the guidance does not demand that two surgeons be available.	Thank you for your comment. This recommendation has now been amended to make clear that it does not require that two people check these calculations on the day itself, but rather that a check be made on the day to ensure that at least two people have previously checked these calculations.

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Royal College of General Practitioners	Short	General	General	The guideline is aimed mainly at secondary care health professionals. These draft guidelines are appropriate, balanced and in keeping with established good practice and good governance. The guidance closely mirrors the Royal College of Ophthalmologists guidance on cataract surgery. The committee at NICE have produced an excellent guideline.	Thank you for your comment and endorsement.
Royal College of General Practitioners	Short	General	General	Other considerations: 1. At referral, health professionals will be expected to provide patients with information on cataracts and cataract surgery. Also, at referral, health professionals need to discuss quality of life issues and patient's preferences. For GPs, this would mean a minor upgrading of knowledge. Or perhaps the provision of a handout with this information. We extensively covered this area as part of the RCGP Clinical Priority in Eye Health (2013-2016). **2.** Commissioners are not permitted to restrict referrals on the basis of visual acuity. This is clinically appropriate, and will do away with the arbitrary cut-offs that some CCGs currently have. For GPs who are also eye health commissioners in these areas, this may mean an increase in the cost to the CCG.	Thank you for your comments.

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Royal College of General Practitioners	Short	General	General	Conflict of Interest: Comments from chairman of the Macular Degeneration Guideline Committee at NICE. Chairman of the Prostate Cancer Guideline Committee at NICE.	Thank you for your comments.
Royal College of General Practitioners	Short	General	1.1.2	Almost all of this guideline addresses secondary care. This is almost the only section that relates to primary care. The recommendations in this section are mostly sensible. further comments: 1. While GPs do discuss risks & benefits with patients they refer for surgery, they don't have the amount of detailed knowledge that patients have every right to expect. Similarly likely recovery time. So while these items should be included under section 1.1.2, both should be repeated at preoperative assessment, and therefore also included under 1.1.3 2. In practice most cataracts are detected by opticians, who advise referral. Most GPs do the referral without seeing the patients. It would make sense for there to be a specific recommendation about ensuring that one or other has had this discussion prior to referral. In other words, GPs should satisfy themselves that the opticians have discussed risks & benefits, etc or	Thanks you for your comment. The committee agreed it was important for information to be offered to patients at multiple points in the pathway, and this is why recommendation 1.1.3 begins by stating that the topics listed in 1.1.2 should be reviewed and expanded on at this point, to ensure patients have all the necessary information to make informed decisions. The committee agreed that there were multiple different models for cataract surgery around the UK, and it was not possible to write recommendations specific to each pathway. Therefore they agreed the most important thing was that all relevant information was reviewed and repeated at the first appointment in specialist care (recommendation 1.1.3). This should ensure that all individuals, regardless of the route by which they are referred, should have all the relevant information at this stage to be able to decide whether to proceed to surgery.

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				invite patients to come and discuss with them before referral (some patients may decline in favour of going direct to ophthalmic surgeons, in which case the latter should go over the items under 1.1.2)	
Royal College of General Practitioners	Short	General	1.8	Two further comments here: 1. The short version lists the complications. In the longer version (section 13.1) there are estimates, based on moderate evidence, for each one. Why are the rates, with a caveat about the quality of evidence, not included in the short version? If, GPs tend only to go to the shorter version this would greatly help their consultations. 2. The main complication that GP met professionally is posterior capsular opacification. It doesn't get a mention here.	Thank you for your comments. The short version of the guideline only contains the recommendations made by the committee, and not the evidence base behind those recommendations. The management of posterior capsule opacification was not a topic included in the scope of this guideline, and therefore it was not possible to make any recommendations on this topic.
Royal National Institute of Blind People	Short	General	General	RNIB carried out a survey of 66 cataract patients recruited from RNIB's membership and beyond to inform the response to this Clinical Guideline draft to ensure patient voice and experience is represented in our response. The rapid survey was carried out in the consultation period to capture patient responses to the content of the draft guidance. Our findings from this survey will be referred to throughout where relevant. Bases vary and are provided.	Thank you for your comment and submission of your survey results.

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				Profile of respondents: • Respondents had either had surgery on one eye only (27 per cent), had surgery on one eye and were awaiting surgery on the second eye (9 per cent) or had already had surgery on both eyes (64 per cent). • 36 per cent of respondents were male and 53 per cent were female (the remaining 11 per cent declined to respond). • A third of respondents were aged 75-84, a following fifth were aged 65 to 74. • The majority of respondents were from England (74 per cent) and there was a good spread of respondents across the regions. 12 per cent of respondents were from Wales. • 68 per cent of respondents were living with another eye condition. • Most respondents had had surgery over five years ago (41 per cent), while 21 per cent had had surgery between 2 and 5 years ago.	
Royal National Institute of Blind People	Short	2-4	All	Literature confirms that information provided in formats appropriate to the individual as well as discussion are linked to positive patient outcomes (Smith and Ross, 2007). RNIB's survey shows us that patients would like more face to face discussion with healthcare professionals about their treatment. Discussions about treatment in	Thank you for your comment and support of the recommendations around patient information. The committee agree that the evidence demonstrates that people want information to be delivered face-to-face as well as in a written format.

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				sections 1.2.1, 1.3.11, 1.5.3, 1.6.4) incorporated within the guideline are welcomed	
Royal National Institute of Blind People	Short	2	9 - 15	RNIB supports the provision of information to patients in a format that is accessible to them. This is now a requirement covered by the NHS Accessible Information Standard (2016). **RNIB recommends this standard be included and highlighted in section 1.1.1 with particular note of the requirement to undertake a patient assessment to identify, capture and record the person's accessibility requirements.** **RNIB recommends that sections 6.4.2 and 6.4.3 of the Accessible Information Standard Implementation Guide be highlighted, with mention of the need to use plain language. This is particularly important for patients when talking about the risks of surgery covered in the draft guideline.**	Thank you for your comment and endorsement of the recommendations regarding patient information. The committee noted that it is a legal requirement for organisations providing NHS care to follow the NHS Accessible Information Standard, and therefore did not feel it was necessary to refer to a document that already has such legal status within a clinical guideline. NICE has produced a guideline on patients experience in adult NHS services, which contains recommendations on making information accessible to people's individual needs. This guideline contains a cross-reference to that source of information.
Royal National Institute of Blind People	Short	2	10 - 13	RNIB supports the provision of information to meet the patient's needs. Twenty four per cent of patients we surveyed' did not know that they could request information in an accessible format and 15 per cent noted that the information provided to them did not suit their needs. Accessible information must be offered to all patients to ensure equality of care.	Thank you for your comment and endorsement of recommendations regarding patient information. The Committee agree that making information accessible is a key part of the cataract pathway, and providers should be ensuring that the information they provide is appropriate to the individual's needs. NICE has produced a guideline on patients experience in adult NHS services, which contains

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				RNIB supports the NHS Accessible Information Standard which requires that patients are explicitly asked and made aware that information is available in an accessible format that meets their needs. RNIB recommends the following wording: **Information must meet the person's needs, for example, in an accessible format. Discuss with the person their needs and inform them of all formats available to them as outlined in the NHS Accessible Information Standard.**	recommendations on making information accessible to people's individual needs. This guideline contains a cross-reference to that source of information.
Royal National Institute of Blind People	Short	2 3	17 - 19 1 - 9	RNIB supports the provision of information outlined at the referral stage. The majority of patients we have surveyed reported that they received the information outlined in section 1.1.2 (between 64 and 78 per cent of patients for each category of information [base 60]) and that primary care professionals have taken time to provide this. However a minority of patients (up to 13 percent for each category of information [base 60]) did not receive all the information listed, confirming the need for inclusion in this guideline to ensure equality of care in terms of information provision. Patients surveyed note that they would like to have more information at the referral stage including information not detailed in section 1.1.2 (the referral stage). This included:	Thank you for your comment and endorsement of recommendations regarding patient information at the referral stage. The recommendations relating to patient information 'at referral for cataract surgery' have been updated to include information regarding long term outcomes, including the possible need to use spectacles for some visual tasks.

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				• More information about surgery including the potential impact on co-existing eye conditions • The need for glasses post surgery • Information about who to contact in case of problems (secondary care, sight loss charities/support groups) **RNIB recommends that the following additions are included in the information provided at the referral stage:** **Possible risks and benefits including the impact on pre-existing eye conditions** **The need for glasses post surgery** **Information about who to contact in case of problems (secondary care, sight loss charities/support groups**	
Royal National Institute of Blind People	Short	3	11 - 27	RNIB supports the provision of information to patients before cataract surgery as outlined in section 1.1.3. The majority of patients we spoke to received the information outlined in this section (between 63 and 81 per cent for each information category [base 60]) apart from line 13 and 14 explored below. However a minority of patients (between 5 and11 per cent for each information category [base 60]) did not have this information provided noting	Thank you for your comment and endorsement of recommendations regarding patient information. Whilst we understand the need for people to be as fully informed as possible the Committee determined that additional information regarding who to contact if they have additional concerns was not as important as some of the other issues identified in the recommendations, and did not merit being specifically

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				that they either didn't have enough information or would have liked more information about the following: • why the procedure was needed • risks involved (including if they had a pre-existing eye condition) • more information about the effect of anaesthetic • advantages and disadvantages of different lenses. This confirms the need for the inclusion of lines 11-17. This will ensure all patients receive equality of care in terms of information. RNIB and Royal College of Ophthalmologists regularly update a joint 'Understanding Series' entitled 'Understanding Cataracts' which covers information on treatment, pre-surgery assessments, cataract surgery, what happens after the operation, post-operative medication and instructions, permissible activities following surgery, arrangements for handling urgent enquiries from patients and a discharge summary. This series is available in CD, large print, Braille and online at http://www.rnib.org.uk/eye-health-eye-conditions-z-eye-conditions/cataracts **RNIB recommends that this series is included in the information to be made available to patients before surgery.** Patients want to know who to contact if they have additional concerns about their cataracts and surgery.	mentioned in the recommendations for the preoperative outpatient appointment. Upon publication, the NICE website related to this guideline will contain a link to sight loss organisations for people to access.

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				Additionally patients expressed that they would like information on how to manage feeling anxious about their surgery. **RNIB recommends that patients be offered information about sight loss organisations and, if available, the contact details of the Eye Clinic Liaison Officer at pre-operative stage.**	
			11 - 12	A significant number of patients are not receiving information about the refractive implications of different types of lenses. A high percentage (40 percent [base 60]) of patients we spoke to said that they did not receive this information before cataract surgery. Some patients specifically stated that they would have liked this information to be made available to them before surgery. Some patients also wanted to know if they would need glasses. This further confirms the need for the inclusion of information about the refractive implications of different lenses. **RNIB recommends that the need for glasses post surgery is also specifically included in this information. The following wording is suggested:** **The refractive implications of different intraocular lenses including the need for glasses post surgery.**	
			13 - 14	This point should also be reiterated in section 1.5.3	

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			16 - 18	**RNIB recommends** that any explanation around risk offered to patients be given in plain language as per the Accessible Information Standard Implementation Guidance sections 6.4.2 and 6.4.3. A minority of patients we spoke to (14 per cent [base 59]) reported that the risks of surgery were not explained to them in a way that they could understand. Patients must clearly understand the risks of surgery outlined by a clinician as per the drafted guidance (lines 16-18).	
Royal National Institute	Short	3	29 – 30	RNIB supports the provision of information to patients on the day of cataract surgery as outlined in section 1.1.4. The majority of patients we surveyed received the information outlined (60 – 83 percent of patients for each	Thank you for your comment and endorsement of recommendations regarding patient information.

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of Blind People		4	1 - 2	information category [base 59]). Patients who felt that they were able to consent to surgery on the basis of information provided to them (83 per cent of patients surveyed [base 59]) said that the risks were explained to them, their questions were answered, the procedure was explained and they knew what to expect. However a minority of patients reported that they were not told about their position on the list (25 per cent [base 59]) and what to expect during and after surgery (8 per cent [base 59]). 10 percent of patients [base 59] reported that the lack of information about what to expect during the surgical procedure meant they felt they didn't really have enough information to consent to surgery (although they did consent). This confirms the need for the inclusion of section 1.1.4. This will ensure all patients are fully enabled to consent to surgery and receive equality of care in terms of information. Existing research shows that patients want to be informed if their surgery will be performed by a trainee and would like to know the name of the clinician performing the operation. The majority of patients are happy for their operation to be performed by a trainee, but they would also like to be informed (Moody et al 2008). **RNIB recommends that the follow information is additionally given to patients on the day of surgery:**	Whilst we understand some people may want to know if the surgeon operating on them is a trainee, the committee decided that this was not as important as some of the other factors listed here, and did not warrant a specific mention within the recommendation.

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				- **Who will perform the surgery and if they are a trainee.**	
Royal National Institute of Blind People	Short	4	12 - 21	RNIB supports the provision of information for patients at the first appointment after cataract surgery outlined in section 1.1.6. The majority of patients we spoke to reported that they had been given the information outlined (73 – 86 percent of patients we spoke to apart from information about second eye surgery (40 per cent) which would not be relevant to all patients [base 57]). However a minority of patients (5 to 13 percent of patient's surveyed [base 57]) did not receive the information outlined and stated that this information would have been helpful to them. Additionally when asked what further information would have been helpful patients noted that they would like further information about the recovery period at this appointment in the pathway. **RNIB recommends that information on recovery be included at the first appointment after surgery.**	Thank you for your comment and endorsement of recommendations regarding patient information. The Committee determined that postoperative recovery was most appropriately covered within the recommendations in the 'on the day of cataract surgery' section and that by the time people attended the first appointment after surgery the majority would have already recovered sufficiently.
Royal National Institute of Blind People	Short	4	3 - 11	RNIB supports the provision of information for patients after cataract surgery as outlined in section 1.1.5. The majority of patients we spoke to received the information outlined (60-83 per cent of patients we spoke to for each information category [base 59]). However a minority of patients (3 to 10 percent of patients [base 59]) were not given the information outlined in lines	Thank you for your comment and endorsement of recommendations regarding patient information.

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				4-11 and highlighted that this information would have been helpful to them at this point in the pathway. This confirms the need for the inclusion of section 1.1.5. This will ensure all patients receive equality of care in terms of information.	
Royal National Institute of Blind People	Short	4 5	23 - 28 1 - 4	RNIB welcomes discussion with patients at the referral stage of the pathway. Patients surveyed report that they want and appreciate time at the referral stage for discussion and to ask questions about their condition and the risks and benefits of surgery.	Thank you for your comment and endorsement of recommendations regarding patient information.
Royal National Institute of Blind People	Short	5	4	**RNIB supports 1.2.2 not to restrict access to cataract surgery on the basis of visual acuity.** Visual acuity has been routinely used to measure visual function and has been used for eligibility criteria in many CCG treatment policies. This has denied surgery to patients whose day to day lives are being impacted by their condition. Visual acuity is not a reasonable and efficient way to measure the problems caused by cataracts. RNIB has advocated for patients who have been denied surgery on the basis of visual acuity alone, in these cases the individual's quality of life had been significantly negatively impacted. By removing the restriction RNIB believe that surgery will be available to those that are unable to manage their day to day living as a result of their cataracts.	Thank you for your comment and endorsement of recommendations regarding access to cataract surgery.

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				Additionally removing restrictions based on visual acuity is in line with the Commissioning Guidance set out by the Royal College of Ophthalmology. RNIB believe that the removal of restriction on this basis is essential for equity of care and avoid a 'post-code lottery' of eligibility and care.	
Royal National Institute of Blind People	Short	6	1 - 4	**1.3.6 RNIB recommends** that any advice offered to patients be given in plain language as per the Accessible Information Standard Implementation Guidance sections 6.4.2 and 6.4.3. Patients must clearly understand the risks of surgery being outlined in 1.3.6.	Thank you for your comment. The Committee agreed that all information provided to patients at any stage of the pathway must always be in an accessible format.
Royal National Institute of Blind People	Short	6	27 - 29	**1.3.13 RNIB recommends** that explanation of risk relating to developing a dense cataract and risks of complications during surgery are given to patients in plain language as per the NHS Accessible Information Standard Implementation Guidance sections 6.4.2 and 6.4.3	Thank you for your comment. The Committee agreed that all information provided to patients at any stage of the pathway must always be in an accessible format.
Royal National Institute of Blind People	Short	6	19 - 20	**1.3.11 RNIB recommends** that explanation of risk must be given to patients must be conducted in plain language as per the Accessible Information Standard Implementation Guidance sections 6.4.2 and 6.4.3.	Thank you for your comment. The Committee agreed that all information provided to patients at any stage of the pathway must always be in an accessible format.
Royal National Institute	Short	8	2 - 4	**1.5.3 RNIB welcomes the opportunity for patients to discuss treatment options and recommends** that discussions relating to the refractive implications of different intraocular lenses are conducted in plain	Thank you for your comment. The Committee agreed that all information provided to patients at any stage of the pathway must always be in an accessible format.

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of Blind People				language as per the NHS Accessible information Standard Implementation Guidance sections 6.4.2 and 6.4.3.	
Royal National Institute of Blind People	Short	10	1 - 3	RNIB welcomes section 1.6.2 to offer second-eye cataract surgery using the same criteria as for first eye surgery. Many Clinical Commissioning Groups across England currently restrict second eye surgery through stricter criteria such as a person having poorer visual acuity in the second eye than was required to be eligible for first eye surgery. Additionally eligibility for second eye surgery in some Clinical Commissioning Group policies is based on the person being a driver or non-driver. These arbitrary restrictions deny patients access to surgery they would benefit from. As with the first eye, surgery should be available to those that are unable to manage their day to day living as a result of their cataracts.	Thank you for your comment and support of the recommendations regarding second eye cataract surgery.
Royal National Institute of Blind People	Short	10	4 - 5	RNIB supports 1.6.3 the consideration of bilateral simultaneous cataract surgery for people who are low risk of complications during and after surgery. Similar surgical and patient satisfaction outcomes can be achieved through bilateral surgery (Leivo et al. Simultaneous bilateral cataract surgery: economic analysis (2011)).	Thank you for your comment and support of the recommendations regarding bilateral cataract surgery.

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Royal National Institute of Blind People	Short	12	7 - 17	RNIB supports the inclusion of section 1.9.1 the collection of data in relation to cataract operations such as the Cataract Dataset for National Audit. This audit is key to driving up standards of clinical practice which will benefit patients. RNIB believe that this recommendation should outline how commissioners can commission services in a way that ensures audit data can be collected. **RNIB recommend:** **Including quality assurance for the well-being of patients through participation in the national cataract audit as a condition of contract for all providers.**	Thank you for your comment and support of the recommendations regarding cataract surgery data collection. Unfortunately, issues around contracts and service provision are not within the scope of the guideline, and therefore it was not possible to make recommendations on these topics.
Royal National Institute of Blind People	Short	12	18 - 19	RNIB support the collection of patient visual function and quality of life data for entry into an electronic dataset. 39 per cent of patients told us that they had not been given the opportunity to feedback their level of satisfaction regarding their treatment. Collecting patient outcomes would capture both positive experiences (that some expressed) and the negative which would help to improve services. This should not be an optional extra. **RNIB recommend that the wording of lines 18 and 19 should change to:** **Collect patient visual function and quality of life data for entry into an electronic dataset.**	Thank you for your comment and support of the recommendations regarding cataract surgery data collection. The committee agreed that at present, not all providers had systems in place to appropriately store patient outcome data collected, and that it would not be appropriate to collect such data unless it were going to be used going forwards. However, the committee hoped that it would not be too long before the collection of this data became routine practice in all centres undertaking cataract surgery.

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Royal Pharmaceutical Society	General	General	General	The Royal Pharmaceutical Society would like to highlight the role of the pharmacist in the management of cataracts in adults. Community pharmacists are ideally placed as the first point of contact to the public to offer advice and information on managing cataracts. This includes supply of information leaflets and signposting to resources. They can offer advice to patients, their families and carers. They can offer advice and information as part of a consultation, Medicines Use Review, or advice when selling over-the-counter products. **1. Referral for diagnosis** Pharmacists are in a position to refer patients presenting to the pharmacy with possible symptoms of cataracts (such as reduction in vision, blurred vision, halos around lights etc.) to their GP or optometrist. **2. Advice before surgery** Advice on what to expect from the surgery and medicines for use after the surgery. Advice on any other medicines they are already taking which may increase the risk of surgery such as anticoagulants. **3. Advice after surgery** Can advise on use of medicines after surgery e.g. eye drops and pain management.	Thank you for your comment. Unfortunately, the role of pharmacists in the management of cataracts was outside the scope of the guideline, and therefore it was not possible to make recommendation on this topic.

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				If have symptoms after surgery which indicate complications such as vision changes, pharmacists are in a position to refer patients promptly to specialist ophthalmology services **Lifestyle advice to reduce risk of developing age related cataracts:** Lifestyle factors such as tobacco smoking and high alcohol intake are associated with an increased risk of developing age related cataracts. Pharmacists routinely offer patients lifestyle advice to promote healthy living and smoking cessation services.	
SeeAbility	Full	General	General	**Section on people with learning disability or cognitive impairment required** SeeAbility is a member of Vision 2020 UK and we endorse and support the response being submitted by Vision 2020 UK. We hope that our additional observations are of interest too SeeAbility considers that the full guideline could benefit from a section which references information, advice and research on the the approach to be taken with patients with a learning disability or cognitive impairment. In particular we have considered the full clinical guideline for areas where there may be a risk of people with learning	Thank you for your comment. The committee agrees with the importance of ensuring equitable access to cataract surgery for people with learning disabilities or cognitive impairment. They noted that no specific evidence was identified during the development of the guideline which would enable specific recommendations to be made about how care should be organised differently. However, they agreed that the duty to adapt care appropriately for people with learning disabilities or cognitive impairment was incumbent on all NHS professionals at all stages of the pathway, and that this duty was not unique to cataract surgery. The committee agreed that the issues raised here would apply across a whole range of care within the NHS, and therefore

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				disabilities not accessing the cataract surgery they need or aftercare. The guideline tends to rely on patients to self report and this is not always going to be the case for patients with learning disabilities. Unfortunately we see too many people, often with their whole lives ahead of them in their 20s or 30s, who are struggling to get the surgery they need because of their learning disability. As time goes on and delays occur this has led to the greater difficulties in operation due to the dense nature of the cataract. Sometimes referrals are made to paediatric ophthalmology because it is felt their skill set is better suited to the care of a vulnerable adult. Sometimes the process of agreeing surgery is undermined by social care professionals refusing to fund the post operative recovery the person needs with packages of care (eg. a person to be there to ensure the person does not rub or poke their eyes) while in hospital or afterwards in the community. Clearly there is a need for a better approach and this is something the clinical guideline could support. Obviously and most importantly active case finding is needed so that people get referred for surgery, but once referred we know these delays occur because many experience barriers including assumptions about the value to the person from surgical intervention or compliance with aftercare. If there was a particular section on learning disability the clinical guideline could	represented a broader structural issue within the health service, and not one that could be addressed solely within the cataract pathway.

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				reference the support of learning disability healthcare professionals, such as the involvement of an Acute Liaison Learning Disability Nurse. In the vast majority of cases with the right support surgical interventions can be hugely successful and lifechanging. However, because the person might not be able to self report – the impact is not fully recognised and research into this field often neglects this group. **Approach and reasonable adjustments** The Management of Visual Problems in adult patients who have learning disabilities is also the subject of a Royal College of Ophthalmologist guideline. See: https://www.rcophth.ac.uk/wp-content/uploads/2014/12/2011_PROF_128_The-management-of-visual-problems-in-people-with-learning-disabilities.pdf We draw attention to this document as it outlines the approach to be taken with people with learning disabilities including the use of best interest meetings and ensuring that support plans are in place so that post operative recovery is possible. We are surprised to see on page 30 of the full guideline that 'there is little evidence to support specific interventions to improve patient centred care in cataract	

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				surgery." The following research advocates a multidisciplinary approach and early support planning to achieve outcomes for these patients - see http://www.magonlinelibrary.com/doi/abs/10.12968/ijop.2014.5.6.212 We contributed to the initial scoping consultation on the guideline and yet there is very little mention of learning disability within the full guideline, and the focus where it does consider cognitive impairment is on those with dementia eg. Anaesthesia.	
SeeAbility	Full	29	General	**Research recommendations** Adults with learning disabilities are 10 times more likely to have serious sight problems than the general population (see research commissioned by RNIB and SeeAbility http://www.rnib.org.uk/knowledge-and-research-hub/research-reports/prevention-sight-loss/prevalence-VI-learning-disabilities).) Cataracts are one of the most common reversible causes of visual loss in patients with a learning disability (for example see: http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1857461/. However because people with learning disabilities are sometimes unable to self report outcomes or those outcomes do not 'fit' standard measures such as being able to return to driving, or work, the benefits of surgery	Thank you for your comment. We agree that health related quality of life measurements should be undertaken as part of any research in this field. Publication of new and validated utility tools to measure these would be valuable in the future development of the evidence base. The committee agreed that it was important to ensure that newly developed measures were also relevant and applicable to people with learning disabilities (and cognitive impairment), and therefore have agreed to modify these research recommendations along the lines proposed. They have therefore been modified to make a specific comment about the importance of developing quality of life measures (reported by either the person themselves or their carers) for people with learning disabilities (or cognitive impairment).

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				for this group has often been neglected. Because 'hard to reach' groups are often overlooked in research is the 'double whammy' of not having evidence based research which would allow NICE to recommend approaches to be taken. We are left having to reference our own knowledge and qualitative evidence. This is why we believe that the research recommendations 1 and 2 which looks at QOL measures should include a particular reference to supporting research into the outcomes for this particular group. A visual function tool has been developed by the Department of Ophthalmology, Bradford Teaching Hospitals NHS Foundation Trust and is due for publication, but we also know that more focus is needed on the social care outcomes and carer reported quality of life, to demonstrate	
SeeAbility	Short	2	11	**Information** Please reference the NHS Accessible Information Standard which all NHS and care organisations are legally obliged to follow https://www.england.nhs.uk/ourwork/accessibleinfo/ Prior to the NHS Accessible Information Standard, but also of importance now it has been introduced is ensuring people with learning disabiltiies have information in Easy Read.	Thank you for your comment. The committee noted that it is a legal requirement for organisations providing NHS care to follow the NHS Accessible Information Standard, and therefore did not feel it was necessary to refer to a document that already has such legal status within a clinical guideline. NICE has produced a guideline on patients experience in adult NHS services, which contains recommendations on making information accessible to

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				For many years we have developed a number of resources on helping someone with learning disabilities understand more about cataract and prepare for eye surgery including an Easy Read Eye Surgery Support Plan, which has been endorsed by Moorfields Hospital. For more information see: https://www.seeability.org/eye-surgery	people's individual needs. This guideline contains a cross-reference to that source of information.
The Clinical Council for Eye Health Commissioning	Full	General	General	The Clinical Council for Eye Health Commissioning (CCEHC) would like to thank NICE for this clinical guideline on cataract. The guidance is all very sensible and sets out what should be done clinically. We would like to make some comments about: 1. the decision to refer a person with a cataract for surgery 2. the postoperative assessment 3. the lack of visual and refractive outcomes after a cataract surgery	Thank you for your comments and recognition of the value of this guidance. Individual comments have been responded to where they appear.
The Clinical Council for Eye Health	Full	30 - 54	768 - 1403	The initial assessment before referring a person with a cataract for surgery is an essential part of cataract care. As mentioned in The Royal College of Ophthalmologists' Commissioning Guide on Cataract Surgery (https://www.rcophth.ac.uk/wp-	Thank you for your comment. The Committee agreed that initial assessment is an important part of the cataract pathway, and therefore made recommendations on information that should be provided to people as part of those assessments. However, it is not within the scope of this guideline to

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Commissioning				content/uploads/2015/03/Commissioning-Guide-Cataract-Surgery-Final-February-2015.pdf), most referrals for consideration for cataract surgery are made following assessment by a community optometrist. We believe that the recommendations about the decision to refer a person with a cataract for surgery can only be implemented by commissioning the service separately from General Ophthalmic Services (GOS), as the GOS contract relates solely to the provision of a NHS sight test. The pre-referral should, therefore, be commissioned as part of extended primary eye care service.	make recommendations on how services should be commissioned or funded.
The Clinical Council for Eye Health Commissioning	Full	35 - 36	912 - 959	The Royal College of Ophthalmologists' Commissioning Guide on Cataract Surgery sets out visual and refractive outcomes that should be made available to commissioners (See section 13 page 10: https://www.rcophth.ac.uk/wp-content/uploads/2015/03/Commissioning-Guide-Cataract-Surgery-Final-February-2015.pdf). These outcomes would allow commissioners and trusts to demonstrate the benefits of cataract surgery, in addition to the risks (quantified by the frequency of complications that are covered in depth in the Guideline). These positive visual and refractive outcomes should also be specified for the discussion with patients, and in the	Thank you for your comment. The committee agreed it would not be appropriate for the guideline to refer to a specific version of the document, as it is subject to potential future update by the Royal College. They also agreed that this was a document that service providers were likely to be aware of, and therefore there was not a need to make specific knowledge of it within the guideline.

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				information materials; along with the complications, given that the effectiveness of surgery is implied. We suggest including The Royal College of Ophthalmologists' Commissioning Guide on Cataract Surgery recommended outcome measures into the NICE Guideline so the two documents are aligned.	
The Clinical Council for Eye Health Commissioning	Full	211	4670 - 4692	Optometrists can deliver postoperative assessment in the community for low risk patients. This has been recommended by NHS Improvement ("Helping NHS providers improve productivity in elective care": https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/466895/Elective_care_main_document_final.pdf), and by the Clinical Council for Eye Health Commissioning Frameworks ("Primary eye care framework for first contact care": https://www.college-optometrists.org/the-college/ccehc/delivery-models.html) to release capacity within the hospital eye service. The cataract postoperative assessment is outside the GOS contract and should be commissioned as part of an extended primary eye care service. Greater commissioning at scale of this assessment would provide the necessary post-operative visual acuity data required for the National Ophthalmology Database Audit on Cataract Surgery (https://www.nodaudit.org.uk/)	Thank you for your comment. The role of optometrists in delivering postoperative assessment in the community was outside the scope of this guideline, and therefore it was not possible to make recommendations in this area.

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The College of Optometrists	Full	General	General	The College of Optometrist would like to thank NICE for this clinical guideline on cataract. The guidance is all very sensible and sets out what should be done clinically. We would like to make some comments about: 4. the decision to refer a person with a cataract for surgery 5. the postoperative assessment 6. the lack of visual and refractive outcomes after a cataract surgery 7. the need to identify who is accountable for patients if they have been discharged for follow-up cataract surgery in the community	Thank you for your comments and recognition of the value of this guidance. Your specific comments made have been responded to individually where they appear.
The College of Optometrists	Full	30 - 54	768 - 1403	The initial assessment before referring a person with a cataract for surgery is an essential part of cataract care. As mentioned in the Royal College of Ophthalmologists' Commissioning Guide: Cataract Surgery (https://www.rcophth.ac.uk/wp-content/uploads/2015/03/Commissioning-Guide-Cataract-Surgery-Final-February-2015.pdf), most referrals for consideration for cataract surgery are made following assessment by a community optometrist. We believe that the recommendations about the decision to refer a person with a cataract for surgery can only be implemented by commissioning the service separately	Thank you for your comment. The Committee agreed that initial assessment is an important part of the cataract pathway, and therefore made recommendations on information that should be provided to people as part of those assessments. However, it is not within the scope of this guideline to make recommendations on how services should be commissioned or funded.

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				from General Ophthalmic Services (GOS), as the GOS contract relates only to the sight test. The pre-referral should, therefore, be commissioned as an extended community service.	
The College of Optometrists	Full	35 - 36	912 - 959	The Royal College of Ophthalmologists' Commissioning Guide: Cataract Surgery sets out visual and refractive outcomes that should be made available to commissioners (See section 13 page 10). These outcomes would allow commissioners and trusts to demonstrate the benefits of cataract surgery. Focusing on quality outcomes / benefits would also help to prioritise access to surgery according to the patients' clinical needs. These positive visual and refractive outcomes should also be specified for the discussion with patients, and in the information materials; along with the complications, given that the effectiveness of surgery is implied. We suggest including the Royal College of Ophthalmologists' Commissioning Guide: Cataract Surgery recommended outcome measures into the guideline so the two documents are aligned.	Thank you for your comment. The committee agreed it would not be appropriate for the guideline to refer to a specific version of the document, as it is subject to potential future update by the Royal College. They also agreed that this was a document that service providers were likely to be aware of, and therefore there was not a need to make specific knowledge of it within the guideline.

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The College of Optometrists	Full	211	4670 - 4692	Optometrists can deliver postoperative assessment in the community for low risk patients – again this would have to be commissioned as an extended community service. See The Clinical Council for Eye health Commissioning frameworks (https://www.college-optometrists.org/the-college/ccehc/delivery-models.html). There is also scope for optometrists to take some of the burden from ophthalmologists within the hospital for patients with more complex needs – see the Royal College of Ophthalmologists' Cataract Common Clinical Competency Framework (https://www.rcophth.ac.uk/wp-content/uploads/2017/01/CCCF-Cataract.pdf) which sets out the competencies needed for various levels of care. The postoperative assessment – which is outside the GOS contract – should be commissioned as an extended community service.	Thank you for your comment. The role of optometrists in delivering postoperative assessment in the community was outside the scope of this guideline, and therefore it was not possible to make recommendations in this area.
The College of Optometrists	Short	12	8 - 17	We believe the guideline should include recommendations on clinical governance and accountability. Who would be accountable for patients if they have been discharged for follow-up cataract surgery in the community?	Thank you for your comment. Unfortunately, issues around clinical governance and accountability were outside the scope of this guideline, and therefore it was not possible to make recommendations on this topic.
The Royal College	Full	24	536	This recommendation should refer to the need to the Hill RBF http://rbfcalculator.com/ method as a self-validating method for IOL power selection and what to use if the	Thank you for your comment. The Committee was aware of the Hill RBF method, and despite efforts to identify any published evidence evaluating its use there

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of Ophthalmologists				patient has had previous refractive surgery (eg American Society of Cataract and Refractive Surgery website calculator http://iolcalc.ascrs.org/, 'No-history method of intraocular lens power calculation for cataract surgery after myopic laser in situ keratomileusis etc. H. John Shammas, MD and Maya C. Shammas MD, Journal of Cataract and Refractive Surgery, 2007 Volume 33, Issue 1, Pages 31–36 http://www.jcrsjournal.org/article/S0886-3350(06)01221-1/abstract	does not appear to be any published evidence validating this method. Therefore it was not possible for any recommendations to be made for its use. The Committee did look at the evidence for the most effective formulas in eyes after previous refractive surgery. However, they agreed that the evidence was not of sufficient quality (in particular the studies in this area had very small sample sizes) to be able to make specific recommendations about the most appropriate formulas to use.
The Royal College of Ophthalmologists	Full	25	562	This statement should be tied to the risk scoring and appropriate level/experience of surgeon should be ensured to carry out surgery in such cases. Day AC, Donachie PH, Sparrow JM, Johnston RL. The Royal College of Ophthalmologists' National Ophthalmology Database study of cataract surgery: report 1, visual outcomes and complications. Eye (Lond). 2015 Apr;29(4):552-60. doi: 10.1038/eye.2015.3. Epub 2015 Feb 13. http://www.nature.com/eye/journal/v29/n4/full/eye20153a.html	Thank you for your comment. The committee agreed that risk stratification was important, and made a separate recommendation to consider the use of validated risks stratification algorithms. However, in the absence of evidence enabling them to make specific recommendations about who should perform operations at specific levels of risk, they agreed that a recommendation about appropriate supervision of surgeons in training when undertaking higher risks procedures was appropriate.
The Royal College of	Full	25	571	Square edged lenses may be associated with negative dysphotopsia and spherical lens models with spherical aberration. This should be mentioned. Issues with Silicone lenses may be present if the eye has or is likely to be filled with silicone oil.	Please note: the recommendations around lens design and material have been removed to allow for further consideration.

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Ophthalmologists					
The Royal College of Ophthalmologists	Full	25	574	This is too strong a statement regarding the routine use of blue-light filtering lenses. Many units use them routinely on the basis that there is very strong evidence of blue light damage to the retina and although there is not yet evidence of prevention of AMD with blue-light filtering lenses, clinical choice should help to guide this decision especially in patients with a family or history of macular problems. Some units have contracts in place which save significant money using such lenses and undoing this nationally would **cost very large amounts of money** for no sustainable reason. There is good published evidence that the blue-light filtering lenses do not disturb circadian rhythm cycles or sleep patterns, and they have been in routine use for many years.	Please note: the recommendations around lens design and material have been removed to allow for further consideration.
The Royal College of Ophthalmologists	Full	25	576	This is too strong a statement regarding the use of multifocal lenses. Prepresbyopic adults (and some children) benefit from these lenses if only one eye is affected particularly (current on-going trial in Oxford 'Binocular Vision in Monocular Pseudophakia (BVMP)' https://clinicaltrials.gov/ct2/show/NCT01872000?cond=Cataract&cntry1=EU%3AGB&draw=1&rank=6) and some personal experience over many years of practice) described by cataract surgeons. For patients, the cost benefit analysis of multifocal may show significant savings over years of post-operative life.	Thank you for your comment. The committee agreed that there are established additional costs associated with multifocal lenses (both the costs of the lenses themselves, and additional pathway costs). The clinical evidence does demonstrate some benefits with multifocal lenses (e.g. increased spectacle independence) but also some harms such as an increase in glare and halos. In the absence of robust evidence on outcomes, such as quality of life, to enable the trade-offs between these benefits and harms to be quantified, the committee agreed that the current

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				Some professional groups may also find them more convenient having considered the relative risks and benefits. Tens of thousands have been implanted in the UK (especially in private patients) and advice should have been sought regarding outcomes from involved surgeons and patients. They are certainly not suitable for all patients but should be able to be discussed and considered for particular patient groups.	evidence base did not support multifocal lenses as being a cost-effective use of NHS resources. Thank you for informing us about this ongoing trial. We have passed the reference on to our surveillance team, who make recommendations on when sufficient new evidence has been published that the recommendations included in a guideline need to be reviewed and possibly updated.
The Royal College of Ophthalmologists	Full	26	595	There is a tendency for some trusts to insist that the IOL strength is hand-written on the white-board in theatre for each patient as their operation is done. This may lead to transcription errors and should be avoided. Only printed data should be used wherever possible.	Thank you for your comment and support of using printed biometry data. It is hoped that the recommendations in this guideline are adopted by all NHS Trusts.
The Royal College of Ophthalmologists	Full	26	603	Where electronic notes are used it may not be possible to print out biometry results but they are available on screen in theatre. Provision should be made to allow for this rather than insisting that a printed version is available.	Thank you for your comment. The recommendation has now been edited to allow provision for biometry results to be viewed electronically.
The Royal College of Ophthalmologists	Full	27	653	If bilateral simultaneous surgery is routinely offered to all eligible patients, there will only be half the number of patients (not eyes) operated on. Each will get more benefit assuming no complications, but only half the number of patients will be able to get an operation. This will have significant effects on waiting times for each individual to get at least one operation. Patient choice should also be offered. It should not be a surgeon's	Thank you for your comment. The recommendation regarding bilateral surgery is a 'consider' recommendation for a particular group of people i.e. people at low risk of ocular complications during and after surgery and those who need general anaesthesia. As such, it is not envisaged to be routinely offered to all people having cataract surgery, and would therefore be

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				choice to carry out bilateral simultaneous procedures but a combined patient/surgeon choice.	likely to have only a minor impact on patient throughput. The committee agreed that discussions regarding the potential benefits and harms of bilateral surgery between people and surgeons is a particularly important point, and a recommendation to this effect is included within the guideline.
The Royal College of Ophthalmologists	Full	27	673	The use of hyaluronidase should not be recommended. There is good evidence that it does not help significantly, is associated with significant allergy/sensitivity and is an unnecessary additional risk/cost. (Reference?) If trying to stop eye movements a GA is the only sure way to do this. Using increased amounts of local anaesthesia and or hyaluronidase are not reliable or repeatable methods of being sure the eye will not move.	Thank you for your comment. The committee noted there were benefits identified in the evidence base for hyaluronidase in terms of improving eye akinesia, together with a very low incidence rate of complications. However, the committee have retained the recommendation at the 'consider' level, both because of the limited size of that evidence base, and the known concerns about its use, such as those stated.
The Royal College of Ophthalmologists	Full	27	677	There needs to be more complete guidance for the use of triamcinolone to visualize vitreous in the anterior segment after PC rupture/vitreous loss. There is currently no other way of doing this and if it is not used there will be many more complications arising from inadequate removal of vitreous from the anterior segment. Notes should be made of the methods recommended for removing lens fragments from the posterior chamber (not using the phaco probe and being sure to use a vitreous cutter via a 3port approach within 5 days of the initial operation to remove cataract.	Thank you for your comment. Unfortunately, no evidence eligible for inclusion in the review was found on the use of triamcinolone as an intervention to reduce the impact of perioperative posterior capsule rupture. Therefore, the Committee agreed that they were unable to make more specific recommendations than those currently presented in the guideline.

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The Royal College of Ophthalmologists	Full	28	684	Capsule tension rings **should** be used if the capsular bag is particularly large or floppy. This significantly reduced the risk of PC rupture. Their use in pseudoexfoliation is at the very least controversial as if there is a progressive zonulopathy such as in pseudoexfoliation, the presence of a ring and an implant in the capsular bag will add to the risk of the zonules disinserting later and the lens/bag complex dropping into the back of the eye. A better way to stabilize the capsular back during surgery where there is zonular laxity is to use iris hooks as capsule anchors and to place the IOL in the ciliary sulcus rather than in the capsular bag. Capsular tension rings should be used in cases of sectoral zonular dehiscence such as congenital colobomatous lens change or after trauma causing sectoral loss.	Thank you for your comment. Unfortunately, no evidence was identified on the use of capsular tension rings in people with large or floppy capsular bags, and therefore it was not possible to make recommendations on this topic. Evidence was identified that capsular tension rings may provide a benefit in people with pseudoexfoliation. However, in recognition that the evidence base was not particular strong, and there may well be reasons in particular cases why their use is not appropriate (such as those stated in the comment), the recommendation has been retained at the weaker 'consider' level.
The Royal College of Ophthalmologists	Full	28	715	It is sensible to offer much of this advice at discharge rather than waiting two weeks to give advice (at the first post-op review) about drops.	Thank you for your comment. Information given to people regarding eye drops forms part of the recommendation at both 'on the day of cataract surgery' (section 1.1.5 of the NICE guideline) and 'after cataract surgery' (section 1.1.6 of the NICE guideline). The committee agreed it was appropriate to recommend this information should be available at multiple points in the pathway, to ensure patients are fully informed.

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The Royal College of Ophthalmologists	Full	66	1704	The most recent version of The Royal College of Ophthalmologists' cataract surgery guidelines was published in 2010 not 2001.Plesae amend,	Thank you for your comment; this has now been corrected.
The Royal College of Ophthalmologists	Full	66	1720	The acronym for The Royal College of Ophthalmologists is RCOphth not RCO. Please amend.	Thank you for your comment; this has now been corrected.
The Royal College of Ophthalmologists	Full	181	4675	This recommendation should be strengthened to give examples of how commissioners can commission services to ensure data required for the national cataract audit can be collected. e.g. Commissioners should ensure all existing or new contracts with NHS funded providers including independent sector treatment centres include quality assurance for the well-being of the population they serve, through participation in the national cataract audit. Commissioners are encouraged to incentivise in quality assurance through participation in the national cataract audit via provider contracts.	Thank you for your comment. The details of how services are commissioned and funded was outside the scope of this guideline, and therefore it was not possible to make recommendations in this area.

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				Commissioners are in a key position to influence visual acuity data returns through appropriate contracting and surgical providers should engage with commissioners and local optometrists to develop such 'enhanced community services'. Commissioners are encouraged to commission services which reward quality assurance regarding visual acuity outcome.	
Thea Pharmaceuticals Ltd	Full	General	General	We would like to highlight that there has been no recommendation or consideration of pre-operative pupil dilation (mydriasis) prior to surgery, an essential step. [Question 27 appeared to refer to intra-operative procedures as opposed to pre-operative.] Current practice is variable and includes the following: a) the use of multiple instillations of topical mydriatic drops (tropicamide, cyclopentolate, phenylephrine in single dose units) b) an ophthalmic insert into the lower fornix which contains phenylephrine and tropicamide c) the use of intracameral mydriatics intra-operatively, as an alternative to pre-operative dilation Our contact with this market means we are acutely aware of variation in clinical practice for mydriasis, and the resultant differences in theatre efficiencies and patient experience. We would urge the panel to consider that there is an opportunity to give much needed guidance on this crucial part of cataract surgery.	Thank you for your comment. Unfortunately, pre-operative pupil dilation was not part of the scope developed and consulted on for this guideline, and therefore it is not possible to make any recommendations in this area.

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				For example, where traditional mydriatic eye drops are the method of choice, patients need to attend at least 1-2 hours before surgery, and some can be waiting for significant periods (hours) before their operation. The drops are in single dose units bringing cost, and the nursing time to administer sometimes 9-12 drops over one hour can be considerable. The patient experiences discomfort from such repeated sequential instillations of such eye drops. Some hospitals do stagger cataract theatre lists to reduce waiting times and prevent the excessive use of mydriatic drugs prior to surgery for maintaining pupil sizes, but many will ask patients to arrive all together, with the potential anxiety that waiting in the pre-operative area brings for some. Where inserts are used, the experience of patients and nurses is much improved from a once-only application of drug prior to surgery, but they still need to attend at a suitable time before surgery. With intracameral mydriatics, the dilation is done in theatre in the hands of the surgeon with no need for mydriasis pre-operatively. We would propose some guidance should be considered in order to set standards for best practice to improve the patient experience and streamline the dilation process for greater efficiency.	
Thea Pharmac	Full	General	General	We would propose that during the preoperative appointment along with providing the patient with	Thank you for your comment. The committee agreed that preoperative discussion regarding pupil dilation

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euticals Ltd				information on the type of anaesthesia which could be used, information on pupil dilation techniques could also be provided.	should be contained within the 'what to expect on the day of cataract surgery' recommendations in the patient information section and as such a specific patient information recommendation regarding pupil dilation was not required.
Thea Pharmaceuticals Ltd	Full	37	962	Number of cataract surgeries in England is now over 400,000 rather than 300,000 (NHS Hospital Episode Statistics 2015-2016. Main Procedures and Interventions, C71-C77).	Thank you for your comment; this number has now been updated.
Thea Pharmaceuticals Ltd	Full	186	4189	We would ask the committee to consider that, not only the correct concentration of intracameral antibiotics should be used to prevent toxicity, but also that the preparation is used in line with manufacturers guidelines as the stability of cefuroxime is widely known to be poor in solution. This has implications for safety as preparations which are not used straight after preparation are at risk of having lower concentrations of cefuroxime and higher levels of degradation products. We would also suggest that the sentence "The antibiotic solution should either be commercially prepared (diluted)' be amended to 'The antibiotic solution should either be commercially prepared (reconstituted)' to avoid any confusion between serially diluted cefuroxime for IV use and the licenced products designed for intracameral use which are reconstituted. There still exists some practices of 'batch-making' unlicensed pre-filled syringes of diluted cefuroxime (intended for IV use), which can carry risk for multiple patients.	Thank you for your comment. The committee discussed this issue and agreed that the current formulation of the recommendation, to 'use commercially prepared or pharmacy-prepared' antibiotics was the appropriate formulation. They also agreed it was appropriate to incorporate the amendment to the evidence to recommendations section suggested, and hence the word diluted has been replaced with reconstituted.

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Thomas Pocklington Trust	Short	General		We are pleased with the guidance and look forward to its release.	Thank you for your comment and endorsement.
Thomas Pocklington Trust	Short	7	10	Our only comment for further investigation relates to the point about not using blue light filtering intraocular lenses in cataract surgery (1.4.4). We are aware some eye health professionals may disagree with not using these lenses other than for research purposes and would recommend this is investigated further before you finalise the guidelines. We are not expert in this specific area to recommend one way or the other.	Please note: the recommendations around lens design and material have been removed to allow for further consideration.
United Kingdom & Ireland Society of Cataract and Refractive Surgeons	**Full**	General	General	Cataract surgery has evolved over the last 15 years with significant improvements in the visual outcomes specially without spectacles. Patients now increasingly want to achieve better vision without spectacles as a result of cataract surgery. The framework for these guidelines need to reflect this paradigm shift in cataract surgery and the importance of improved refractive outcomes translating to a reduced dependence on spectacles. There is good quality evidence that reduced spectacle dependence translates to an improvement in quality of life measures. Pesudovs K, Garamendi E, Elliott DB. A quality of life comparison of people wearing spectacles or contact lenses or having undergone refractive surgery. J Refract Surg. 2006 Jan-Feb;22(1):19-27, Blaylock JF, Si Z, Aitchison S, Prescott C. Visual function and change in quality of life after bilateral refractive lens exchange with	Thank you for your comment. The Committee agreed that spectacle independence is an important outcome for many people after cataract surgery, and this was reported as an outcome in a number of the reviews in this guideline. The Committee also made a number of comments about the inadequacy of a number of visual function measures (including the VF-14) for measuring visual outcomes after cataract surgery, and made a specific research recommendation around validating vision-related quality of life measures in people after cataract surgery.

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				the ReSTOR multifocal intraocular lens. J Refract Surg. 2008 Mar;24(3):265-73 The quality of life improvement with reduced spectacle usage can only be demonstrated by measures specifically designed to assess it and generic quality of life measures used in cataract surgery like the VF-14 are not designed to test for impooprvemnts in quality of life due to reduced spectacle use. The two studies referenced above use specific validated measures like the NEI-RQL or the QIRC (Quality of Life Impact of Refractive Correction). Patients rightly consider the value of cataract surgery in terms of their visual outcomes. Within this perspective the following statements specify different visual outcomes for cataract surgery. 1. Improve the clouding/clarity due to cataract and get patients good vision with spectacles. Patients with this outcome will need to wear spectacles for almost all activities after surgery but will benefit from improved visual function due to the improvement in clarity of their vision. 2. In addition to improved clarity get patients improved distance vision without spectacles so that they can legally drive without spectacles. Patients with this outcome will need to wear spectacles for all intermediate and near vision tasks. this is similar vision	

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				to that of a normal 50 year person who has established presbyopia. 3. In addition to achieving the driving standard of vision without spectacles get patients improved intermediate and near vision without spectacles to the extent that they only need spectacles to read small print in dim lights. This translates to most patients being practically spectacle free except for the very demanding near vision tasks.	
United Kingdom & Ireland Society of Cataract and Refractive Surgeons	Full	General	General	It is critical that the committee provide a clear and specific recommendation on which of the above objectives are optimal within the NHS setting as there are significant and large resource implications both in terms of cost and complexity of the process of delivering surgery between these options. Option 3 outlined above would provide most benefit to patients but comes with added cost in terms of prolonged chair time in clinics to explain the pros and cons of this option, more detailed and accurate optical diagnostics and biometry both for the spherical and astigmatism outcomes, presbyopia correcting lenses and secondary enhancement procedures to fine tune the focus in a small but significant minority of patients. Our Society believes that the objective stated in option 2 above should be the visual outcome aimed for NHS cataract surgery as the resource implications are minimal and cost effective. In order to archive this objective it is	Thank you for your comment. NICE guidelines are only able to make recommendations in areas included within the scope of the guideline. Unfortunately, the appropriate target to aim for after cataract surgery was not an issue included within the scope of the guideline, and therefore it was not possible for any recommendations to be made on this topic.

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				critical to have accurate biometry and astigmatism correction methods available on the NHS. Curent practice as evidenced by The Royal College of Ophthalmologists' National Ophthalmology Database study ofcataract surgery: report 1, visual outcomes and complications. Day AC, Donachie PH, Sparrow JM, Johnston RL; Royal College of Ophthalmologists' National Ophthalmology Database. Eye (Lond). 2015 Apr;29(4):552-6 shows that this objective is currently achieved in more than 80 % of eyes without any comorbidity. Thus the implications of trying to improve this to 95% or more would be minimal and more about improved process rather than any significant addition to the cost of the procedure. As a society we believe that the committee should recommend that cataract surgery in the NHS should be carried out with a stated objective of achieving the driving standard of vision without spectacles in 95% or more patients who do not suffer from any comorbidity.	
United Kingdom & Ireland Society of Cataract and Refractive Surgeons	Full	30	791-795	We believe it is critical to give all relevant information to patients so that they may be able to make a clear and reasoned judgement on the treatment options available. The level of vision with and without spectacles that may be reasonably expected after successful surgery is very important for the patient to define the benefit of surgery. The level of vision with and without spectacles has been reported in large national audit publications in the NHS: The Royal College of Ophthalmologists' National	Thank you for your comment and taking the time to provide the audit data. The Committee agreed that patient information is a key aspect of the cataract pathway, and therefore a number of recommendations were made about the information that should be provided to patients. The Committee agreed that routine audit data could provide a valuable resource to be able to provide individuals with quantitative information about the outcomes they can expect post-surgery.

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				Ophthalmology Database study ofcataract surgery: report 1, visual outcomes and complications. Day AC, Donachie PH, Sparrow JM, Johnston RL; Royal College of Ophthalmologists' National Ophthalmology Database. Eye (Lond). 2015 Apr;29(4):552-60 The figures from this large audit should be used to inform patients of the likely benefit from surgery. figures form this audit clearly show that 81.5% saw an improvement in their visual acuity, 15.8 % showed no change while 3% had worse visual acuity after surgery when compared to the pre surgery levels. In eyes without any co-morbidity 94.6% achieved 6/12 or better distance vision with spectacles, and 80.9% achieved 6/12 or better distance vision without spectacles. Another way of presenting this data will be to inform patients without any comorbidity that there is a 95% chance that they will achieve 6/12 or better distance vision with spectacles and 6/18 distance vision without spectacles. The 6/12 level is generally compatible with the driving standard of vision and hence patients may be told that there is a 95% chance of achieving the driving standard of vision with spectacles but a 80% chance of them achieving this level without spectacles. These figures are NHS audit figures and reflect the current standard of cataract surgery practice in the NHS. Individual units may present their own audit data in these terms for patients to decide.	
United Kingdom	Short	5	7 - 18	The recommendation should be modified so that immersion ultrasound is recommended in preference to	Thank you for your comment. No evidence was identified as part of the guideline that enabled the

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& Ireland Society of Cataract and Refractive Surgeons				contact ultrasound. Optical AxL measurements are calibrated to be equivalent to immersion ultrasound measurements so immersion ultrasound measurements would be preferable to contact ultrasound measurements. In addition to the Axial Length and Keratometry, Anterior Chamber Depth, Lens Thickness, White To White and the refraction history prior to cataract development. Some or all of these parameters are used in the recommended formulas in section 1.3.5. Without these measurements it is not possible to use the Haigis, Olsen or the Barrett formulas.	committee to make specific recommendations about the type of ultrasound that should be used. However, the committee noted that it was necessary for service providers to ensure that whatever equipment was used enabled the use of the most appropriate IOL formulas.
United Kingdom & Ireland Society of Cataract and Refractive Surgeons	Short	5	13 - 18	There is a contradiction in the recommendation as it is impossible to identify patients with irregular corneas on keratometry. Corneal topography is essential to diagnose an irregular cornea. It is of concern that corneal topography is recommended only in the conditions listed rather than in all patients where an astigmatic correction is being considered, prior refractive surgery and any patient with an abnormal corneal or ocular surface condition. We believe this recommendation needs to be changed to reflect current clinical practice.	Thank you for your comment. The committee discussed the range of indications given for the use of corneal topography, and agreed that the current recommendation represented an appropriate list of the circumstances in which corneal topography should be considered. The reasons behind this decision are given in the evidence to recommendations section of this chapter. In particular, they noted that the evidence quality of corneal topography was low (as well as there being additional costs associated with its use), and therefore did not feel it was appropriate to make anything stronger than a consider 'recommendation'
United Kingdom & Ireland Society of	Short	5	27	The recommendation should also include the wang koch correction for patients with long Axial lengths as it has been conclusively proven that applying this correction to formulas produces a more accurate Axial length measurement.	Thank you for your comment. The committee noted that some of the new lens formulas considered in the guidelines (e.g. the Ladas formula) incorporated the Wang Koch correction within them, and did not perform better than other formulas not making use of this

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Cataract and Refractive Surgeons				Wang L, Shirayama M, Ma XJ, Kohnen T, Koch DD. Optimizing intraocular lens power calculations in eyes with axial lengths above 25.0 mm. J Cataract Refract Surg. 2011 Nov;37(11):2018-27	correction. On this basis, the committee agreed not to make a specific recommendation for its routine use, but did agree that it remained a relevant option for surgeons to use, when making use of older lens formulas.
United Kingdom & Ireland Society of Cataract and Refractive Surgeons	Short	6	1 - 10	We are concerned that this raises questions on the resource allocation for this patient subgroup. Will patients who have had previous refractive surgery be funded to have secondary enhancement procedures to achieve good distance vision without spectacles ? If yes will this be restricted to Piggyback lenses or also allow LASIK or PRK excimer laser procedures ? Why should such a resource allocation be restricted to only this subgroup. Achieving good distance vision without spectacles for distance should be an objective for all patients and not just patients who have had prior refractive surgery. Biometry calculations in patients after refractive surgery are subject to a double K error in addition to the altered relationship between the front and back surface of the cornea. Adjustment for this error is also essential and should be added to the recommendation. We would recommend that the ASCRS calculator which will calculate for multiple methods provides the best option in such patients.	Thank you for your comments. Whilst the evidence identified for biometry clearly demonstrated that formulas that do not adjust for post-corneal refractive surgery differences have worse outcomes than those that do, no evidence was identified that enabled the Committee to be more specific about the appropriate formula to use. Issues around the referral criteria for LASIK/PRK procedures are not within the scope of this guideline, and therefore no recommendations were made on this topic. Whilst evidence was found showing that modifying lens constants may improve outcomes, the evidence was not sufficiently robust for the Committee to feel confident in making a stronger recommendation than the one currently in the guideline.

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				It has been clearly shown in the refractive outcomes NHS audit Gale RP, Saldana M, Johnston RL, Zuberbuhler B, McKibbin M. Benchmark standards for refractive outcomes after NHS cataract surgery. Eye (Lond). 2009 Jan;23(1):149-52 that personalisation of biometry constants improves the outcomes significantly. The recommendation should be changed to surgeons should personalise constants rather than think about it. Modern EMR and data systems allow for these personalisations to occur on a continuous basis.	
United Kingdom & Ireland Society of Cataract and Refractive Surgeons	Short	7	2 - 4	We are concerned with this recommendation as there is no credible evidence on the basis of which hydrophilic acrylic IOLs should be excluded. All studies in this area have been carried out with lenses which differ in more criteria than the material. The Findel led cochrane metaanalysis clearly states that there is no evidence to support the view that any material provides a significant advantage but rather there is a combination of material and design factors which influence PCO rates. The Hayashi study Anterior capsule contraction and intraocular lens decentration and tilt after hydrogel lens implantation Ken Hayashi, Hideyuki Hayashi, Fuminori Nakao, Fumihiko Hayashi. Br J Ophthalmol 2001;85:1294–1297	Please note: the recommendations around lens design and material have been removed to allow for further consideration.

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				referenced in Appendix E in support of this recommendation reports on Anterior Capsular Opacification as its outcome measure and not as incorrectly implied on posterior capsular opacification. We believe this recommendation should change to read that square edged IOLs should be used and not exclude any specific material.	
United Kingdom & Ireland Society of Cataract and Refractive Surgeons	Short	7	7 - 9	We are very concerned about this recommendation. Why should only one method of presbyopia correction be allowed and not others like multifocal and extended range of vision IOLs. Monovision also has significant resource issues as well as significant side effects and hence is only appropriate in selected patients. It will be more consistent to not recommend any presbyopia correction or recommend all of them.	Thank you for your comment. The committee reconsidered the recommendation made around monovision, and agreed that the reference to a contact lens trial should be removed. With this removal, the committee is keen to emphasise that monovision is not being suggested as an alternative to multifocal lenses, but rather that for people who already have anisometropia or monovision pre-operatively, they should be offered the option to remain this way after surgery.
United Kingdom & Ireland Society of Cataract and Refractive Surgeons	Short	7	10 - 11	This recommendation is not consistent with the fact that millions of BLF IOLs have been implanted without any harm. The evidence interpretation is flawed and inconsistent with the reality of BLF IOLs. We would recommend that this recommendation be altered to allow BLF IOLs to be implanted at the discretion of the surgeon and patient.	Please note: the recommendations around lens design and material have been removed to allow for further consideration.

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United Kingdom & Ireland Society of Cataract and Refractive Surgeons	Short	7	13 - 14	Astigmatism Correction should be within the remit of NHS cataract surgery as it is needed to achieve good distance vision without spectacles. On Axis Surgery and Corneal Relaxing incisions are options with very limited efficacy, can have issues with surgeon position and dryness of the cornea. We believe this recommendation should be changed to allow for all methods of astigmatism reduction including Topic IOLS to be available on the NHS. Topic IOLs generally cost the same if part of a lens contract including monofocal IOLs and hence should not have any significant resource implications.	Thank you for your comment. The committee agreed that, whilst lens costs are often equivalent between toric and non-toric lenses, there were significant additional pathway costs with toric lenses, as detailed in the evidence to recommendations section of this chapter. In the absence of robust economic evidence on the use of toric lenses, the committee did not feel confident to say they represent a cost-effective use of NHS resources, and therefore were unable to make a positive recommendation for their use.
United Kingdom & Ireland Society of Cataract and Refractive Surgeons	Short	7	5 - 6	We are concerned by the blanket recommendation to not offer multifocal IOLs. This is contrary to the NICE Guidance on Implantation of multifocal (non-accommodative) intraocular lenses during cataract surgery Interventional procedures guidance [IPG264] Published date: June 2008 The Guidance states 1.1 The evidence on the implantation of multifocal (non-accommodative) intraocular lenses (IOLs) during cataract surgery raises no major safety concerns. Current evidence on the procedure's efficacy shows that it can provide good near and distance vision without the need	Thank you for your comment. The recommendation regarding multifocal lenses was determined by the Committee following review of the efficacy and cost effectiveness evidence. Whilst we agree that multifocal lenses improve aspects of vision the "care pathway" is considerably more expensive than monofocal lenses without the major gains in improved vision to justify their recommendation without robust cost-effectiveness evidence. The IPG process contains no consideration of costs, and therefore has very different decision rules when compared to a full clinical guideline. It should be noted that there is no contradiction between the two conclusions reached, as in the absence of any cost considerations the guideline committee would also

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				for spectacles, but this is at the risk of a variety of potential visual disturbances. Clinicians wishing to use multifocal (non-accommodative) IOL implants during cataract surgery should therefore do so with normal arrangements for clinical governance and audit, but with special arrangements for consent. 1.2 Clinicians wishing to undertake implantation of multifocal (non-accommodative) IOLs during cataract surgery should ensure that patients understand the risks of experiencing halos and glare, and the probability of reduced contrast sensitivity. Patients should also be made aware that lenses may be difficult to remove or replace. Patients should be provided with clear written information. In addition, the use of the Institute's information for patients ('Understanding NICE guidance') is recommended. 1.3 Patient selection should take into account factors that may prevent patients from wearing spectacles, such as disabilities that interfere with spectacle use, because these may be additional indications for the use of multifocal lenses. We would recommend that the recommendation should be changed to allow for Multifocal to be used in special circumstances and under controlled conditions.	have agreed that multifocal lenses represented a relevant option for some individuals.
United Kingdom	Short	8	3 - 7	The recommendation should also state that a specific discussion about the level of vision with and without	Thank you for your comment. Discussions should take place with regard to vision with and without spectacles

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& Ireland Society of Cataract and Refractive Surgeons				spectacles should occur and be recorded. Patients should also be made aware of all the possible IOLs irrespective of their availability within the NHS as per GMC and College guidance.	as set out in the recommendations with respect to patient information – at referral, before and after cataract surgery.
United Kingdom & Ireland Society of Cataract and Refractive Surgeons	Short	9	25 - 27	We are disappointed that Femto-second laser assisted cataract surgery (FLACS) has not been recommended by NICE for use in the NHS. FLACS brings potential advances to conventional phacoemulsification surgery with multiple studies supporting improved outcomes in terms of post-operative endothelial cell loss with FLACS. FLACS technology is continuously evolving and has the potential to improve the outcomes of cataract surgery especially in complex cases such as dense cataracts (Chen JCRS 2017). We are therefore seriously concerned that this 'do not do' recommendation does not foster innovation in the NHS. We would therefore suggest that "do not do" is far too strong a negative recommendation and not supported by the current published evidence, as current meta-analyses support reduced total phakoemulsification energies with FLACS and less endothelial cell loss. We therefore feel that the recommendation might be better phased by stating "that while at present published evidence does not support the widespread implementation of Femtosecond	Thank you for your comment. The "do not" recommendation reflects the clinical and health economic evidence which do not support the use of the technology in an NHS context. We are aware that 2 large RCTs (FACT and FEMCAT), at least 1 of which will include a parallel economic analysis, are due to publish in 2018. Details of both have been passed to the NICE surveillance team, and there are processes by which a rapid, targeted update of that part of the guideline can be undertaken, should that new evidence imply the recommendations need to be reviewed. For more information about how NICE formulates the wording of recommendations, please see https://www.nice.org.uk/process/pmg6/chapter/developing-and-wording-guideline-recommendations

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				laser cataract surgery into the NHS, especially as there are associated financial costs with its usage, it does offer potential surgical advantages especially in complex cases, with reduced endothelial cell loss and/or dense cataracts, and further randomized controlled studies are indicated and its usage for research purposes is supported".	
United Kingdom & Ireland Society of Cataract and Refractive Surgeons	Short	9	25 - 27	We feel the evidence review conducted to evaluate laser assisted cataract surgery in its current form in this review does not capture all relevant outcomes to compare FLACS vs. conventional phacoemulsification surgery (CPS). We believe that the review question should have included comparative assessment between laser assisted cataract surgery devices and PCS on efficiency parameters (effective phacoemulsification time) as well as safety parameters (phaco or ultrasound energy) and reduced endothelial cell loss. It is well documented in the published evidence that phacoemulsification time and ultrasound (or phaco) energy used during cataract surgery are known to directly cause endothelial cell loss (Chen et. al, 2016; Cho et al, 2010; Hayashi et al, 1996) which may impact corneal endothelium and that in FLACS these energies are reduced as is endothelial cell loss Chen et. al, 2016; Schargus et al. (2015) It appears that 'endothelial cell loss' (ECL), an important complication of PCS, has not been evaluated in this review while several studies have reported this outcome:	Thank you for your comment. The currently available randomised controlled trials, including a recent Cochrane Review, do not support these conclusions. Whilst we agree that some cohort studies have reported reduced endothelial cell loss and reduced phacoemulsification energies, the study type searched and included as the most appropriate, in this case RCTs, within the review question was determined and ratified by the guideline committee prior to its commencement. We are aware that 2 large RCTs (FACT and FEMCAT), at least 1 of which will include a parallel economic analysis, are due to publish in 2018. Details of both have been passed to the NICE surveillance team, and there are processes by which a rapid, targeted update of that part of the guideline can be undertaken, should that new evidence imply the recommendations need to be reviewed. It should be noted that the decision to recommend FLACS only as part of a trial reflects the economic

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				An independently conducted SLR and meta-analysis (Chen et al, 2016) concluded that the mean ECL was significantly lower for patients undergoing FLACS versus PCS at 1 week, 1 month and 3 months after surgery. Schargus et al. (2015) found that ECC significantly decreased in both the FLACS group vs. PCS by 6 months (P=0.046 and P=0.002, respectively). Phacoemulsification power is an important determinant of intra-and post-operative complications associated with phacoemulsification cataract surgery. An independently conducted meta-analysis (Chen 2016) synthesized evidence from studies reporting mean phacoemulsification power (MP) and findings show that "the mean phacoemulsification power in the FLACS group was significantly lower than in the PCS group (WMD: -7.09, 95% CI: -7.64 to -6.55, P < .001, I2 > 50%). Therefore, the overall effect in phacoemulsification power favored FLACS (WMD: -6.57, 95% CI: -7.08 to -6.05, P < .001, I2 > 50%)."	evidence which does not at the time of writing support FLACS as a cost-effective option for cataract surgery. ECL was not included as an outcome of interest because we did not find evidence, including in the trials in the Cochrane review that the differences in ECL between phacoemulsification and FLACS impacted on key outcomes such as acuity. Furthermore, the existing economic evidence does not suggest that the differences in ECL translate into tangible health economic benefits which would offset the costs of the device, disposables and estate costs associated.
United Kingdom & Ireland Society of Cataract and	Short	9	25-27	Therefore, we request to the guideline committee to consider modifying recommendations on laser assisted cataract surgery to recommend that while at present published evidence does not support the widespread implementation of Femtosecond laser cataract surgery into the NHS, especially as there are associated financial costs with its usage, it does offer potential surgical	Thank you for your comment. The "do not" recommendation reflects the clinical and health economic evidence which do not support the use of the technology in an NHS context. For more information about how NICE formulates the wording of recommendations, please see

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Refractive Surgeons				advantages especially in complex cases, with reduced endothelial cell loss and/or dense cataracts, and further randomized controlled studies are indicated and its usage for research purposes is supported".	https://www.nice.org.uk/process/pmg6/chapter/developing-and-wording-guideline-recommendations
University Hospital Coventry & Warwickshire	Full	24 56	523 1394-1403	We welcome the recommendation for offering cataract surgery based on individual needs and individualised risk factors and not limited by visual acuity level.	Thank you for your comment and recognition of the value of this recommendation.
University Hospital Coventry & Warwickshire	Full Short	23 3	484-485 13 - 14	There is a discrepancy between full version and the short version of the guideline. Line 484-5 (guideline 3) refers the reader to Guideline 29 in the full version. It appears it should be referring to guideline 28 which expands on the first statement in guideline 3. The same text refers the reader to a different guideline in the short version as described in the next comment below. Refers attention to section 1.5.3 which is equivalent to guideline 28 in the full document. Guideline 29 is equivalent to section 1.5.4 in the short version. It will be helpful if this discrepancy is corrected in the final guideline.	Thank you for your comment. These corrections have been made.

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University Hospital Coventry & Warwickshire	Full	21 106	571 - 2 2509 - 10	We are concerned that recommendation to offer silicone intraocular lenses to reduce the risk of posterior capsule opacification might have not been made after considering the evidence of potential risk of increased rate of endophthalmitis with these lenses. This concern is based on some published studies and it also appears in the published ESCRS guideline on prevention of endophthalmitis following cataract surgery Reference: Barry P, Cordoves L, Gardner S ESCRS guidelines for prevention and treatment of endophthalmitis following cataract surgery: data, dilemmas and conclusions 2013. Acrylic Hydrophobic lenses seem to offer the same advantage of reducing the risk of posterior capsule opacification without the potential risk of increased rate of endophthalmitis and have replaced the practice of using silicon lenses by many ophthalmologists. For example our team has been using hydrophobic acrylic lenses with square edge design as a routine standard for many years. It will be useful to have evidence-based review, as the guidelines specifically recommend offering silicon lenses. In case current evidence is not of high quality then it may be worth considering a research question comparing effect of hydrophobic acrylic and Silicon lenses on rates of endophthalmitis.	Please note: the recommendations around lens design and material have been removed to allow for further consideration.

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VISION 2020 UK.	Full	General	General	In general VISION 2020 UK is supportive of the positivity and innovation of the new guidelines however there are a few specific points below and we support SeeAbility's call for a Section on people with learning disability or cognitive impairment being required. The guideline tends to rely on patients to self-report and this is not always going to be the case for patients with learning disabilities, dementia and other cognitive or also physical disabilities.	Thank you for your comment. The committee agrees with the importance of ensuring equitable access to cataract surgery for people with learning disabilities or cognitive impairment. They noted that no specific evidence was identified during the development of the guideline which would enable specific recommendations to be made about how care should be organised differently. However, they agreed that the duty to adapt care appropriately for people with learning disabilities or cognitive impairment was incumbent on all NHS professionals at all stages of the pathway, and that this duty was not unique to cataract surgery. The committee agreed that the issues raised here would apply across a whole range of care within the NHS, and therefore represented broader structural issue within the health service, and not one that could be addressed solely within the cataract pathway.
VISION 2020 UK.	Full	10	26 - 28	There is an assumption that people with cataract will be referred following self reported symptoms or from their optometrists. For many adults with learning disability or dementia reporting symptoms is not possible. For many adults with learning disability or Dementia accessing high street optometry services is a challenge. Carers do not routinely consider eye checks a necessity, making assumptions about ability to perform eye tests in someone with complex needs. (http://www.vision2020uk.org.uk/eye-examinations-	Thank you for your comment. The committee agrees with the importance of ensuring equitable access to cataract surgery for people with learning disabilities or cognitive impairment. They noted that no specific evidence was identified during the development of the guideline which would enable specific recommendations to be made about how care should be organised differently. However, they agreed that the duty to adapt care appropriately

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				people-dementia-vision-2020-uk-dementia-sight-loss-committee/) For those with complex needs, accessing high street optometry is not possible. This group rely on referral into hospital eye services at the point at which visual loss is noted by the carer. In many cases there is diagnostic overshadowing and a change in behaviour is attributed to other causes than loss of vision. Increasing awareness in the Learning Disability population – both patients and carers – of the need for regular eye checks in order for cataract, and other ocular conditions, to be diagnosed before sight loss occurs is essential. The provision of adequately trained and experience optometrists to offer community eye tests is needed.	for people with learning disabilities or cognitive impairment was incumbent on all NHS professionals at all stages of the pathway, and that this duty was not unique to cataract surgery. The committee agreed that the issues raised here would apply across a whole range of care within the NHS, and therefore represented broader structural issue within the health service, and not one that could be addressed solely within the cataract pathway.
VISION 2020 UK.	Full	29	726	Consider health related quality of life associations in those with learning disability, and also those with Dementia http://www.vision2020uk.org.uk/cataracts-and-dementia-factsheet-report-etc/	Thank you for your comment. The committee agreed there were specific issues around access to cataract surgery for people with learning disabilities or cognitive impairment, but agreed these were representative of the general difficulties these groups encounter across a range of NHS services However no evidence was identified to support specific recommendations for these groups. The committee were however keen to emphasise that people should not be denied access to cataract surgery solely on the basis of learning disabilities or cognitive impairment, and that it was important for people working in the NHS to make appropriate adjustments to

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					ensure this group of people have access to services, in the same way as adjustments should be made across the whole range of services the NHS offers.
VISION 2020 UK.	Full	30	783	For patients with learning disability this would include EasyRead information such as that provided by SeeAbility https://www.seeability.org/Handlers/Download.ashx?IDMF=0bf6145d-74fd-4ead-9845-f0bbd32f2692	Thank you for your comment. The Committee agree on the importance of clear written information being given to patients, and that this information should be tailored to the needs of the individual.
VISION 2020 UK.	Full	37	967	For patients with learning disability, Dementia and other cognitive issues, the decision to refer should not be made on the basis of patient agreement to surgery. Any patient with reduced vision and cataract should be offered the opportunity to discuss surgery rather than the decision being made by a carer: all too often negative assumptions are made about the patients ability to cooperate during and after surgery or about the possible improvement in quality of life that could be gained with an improvement in vision. Knowledge and experience is required in the Hospital Eye Service to support this.	Thank you for your comment. While the evidence base did not enable the committee to make specific recommendations on this topic, they were keen to emphasise that people should not be denied access to cataract surgery solely on the basis of learning disabilities or cognitive impairment, and that it was important for people working in the NHS to make appropriate adjustments to ensure this group of people have access to services, in the same way as adjustments should be made across the whole range of services the NHS offers.
VISION 2020 UK.	Full	53		The committee noted that in certain places there are issues with lack of access to optometry services. In most areas of the U.K., there is a lack of access to optometry services for adults with learning disability. This restricts their access to surgery by the lack of a community referral route. This is also reflected fro people with sight loss and Dementia in the recent prOVIDe staudy by the College of Optometrists https://www.college-optometrists.org/the-college/research/research-projects/provide-dementia.html	Thank you for your comment. Unfortunately, access to optometry services was outside of the scope of this guideline, and therefore it was not possible to make any recommendations on this topic.

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VISION 2020 UK.	Full	61 64	7.1.6 1665	Optical biometry may not be suitable for some adults with learning disability who are unable to cooperate. In this instance ultrasound biometry should be used. The inability to cooperate with biometry pre operatively should not impose a barrier to accessing surgery as biometry can be undertaken during anaesthesia prior to commencing the surgical procedure.	Thank you for your comment. The committee noted the point raised in your comment and agreed to amend the biometry recommendation to make clear that ultrasound biometry should be undertaken in situations where it is not practical to use optical biometry.
VISION 2020 UK.	Full	95	2309	The evidence supporting the increased risk of surgical complications for patients with a dense cataract should be considered when discussing surgery for a patient with learning disabilities and those with Dementia and also when considering the provision of community services to monitor eye health of the LD and Dementia population such that cataracts can be detected in a timely manner	Thank you for your comment. The committee agreed that discussions regarding the risk of surgical complications (and the increased risk with dense cataracts) should take place when making decisions about any patients considering cataract surgery, and this would include those with learning disabilities or cognitive impairment.
VISION 2020 UK.	Full	111	2599	The position on blue-light filtering intraocular lenses seems harsh given the level of available evidence and the fact that these lenses have been in world wide use for decades with no public outcry or measurable effect on the community. There is available evidence of their beneficial effect and we recommend that NICE keep this recommendation under close scrutiny.	Please note: the recommendations around lens design and material have been removed to allow for further consideration.
VISION 2020 UK.	Full	150	3504 3515	The population of adults with learning disability over 70 will double by 2030. The prevalence of cataract in this population is between 12-30%. The use of general anaesthesia should be considered in patients with learning disability. Lack of facilities should not be a barrier to surgery.	Thank you for your comment. The committee agreed that whilst there was not specific evidence enabling them to make recommendations around who should receive general anaesthesia, there were some individuals who would require it to have surgery, and this should not by itself be a reason for denying some access to cataract surgery.

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Cataracts in adults: management

Consultation on draft guideline - Stakeholder comments table
12/05/2017 to 23/06/2017

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				Equally 1/3 of the 850000 patients with dementia in the UK have a Visual Impairment which means about 283,000 people have both conditions again consideration needs to be given this population	
VISION 2020 UK.	Full	181	4675	This recommendation should be strengthened to give examples of how commissioners can commission services to ensure data required for the national cataract audit can be collected. e.g. Commissioners should ensure all existing or new contracts with NHS funded providers including independent sector treatment centres include quality assurance for the well-being of the population they serve, through participation in the national cataract audit. Commissioners are encouraged to incentivise in quality assurance through participation in the national cataract audit via provider contracts. Commissioners are in a key position to influence visual acuity data returns through appropriate contracting and surgical providers should engage with commissioners and local optometrists to develop such 'enhanced community services'. Commissioners are encouraged to commission services which reward quality assurance regarding visual acuity outcome.	Thank you for your comment. The details of how services are commissioned and funded was outside the scope of this guideline, and therefore it was not possible to make recommendations in this area.

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Wales Ophthalmic Planned Care Board	General	General	General	The Wales Ophthalmic Planned Care Board supports the NICE Guidelines for the management of patients with cataract (2017). The guidelines are consistent with the tenets and processes of the Wales clinical pathway for patients with cataract. We give your work our wholehearted endorsement.	Thank you for your comment and recognition of the value of this guidance.

Document processed	Organisation name – Stakeholder or respondent	Disclosure on tobacco funding / links	Number of comments extracted	Comments
Full	Guy's and St. Thomas' NHS Foundation Trust	One of the reviewers (name supplied) holds a non-commercial research grant from Alcon Inc. He has also agreed to review these documents for the United Kingdom Society of Cataract and Refractive Surgeons and Alcon Inc as well as Guy's and St. Thomas' NHS Foundation Trust	6	

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