NICE National Institute for Health and Care Excellence

Glaucoma (update)

Consultation on draft guideline – deadline for comments 5.00pm on 4 July 2017
email: glaucoma@nice.org.uk

	Please read the checklist for submitting comments at the end of this form. We cannot accept forms that are not filled in correctly. We would like to hear your views on the draft recommendations presented in the short version and any comments you may have on the evidence presented in the full version. We would also welcome views on the Equality Impact Assessment. We would like to hear your views on these questions: 1. Which areas will have the biggest impact on practice and be challenging to implement? Please say for whom and why. 2. Would implementation of any of the draft recommendations have significant cost implications? 3. What would help users overcome any challenges? (For example, existing practical resources or national initiatives, or examples of good practice.) 4. [Insert any specific questions about the recommendations from the Developer, or delete if not needed] See section 3.9 of Developing NICE guidance: how to get involved for suggestions of general points to think about when commenting.
Organisation name – Stakeholder or respondent (if you are responding as an individual rather than a registered stakeholder please leave blank):	**The Royal College of Ophthalmologists**
Disclosure Please disclose any past or current, direct or indirect links to, or funding from, the tobacco industry.	N/A
Name of commentator person completing form:	Professor Andrew Lotery, Chair of the Scientific Committee
Type	[office use only]

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Comment number	Document (**full** version, **short** version or the **appendices**	Page number Or **'general'** for comments on the whole document	Line number Or **'general'** for comments on the whole document	Comments Insert each comment in a new row. Do not paste other tables into this table, because your comments could get lost – type directly into this table.
1	Both	General	General	Comments made on the Short version apply also to the long version
2	Both	General	General	Most of the new recommendations seem very sensible (subject to concerns outlined below). A further practice recommendation is suggested (comment #15)
3	Full	General	General	The guideline does not discuss Normal Tension Glaucoma (NTG) separately. This is a different form of COAG as the management is slightly different for these patients. It should either be mentioned/ discussed separately or it should be mentioned that the management is the same as COAG.
4	Full	General	General	The guideline does not consider lifestyle factors in detail. There is some evidence even though it might not be high quality evidence that things like drinking too much coffee, exercise and other factors can have an influence on the pressure in the eye which could have an impact on advanced glaucoma patients. These need to be looked at and advise given in the guidelines regarding need to follow them or disregard them.
5	Full	General	General	The guideline does not discuss the option of Primary Trabeculectomy in patients with advanced glaucoma that is the practice in some cases. Does it need to consider the evidence for that.
6	Full	General	General	The guideline does not look at the evidence of using the different MIGS techniques in patients with Ocular Hypertension or Early glaucoma who need some lowering of IOP but not very low target pressures.
7	Full	General	General	There is evidence in literature that doing 5 visual fields in the first year helps to plot the rate of progression in glaucoma patients. This has not been looked at in the guideline and needs to be looked at.
8	Full	General	General	There is a much higher incidence of dry eyes in patients with glaucoma. This is usually missed and the patients are labelled as being allergic to the drops. The guideline needs to look at the option of combining glaucoma drops with artificial tears eye drops to reduce the number of hospital visits and also the conversion to surgery
9	Full	General	General	The guideline has looked at the cost effectiveness of various imaging techniques in glaucoma. It would be good if it looks at what could class as progression on the OCT scan as there is some natural decay in the nerve fibre layer which is not progression go glaucoma.
10	Both	General	General	Key research recommendations: The College supports the recommendations and suggest two more

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				(comments #14 and 16).
11	Both	General	General	Failure to revise the review questions for Sections 6.3 and 6.4 (Accuracy of structural tests and Accuracy of intraocular pressure tests) seriously undermines the utility of these parts of the Guidelines. The Review questions are inappropriate to provide the evidence needed by the guideline committee (see Comments 40 and 42, below). The consequence of failure to ask the correct review questions are: no useful evidence, wasted public funds, reputational damage (consequent on poorly-thought-out questions).
12	Both	General	General	The draft guidance with potentially the biggest impact on practice is discussed in Comments #23 and #47.
13	Both	General	General	The draft guidance with potentially the biggest cost impact is discussed in Comment #17
14	Both	General	General	Addition research questions to consider. This research question is #1 on the James Lind Alliance list: a) What are the most effective treatments for glaucoma and how can treatments be improved? Why is this important Glaucoma is a lifelong condition which is progressive if not treated adequately during this time. Many patients live for many years following the diagnosis of their glaucoma. Patients need to make treatment choices on the basis of lifetime outcomes for interventions rather than on the basis of outcome information which may only measure outcomes over 1-3 years. This information is essential for patients in helping them with their treatment choices. b) Does OCT technology facilitate more prompt decision-making for glaucoma diagnosis and identification of progressive glaucoma?
15	Both	General	General	Practice recommendation, related to the research recommendation in comment #14: Ensure medium and long term outcomes are recorded for glaucoma interventions (visual field and IOP)
16	Both	General	General	Addition research question to consider. This research question is #6 on the James Lind Alliance list: What is the most effective way of monitoring the progression of glaucoma? This would be helped by identification of effective patient reported outcome methods and evidence from longer term outcomes for treatment interventions Which patient reported outcome measures are most effective in defining quality of life in patients with glaucoma? Why is this important Quality of life is the most important overall measure of

				treatment effect for patients as it measures their life experience and how their life experience is affected by interventions. Patient reported outcome measures are an important instrument for informing patients of the value of interventions which may affect their treatment choices. They also offer an effective tool in audit or service evaluations of a glaucoma services. However, uncertainty exists as to which patient reported outcome measures best measure outcomes of treatment in patients with glaucoma. Identifying the most effective PROM for measuring glaucoma outcomes would ensure this was adopted in all future clinical trials and glaucoma audits and would ensure that meaningful comparisons could be made between different interventions. This would further enhance a patient's ability to make treatment choices based on accurate quality of life information.
17	Short	4	8	Threshold perimetry in primary care. Is this feasible? What proportion of optometry practices have threshold perimetry? Some practices may have only suprathreshold tests available. Implementation of this recommendation could have high cost either through 1) primary care optometry practices having to buy new equipment or 2) generating additional referrals for referral refinement. Is threshold testing sufficiently superior to require optometry practices (which are not paid to do the tests) to invest? This recommendation is based on committee opinion and not on any evidence for this setting.
18	Short	5	3	Consider always requiring a repeat VF if abnormality is an isolated finding
19	Short	5	5	Consider always requiring a repeat IOP if >24 <28 if an isolated finding
20	Short	5	10	An earlier recommendation for case-finding is to use OCT, if available. It would make sense to refer to OCT here (eg unequivocal OCT abnormality not explained by non-glaucomatous conditions, such as myopia)
21	Short	7	19	Reassessment need not be with a Goldmann-type tonometer – non-contact tonometry is adequate. There is no evidence presented in the guideline to support GAT for monitoring. Patients under care have had central corneal thickness measurement and spurious readings caused by abnormal CCT will have been identified; monitoring with air-puff tonometry is perfectly reasonable.
22	Short	7	20	There is no need to perform an angle assessment at each re-assessment visit for patients identified as having open angles (COAG). What is the evidence base for this recommendation? Suggest using 'when

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				clinically indicated'
23	Short	9	Table 1	It is not clear in which clinical scenarios much of the re-assessment guidance applies. There is text in the full guidance (page 146 "For people with an acceptable IOP who have no signs of progression, the committee decided that...") that makes the intention clear, but this does not come through in the Guidance itself. The judgement of "no signs of progression" can only be made in the context that there is sufficient data to inform that judgement. For Humphrey perimetry, at least 4 VFs are needed to identify 'possible progression' and 5 to identify 'probable progression'. It would be very helpful if a comment was added to the tables that "uncertain conversion" includes insufficient data to make the judgement. This would allow the clinician flexibility to shorten the re-assessment interval (according to risk level) until sufficient data are available. The committee has lost an opportunity to provide guidance on how much VF data is required to identify progression. There is plenty in the literature to support such guidance and some is just common sense (eg needing at least two baseline VFs close together as a baseline and needing at least two more before even tentative progression can be identified). This general point is reiterated in comments #24, 25 and 47. Consider adding a line in the table for 'newly-initiated treatment' – review with repeat threshold VF testing and ONH assessment 1 to 4 months [it may be that the Committee consider this is covered under the existing first line, but this would emphasise the benefit of good baseline measurements]
24	Short	9	Table 2	Similar comment – it should be emphasised to get two baselines tests close together if they are at moderate or high risk of conversion, before extending the follow-up interval
25	Short	10	Table 4	In general, the 3rd line ('not detected') is OK, but there should be a comment that this holds provided there are enough data to detect progression. E.g. the GPA analysis of the HFA requires 4 VFs before 'possible progression' can be flagged. A suggestion for all these recommendations (#16 to 18) is that could be worded so that they apply to patients after the first year of assessment (recognising that patients need more frequent visits in their 1st year) or that the 'uncertain progression status' includes situations in which there is insufficient information.
26	Short	20	11	"Sight loss may progress and become symptomatic and eventually cause visual impairment."

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				Consider rewording, because vision may be impaired in glaucoma before it becomes symptomatic – falls and motor vehicle accidents are more frequent, even when the VF impairment is not advanced and many patients are unaware of this impairment.
27	Short	27	Table	First item "leaving it open to either biomicroscopy slit lamp examination or stereo photography" – this suggests that a "picture" can be obtained by slit lamp biomicroscopy; unless there is a special attachment, it cannot. This is repeated at least twice in the Full guideline.
28	Full	12	Figure 1	Clarity: 'consider repeat measures' box – as you have "if any of", the "and/or" after each bullet is unnecessary. For consistency, the "Refer if" box could say "Refer if any of:" and delete the "and/or"
29	Full	12	general	Most areas in the country do not have systems set up in primary care that do repeat measures, enhanced case finding or referral refinement. These will need to be set up very quickly and this is going to be difficult as some if it will require training of Optometrists to be able to do the relevant tests. There will also be a cost implication as these clinics will need to be resourced and the optometrists paid for performing these tests
30	Full	12	General	The algorithm does not mention doing Central corneal thickness as part of the referral algorithm .I feel this is important as a pressure of 22 with a very thin cornea is much worse than a pressure of 24-25 with a thick cornea. The Ocular Hypertension treatment study established that a thin cornea was an independent risk factor for glaucoma. So it should form part of the referral algorithm.
31	Full	13	General	The diagnostic algorithm also does not mention the need and value of doing a Central Corneal thickness. This should form an important part of the diagnosis and management of glaucoma and needs to be included.
32	Full	14	General	The algorithm advises that patients with OHT have no evidence of conversion to COAG they should be seen every 18-24 months. At the moment patients who have a family history of glaucoma are seen every 24 months by their optometrists for a glaucoma check. Do we need to change the advise to the optometrists where they do not need to provide free eye tests if people are under the hospital as this has a major cost implication for the NHS.
33	Full	15	Figure 4	This flow chart is confusing – it seems possible to follow a patient with IOP >24mmHg, offered treatment, conversion not detected, IOP controlled, discharge! Is it possible to simplify the flow chart by assuming that OAG Suspects with IOP >24mmHg are managed

				according to the OHT pathway? The College notes the committee considered that suspects might be at higher risk of converting than OHT, but they are probably not at greater risk of visual disability, especially if their IOP is controlled, so this simplification is probably justified. The IOP treatment threshold is the same for OHT and glaucoma suspects, so it would be consistent to have the follow-up interval the same.
34	Full	16	Figure 5	There seems an inconsistency between the OHT and COAG pathway in terminology – OHT used the term 'controlled or at target' whereas the OAG only uses 'controlled' The OHT pathway contains recommendations for escalating therapy, whereas the COAG one merely states "reassess". On page 138, there is text explaining that 'clinically acceptable control of IOP' is replacing use of 'target'. Does this adequately address the question? We treat patients to obtain an IOP in a certain range – that's a target. It is individualized and changes over time, but it is still a target. Reference to 'Target pressure' is retained in Chapter 8 (eg page 148, line 5), explaining what is meant by 'target IOP' so there is a lack of consistency in the Guideline. The College favours retaining the Target IOP concept.
35	Full	19	Line 5	Consider adding a re-evaluation of the target IOP (or treatment intensity) – this goes along with the re-evaluation of risk
36	Full	21	24-26	The guidelines mention that once drugs from 2 therapeutic classes have been tried surgery should be offered. With the new combination drops available this would amount to one bottle in most of the cases. Does this need to be changed to 2 bottles which would vary from patient to patient and might be 2 therapeutic classes or 3 as most patients are fine with upto 2 bottles and it works fine in practice including my practice.
37	Full	26	11-15	The guideline talks about having 1 pressure cut off for Ocular Hypertension which is 24. This would equate to less patients with pressures under 24 being on treatment but more patients with IOP more than 24 but thick corneas being on treatment. The cost of this needs to be looked at as in the old guidance talked about stopping drops at age cut off's but patients will be having drops for longer.
38	Full	26	11-15	The guideline mentions that the cost of the prostaglandins has gone down and so cost is not an issue. It does not mention about the side effects of the drops as a balance for the low cost as a good

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				proportion of patients experience side effects. So the side effects and the cost need to be balanced.
39	Full	68	Line 13	Guided Progression Analysis is not a risk tool. It is a method for detecting progression. The paper i40a technology evaluation (diagnostic precision study) and not a very good one at that. It is of concern that this paper has been evaluated as an assessment of a risk tool and has made it into the draft report.
40	Full	76	Table 14	The reference standard for the Review Question of the value of imaging (both for diagnosis and for progression) is inappropriate (see Comment #4). Biomicroscopic examination at the slit lamp cannot seriously be considered the reference standard for *progressive* glaucoma? It is also not appropriate for assessment of diagnostic imaging devices. The optimal study deign for these studies a difficult problem, but the reference standard chosen for this review question is highly inappropriate. There is a valid argument that biomicroscopic evaluation of the ONH is an inappropriate reference standard for imaging device assessment (see Sources of bias in studies of optic disc and retinal nerve fibre layer morphology. Garway-Heath DF, Hitchings RA. Br J Ophthalmol. 1998 Sep;82(9):986). Not only is biomicroscopic evaluation highly error prone, it introduces differential bias in the evaluation of different imaging technologies. This question must be addressed in future updates. Perhaps it could be included as a Research question – what it the appropriate methodology for evaluation of diagnostic imaging devices for glaucoma?
41	Full	94	Table 19	Pneumotonometry is not the same as NCT/air-puff tonometry. It is a different technique (ie Ocular blood flow pneumotonometry)
42	Full	94	Table 20	The Review Question of the value of alternative forms of tonometry is inappropriate (see Comment #4). It appears that the evaluation of the tonometers is sensitivity and specificity to detect an IOP >21mmHg by GAT. This is a meaningless evaluation and repeats the mistake of the last Guideline. Given the within- and between-person variability in GAT measurements, it is highly unlikely that GAT itself would meet the criteria set by the committee. The College notes that the committee has reservations that only one threshold was assessed. This isn't really the point – the whole approach to the evaluation is wrong. As mentioned in response to the last version of the Guideline, the important metrics are agreement (bias) and measurement precision. Ultimately, the association of IOP measurement with VF progression rate will tell us the most useful

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				tonometer. The most useful form of tonometry will never be established with the current question and this question should be changed in any future guideline revision.
43	Full	118	Table	There is a flaw in the argument for referral based on NCT. The text says that the committee was concerned about the poor sensitivity of NCT to identify IOP >21mmHg by GAT and, therefore, would not accept NCT referrals from Primary Care. The flaw is that referrals are made for IOPs *above* 21 (now 24) mmHg; optometrists will not repeat an NCT IOP <21mmHg with GAT. The argument would only make sense if GAT were required for all IOP measurements in Primary Care.
44	Full	122	Table	First paragraph – setting a test sensitivity threshold is not meaningful unless the stage of disease to be identified is also specified.
45	Full	128	Text	Setting a threshold for acceptable sensitivity to identify progression is meaningless without first quantifying the amount of progression that needs to be identified.
46	Full	136	4	The cost mentioned for a monitoring visit in the HES is not correct. With the latest tariff for 2017-18 the new cost is GBP 59 per visit. Also till last year the cost was GBP 67 per visit. This needs to be corrected and also the economic modelling needs to be looked at again to see if the model needs to change based on the new costs.
47	Full	144	Recommendations	"Progression not detected, IOP controlled, Reassess between 12 and 18 months". Similar to point in Comment #23. The College has serious concerns that, unless the recommendation is qualified, this will lead to poor management of many patients. Progression may be undetected because there are insufficient data (either because the patient is newly-diagnosed or because VFs have been done every 18 months). There is presently no recommendation to obtain good baseline data (at least 2 VFs). 'IOP control' is just a guess at baseline, based on risk factors (and these guidelines have established that risk assessment is poor). Our clinical guess is often incorrect. The only way we know if a patient is stable is by measuring non-progression and we need VFs to do that. The qualification the College recommends is that at least 2 baseline VFs should be obtained soon after referral, then follow-up intervals should be based on risk of visual disability and IOP control. If risk is high and IOP control equivocal (or even acceptable according to initial guess), intervals may be 4 to 6-monthly. Low-risk patients may be seen less frequently. High risk patients with demonstrated stability may also be seen less frequently.

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				The bottom line is that an interval of 12 months for a new OAG patient who has 'controlled IOP' is too long, especially if they are high risk. That some of this has been considered is apparent in the discussion text of the Guideline, but it is not at all clear from the recommendations. The justification seems to be to give more leeway for the clinicians to decide what is needed, but this is at the expense of giving guidance, which is what guidelines are supposed to do. A way around this would be to specify that 'Uncertain progression' includes too little data.
48	Full	144	6	The cost for the HES visit needs be changed to the new costs of GBP 59 per visit and the economic model adjusted if needed.
49	Full	201	Table 65	The 3rd column is headed '% of their class', yet the contents of the column appear to be decimal proportions. There are no units given to columns 4 to 6.
50	Full	209	32	The central corneal thickness mentioned is 55 microns which is possibly a typing error. It needs to be corrected.
51	Full	209	39	The pressure readings mentioned are 21 and 24 mm Hg and then above 24 mm Hg. Is this correct or does it need to be changed to the ones in line 30 which is 21-25mm Hg and above 25 mm Hg
52	Short	11	10	The guideline mentions choice of alternative generic PGA- Do the authors mean a different type of prostaglandin in generic form than the same prostaglandin in a different Generic bottle? This needs to be clarified.

Insert extra rows as needed

Checklist for submitting comments

- Use this comment form and submit it as a Word document (not a PDF).
- Complete the disclosure about links with, or funding from, the tobacco industry.
- Include page and line number (not section number) of the text each comment is about.
- Combine all comments from your organisation into 1 response. We cannot accept more than 1 response from each organisation.
- Do not paste other tables into this table – type directly into the table.
- Underline and highlight any confidential information or other material that you do not wish to be made public.
- Do not include medical information about yourself or another person from which you or the person could be identified.
- Spell out any abbreviations you use
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Note: We reserve the right to summarise and edit comments received during consultations, or

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Comments received during our consultations are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the comments we received, and are not endorsed by NICE, its officers or advisory Committees.