Glaucoma (update)

Consultation on draft scope
Stakeholder comments table

19 May 2016 – 16 June 2016

ID	Type	Stakeholder	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
1	SH	Royal college of General Practitioners (RCGP)	General	General	The RCGP advises that GPs and practice staff have an important role in glaucoma care in the community. As well as providing records of significant past medical history, current medication and allergies to optician's request for referral, GPs and practice nurses encourage patients and their carers to adhere to the glaucoma care pathway. This includes monitoring prescription refills, assessing the ability to use eye drops and any requirement for compliance aids, managing co-morbidities, ensuring communication between professionals and monitoring any side effects of treatment. There are many new developments that are likely to transform glaucoma care and it is unclear whether this will be in scope. There include · 24-hour IOP monitoring · advanced technologies for structural and functional imaging · increased understanding of glaucoma's genetic associations and variations to identify patients who are at the highest risk of progression · looking at potentially modifiable risk factors like smoking, diet, obesity, and exercise · new surgical techniques including Micropulse Laser Trabeculoplasty (MLT), Canaloplasty, Trabectome Surgery and the Ex-Press Mini Shunt	Thank you for your comment. We agree GPs have an important role in Glaucoma care. With regards to the new developments, please see our responses in turn: 24-hour Intraocular Pressure (IOP) monitoring – whilst continuous 24-hour monitoring may be suitable in some cases, the technology does not exist for this to be used widely and therefore will not be covered in the update of the guideline at this time. More broadly we will be looking at IOP measurement devices and the options for measurement. Advanced technologies – the technology for structural imaging will be included in the review as new evidence exists. The functional imaging technology will not be included in the update at this time as the NICE surveillance report did not identify this as a priority for update. Where appropriate the original recommendations will remain in the update. Genetic associations – this very specific area is not within the remit of our scope; however, we will be looking at clinical prognostic risk tools for identifying high risk groups. Modifiable risk factors – these are standard across all areas of health and we will be

Glaucoma (update)

Consultation on draft scope
Stakeholder comments table

19 May 2016 – 16 June 2016

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						looking at prognostic risk tools for identifying high risk groups. Surgical techniques – the NICE surveillance decision report identified that there was insufficient new evidence to include surgery in the update of CG85 at this time but it will be considered at the next surveillance review of the guideline.
2	SH	Royal college of General Practitioners (RCGP)	3	lines 22- 25	The RCGP finds this section confusing "Areas from the published guideline that will be updated". The guideline advises "We cannot accept comments on key areas 1–3 in this section but we will accept comments on key area 4 in this section and, all key questions in (section 1.5)." but the areas 1-3 appear to be included in section 1.5 on page 6 where comments will be accepted.	Thank you for your comment. We apologise for the confusion caused. It is only the key areas 1-3 in section 1.3 (Areas from the published guideline that will be updated) that we could not accept comments on. In section 1.5 (Key questions and issues), we welcomed comments on all points (1-4) in order to check we were asking the right questions. These prompts were for the purpose of the stakeholder consultation only and have been removed for the final scope.
3	SH	Royal college of General Practitioners (RCGP)	5	lines 14-16	The RCGP would like to know why population based screening is out of scope for this guideline.	Thank you for your comment. These were not included in the previous guideline (CG85) as it was under the remit of the National Screening Committee. This is still the case.

Glaucoma (update)

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Stakeholder comments table

19 May 2016 – 16 June 2016

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4	SH	Novartis Pharmaceuticals	6	27	We suggest that the test for "measuring intraocular pressure" should be broken down into subtypes e.g. Goldmann Applanation Tonometry (GAT) and other alternative tonometry techniques for measuring intraocular pressure in patients with glaucoma.	Thank you for your comment. The committee will consider which techniques to include in the review when they write the protocol for this question. We will ensure the committee is informed of your suggestion.
5	SH	Novartis Pharmaceuticals	7	8	Consideration needs to be given to full 24 hour monitoring of newly diagnosed patients or patients in whom reaching target IOPs is a challenge	Thank you for your comment. Whilst continuous 24-hour monitoring may be suitable in some cases, the technology does not exist for this to be standard practice and therefore will not be covered in the update of the guideline.
6	SH	Novartis Pharmaceuticals	7	17	When evaluating eye drops and their efficacy, consideration should be given to the full 24 hour effectiveness since not all agents work during the nocturnal period.	Thank you for your comment. We will review the effectiveness of eye drops and ensure the committee is informed of your suggestion when they are designing the review protocol and the outcomes to analyse for this area.
7	SH	Novartis Pharmaceuticals	7	8	We believe that it is important to look into issues of when to discharge people from secondary care to the community setting; and what tools health care professionals should use to access/identify risks of readmission.	Thank you for your comment. We agree this is an important area and to "clarify the role of optometrists" is included in the scope. We will consider the role of optometrists in re-referring patients who have been discharged from secondary care. The relevant tools for use by community optometrists will be considered as part of the discussion on case finding. In addition, question 4.2.1 is about whom

Glaucoma (update)

Consultation on draft scope
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19 May 2016 – 16 June 2016

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						should monitor patients and what tools should be used. Observation following discharge to the community will be considered in the context of these areas.
8	SH	Novartis Pharmaceuticals	7	18-30	The draft scope does not make any specific reference to clinical and cost-effectiveness of treatment as a function of varying disease severity in glaucoma. However, with the advent of new treatment classes (such as fixed combinations of Carbonic Anhydrase Inhibitors plus Alpha Agonist combinations), it is valuable to understand the value and potential economic impact of treatment associated with progressive disease severity. The development of new therapies may cost more at an earlier stage of care but ultimately could be associated with a reduced cost over the course of treatment by delaying progression of disease to later stages.	Thank you for your comment. The previous economic model conducted for this guideline took into account the different levels of disease severity and this will be included for the update of the guideline as well. In addition, this is addressed because the outcome is loss of sight from glaucoma within a patient's lifetime. Intensity of treatment is addressed in terms of progression to advanced glaucoma.
9	SH	Novartis Pharmaceuticals	7 & 8	18- 32 1-11	We believe that the guideline should cover effectiveness of switching therapies where first–line beta blocker combination therapy is contraindicated.	Thank you for your comment. Where initial therapy is inadequate or not tolerated, options for switching treatments will be considered when the guideline committee discusses the data, although we won't be conducting a separate review on switching treatments. In the previous guideline, recommendations took into account options for altering therapies when the recommended therapy was

Glaucoma (update)

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Stakeholder comments table

19 May 2016 – 16 June 2016

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						contraindicated. Beta-blocker fixed combination therapy was not recommended as a first line therapy. We will follow the same approach as CG85 for the update of the guideline.
10	SH	Novartis Pharmaceuticals	7 & 8	18-32 1-11	Minimally invasive glaucoma surgery devices should be included and evaluated in the same way that pharmacological treatments are being updated.	Thank you for your comment. The NICE surveillance decision report identified that there was insufficient new evidence to include surgery in the update of CG85 at this time but it will be considered at the next surveillance review of the guideline. There are on-going RCTs but these will not be published whilst the guideline is in development.
11	SH	Novartis Pharmaceuticals	8	1-24	There is an opportunity to estimate clinical and cost-effectiveness of treatment switching (i.e. patients who had switched from prior prostaglandin analogues to newer fixed –combination formulations).	Thank you for your comment. Where initial therapy is inadequate or not tolerated, options for switching treatments will be considered when the guideline committee discusses the data, although we won't be conducting a separate review on switching treatments. In the previous guideline, recommendations took into account options for altering therapies when the recommended therapy was contraindicated.
12	SH	Novartis Pharmaceuticals	8	21-24	The draft scope currently excludes patients who do not attend (DNA) the service; and we recommend that consideration should be given comparing disease progression in patients with high and low DNA rate.	Thank you for your comment. We recognise that this is an important area and that those who do not attend would be expected to have

Glaucoma (update)

Consultation on draft scope
Stakeholder comments table

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						worse outcomes. However this is not an area for the update as it is already covered within the NICE quality standard Glaucoma in adults (QS7 – Quality statement 8: Service capacity).
13	SH	Novartis Pharmaceuticals	9	3	It is important to consider the impact of treatment satisfaction and adherence on quality of life for patients switching to newer therapies.	Thank you for your comment. The guideline committee will consider the appropriate outcomes for each question when constructing the protocols.
14	SH	Novartis Pharmaceuticals	9	6	Currently, there are no data on the long term economic burden of the management of glaucoma. Hence, it would be important to consider annual direct medical cost of the management of glaucoma (i.e. first two years after diagnosis); and long term resource use and costs.	Thank you for your comment. In the previous guideline the long term burden of glaucoma was taken into account in the economic model and we will do the same in the guideline update.
15	SH	Novartis Pharmaceuticals	general	general	Poor adherence to medication is the biggest challenge of glaucoma management. For this reason, we welcome NICE clinical guideline to elucidate methods/strategies for improving patient adherence to glaucoma therapy.	Thank you for your comment. We agree that adherence is an important issue, and this is dealt with in more detail in the NICE guideline on Medicines Adherence CG76. During the update of this guideline, the guideline committee will consider the appropriate outcomes for each question (including adherence) when constructing the protocols.
23	SH	Royal College of Nursing (RCN)			No comments to submit to inform on the above draft scope consultation.	Thank you.

Glaucoma (update)

Consultation on draft scope
Stakeholder comments table

19 May 2016 – 16 June 2016

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24	SH	Department of Health (DH)			Thank you for the opportunity to comment on the draft scope for the above clinical guideline. I wish to confirm that the Department of Health has no substantive comments to make, regarding this consultation.	Thank you.
25	SH	NHS England	9	6	Section 1.6 Main Outcomes, the scope includes 'vision loss'; it is suggested that this should include patient perception of vision loss and impact on life skills.	Thank you for your comment. The guideline committee will consider the appropriate outcomes for each question when constructing the protocols. We will however ensure the committee is informed of your suggestion. Impact on life skills will be captured by health-related quality of life, which is an outcome that we will use to assess the evidence.
26	SH	NHS England	7	17	Section 1.5 Key Issues and Questions: 3 Treatment. It is suggested that patient choice of treatment and best practice associated with this decision making could be considered alongside cost and clinical effectiveness.	Thank you for your comment. Lay members (patient/carer representatives) form part of the guideline committee and they will help ensure that patient views are taken into consideration, where relevant. Please also see the NICE quality standard on Patient experience in adult NHS services (QS15) which includes shared decision making and the NICE medicines optimisation guideline NG5.

Glaucoma (update)

Consultation on draft scope
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						Please note the draft outcomes listed in 1.6 of the scope include side effects and treatment adherence.
27	SH	NHS England	13	20	Commissioning: Will the commissioning tools and associated documents be updated alongside the clinical guideline?	Thank you for your comment. The implementation needs of the topic will be reviewed nearer the time of publication.
28	SH	NHS England	12	12	Work carried out by the National Patient Safety Agency (NPSA) in 2009 found delays in patient follow up or patients who were 'lost' to follow up for glaucoma who suffered loss or deterioration in their vision. This ought to be mentioned alongside recommended review intervals. A Rapid Response Report alert was issued and can be found at: http://www.nrls.npsa.nhs.uk/resources/?EntryId45=61908	Thank you for your comment. We recognise that this is an important area and that those who do not attend would be expected to have worse outcomes. However this is not an area for the update as it is covered within the NICE quality standard Glaucoma in adults (QS7 – Quality Statement 8: Service capacity). The recently published RCOphth glaucoma commissioning guideline suggests a glaucoma register to assist with this problem.
29	SH	NHS England	1	18	The draft scope details who the guideline is for, we feel this this should include orthoptists as there are a significant number of specialist orthoptists working in both HES and community glaucoma services that this would be applicable to.	Thank you for your comment. We agree and have added orthoptists to the scope under 'who the guideline is for' on page 1.
30	SH	NHS England	general	general	We feel that the draft scope should include more specific examples of models for repeat measure, referral refinement and enhanced case finding with detail of the requirements of expected level of competence and accreditation. There should also be different case setting options included for low risk to high risk.	Thank you for your comment. We will consider the working relationship between the hospital eye services (HES) and primary care, including GPs, community optometrists and other Health Care Professionals in the update of this

Glaucoma (update)

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					Shared care should be considered for low risk patients that can be monitored in the community by the optometrist with established links (feedback to the HES). HES optometry led/orthoptic led services should be considered in the draft scope as there are a number of established schemes up and running that provide cost savings that are either based at the hospital or in the community. Clinics that run specifically for e.g. Direct repeat measure optometrist referrals to the HES, stable glaucoma clinics (low risk monitoring and management) in the community, mobile glaucoma services.	guideline.
31	SH	Glaukos Corporation	General	General1	The guideline Committee, in their consideration of the evidence, have made some very balanced and pragmatic observations that capture the realities of managing glaucoma in real world clinical settings. However, given that there is an opportunity to update the guideline from 2009, we find the exclusion of specific surgical options to be perverse. The objective of glaucoma management is to provide a significant and sustained decrease in intraocular pressure (IOP) that minimizes the risk of progression (i.e. visual field loss) and impact on the patient's quality of life. The current guidance only addresses pharmacological treatments for the treatment of ocular hypertension or suspected chronic open angle glaucoma (COAG), and surgery with pharmacological augmentation (mitomycin C [MMC] or 5-fluorouracil [5-FU]) for those with newly diagnosed early or moderate COAG whose IOP has not been reduced sufficiently to prevent the risk of progression to sight loss despite treatment with a prostaglandin analogue. Surgery to be considered is solely laser trabeculoplasty or cyclodiode laser	Thank you for your comment and information. The NICE surveillance decision report identified that there was insufficient new evidence to include surgery in the update of CG85 at this time but it will be considered at the next surveillance review of the guideline.

Glaucoma (update)

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Stakeholder comments table

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					treatment. The 2014 guidelines of the European Glaucoma Society note that laser trabeculoplasty is initially effective in 80-85% of cases with a mean IOP reduction of 20-25% (6-9 mmHg) but that the effect wears off over time. With trabeculectomy, long term IOP is achieved in many patients, although some patients may require further therapy or repeat surgery. Thereafter, invasive surgical management of glaucoma is recommended when medication and/or laser trabeculoplasty fail to lower IOP satisfactorily. However, filtering procedures such as trabeculectomy and glaucoma drainage devices, which are effective in lowering IOP, are associated with significant adverse events and failure rates. There therefore remains a significant demand for procedures that can effectively treat glaucoma with low risk and good visual outcomes. Although the NICE analysis found trabeculectomy to be most cost-effective for COAG, it was acknowledged that it was an invasive procedure and that the cost of complications may have been underestimated. In the Interventional Procedures Guidance 396, the Committee noted that compliance with glaucoma medication is often poor and that the usual surgical treatment is trabeculectomy. The Committee was advised that efficacious alternatives could also be useful for selected patients and that trabecular stent bypass microsurgery may be performed at the same time as cataract surgery, enabling cataracts and glaucoma to be treated simultaneously. The emerging field of minimally invasive glaucoma surgery (MIGS) has seen the introduction of the *ab interno* trabecular microbypass iStent,	

Glaucoma (update)

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Stakeholder comments table

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					which has been approved by both the US FDA and European CE process, and data from long-term randomized prospective trials have demonstrated the microbypass stent to be a relatively safe procedure, with limited complications and no serious adverse sequelae. MIGS devices are a new surgical treatment option with the following characteristics: (i) they can be implanted through a micro incision; (ii) they are implanted in *ab interno* procedures (i.e. without incising the conjunctiva or sclera); (iii) they improve physiological aqueous outflow; and (iv) they significantly lower IOP and reduce the need for multiple topical medications. The successful management of a patient's glaucoma, in terms of slowing the disease progression, is dependent on the patient's ability to adhere to the recommended medication regimen and to persist with the therapy. Nonadherence rates in glaucoma have been reported in up to 60% of patients, with reasons including forgetfulness, side effects, lack of affordability, difficulty administering drops, complicated medication schedules, poor understanding of the disease, and poor patient-doctor communication leading to lack of awareness of the slow but inevitable loss of vision. The problems with medication administration are of significant clinical concern in view of the need to reduce IOP in order to retard damage to the optic nerve and associated visual field loss. Therefore, reduction of medication burden would be of significant benefit to patients. Two prospective studies found that 70% of patients with mild to moderate OAG undergoing cataract surgery with iStent insertion were free of medications at 12 months of follow up, with a	

Glaucoma (update)

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					mean decrease of 1 medication. MIGS technology therefore has the potential to solve a variety of problems in current glaucoma management. These include minimizing patient adherence problems, increasing quality of life for patients with ocular toxicity, and potentially reducing lifetime costs of expensive glaucoma medications, all while preserving the conjunctiva if additional, more invasive glaucoma surgeries are necessary in the future. A recent review (April 2016) by the Canadian Agency for Drugs and Technologies in Health (CADTH) reviewed the evidence-based guidelines associated with surgical treatments for glaucoma, and identified several randomised clinical trials and observational studies that demonstrated both the clinical and cost effectiveness of MIGS in adult patients with glaucoma. In summary, the goal of glaucoma treatment is to maintain the patient's visual function and related quality of life, at a sustainable cost. We believe that surgical interventions, and especially trabecular stent bypass microsurgery, should be considered as a treatment option, and introduced sooner in patients diagnosed with open-angle, pigmentary or pseudoexfoliation glaucoma, mild to moderate in severity that is in the early stages who are not adequately managed with pharmacotherapy alone.	
32	SH	Glaukos Corporation	13	20	As noted in the Commissioning Guide for Glaucoma published by the Royal College of Ophthalmologists in June 2016, and accredited by NICE, "Commissioners should ensure they commission services that	Thank you for your comment. The NICE surveillance decision report identified that there was insufficient new evidence to include

Glaucoma (update)

Consultation on draft scope
Stakeholder comments table

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					offer surgery, with augmentation as appropriate, as detailed in the NICE glaucoma guideline and quality standard (Recommendation 19)" and "Commissioners should also note NICE guidance regarding new emerging surgical treatments and ensure they commission providers that are compliant with this guidance (Recommendation 20)". We feel it is important that evidence on all potential interventions, especially the new emerging surgical treatments such as MIGS, is adequately described and evaluated.	surgery in the update of CG85 at this time but it will be considered at the next surveillance review of the guideline.
33	SH	Optical Confederation + LOC Support Unit	General	General	We are very pleased that the vital role that community optometrists play in glaucoma case finding & their potential role for ongoing monitoring has been recognised. As the scope of the review of the NICE guidelines for Glaucoma has been expanded to include the important role that community optometrists have to play in glaucoma care it is essential that there is adequate representation from community optometrists on the Glaucoma guideline committee. NICE are in the process of recruiting members for this committee & we see that there are 4 consultant ophthalmologists, 2 community optometrists with an interest in glaucoma & 1 glaucoma trained optometrist so the balance is more towards hospital eye services rather than community. The range of community IOP and glaucoma practice is very wide - having evolved to meet the requirements of different hospital and commissioner models. To ensue this is captured we would strongly advise that there be three community optometrists, as well as a hospital optometrist (different type of clinician), with experience of the range of community service models in the community as well as straightforward referral, on the working group to ensure the full scope of community practice,	In addition to the Chair we plan to have 3 Ophthalmologists and 3 optometrists (community and hospital trained) represented on the guideline committee. The mix of optometrists has been chosen to mirror the volume of practice likely to be undertaken by optometrists.

Glaucoma (update)

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					model options and future possibilities is considered.	
34	SH	Optical Confederation + LOC Support Unit	General	General	It is important for NICE to recognise that NHS capacity for addressing the rising and unidentified levels of glaucoma in the population includes not only hospitals but also community ophthalmic services (commissioned locally just as hospital services are). They are both part of a continuum and need to be considered together, especially as the community sector has fewer workforce and facilities constraints than the hospital sector and can flex more easily to meet demand.	Thank you for your comments. We agree that community optometrists could potentially have an important role to play and to "clarify the role of optometrists" is included in the scope.
35	SH	Optical Confederation + LOC Support Unit	General	General	Although the tone of the surveillance report still reads as if the main issues are about hospital capacity, it is nevertheless reassuring to see that, this time round, the important role that community optometry plays in glaucoma case finding, pressure checking and ongoing monitoring has been recognised and included within the scope.	Thank you for your comments. We agree that community optometrists could potentially have an important role to play and are therefore included in the scope and represented on the guideline committee.
36	SH	Optical Confederation + LOC Support Unit	General	General	NICE should also be aware of the wider roles that optometry can play both within core skills and with higher training and qualifications to help the NHS respond to growing demand and unidentified need.	Thank you for your comment. As noted above to "clarify the role of optometrists" is included in the scope.
37	SH	Optical Confederation + LOC Support Unit	General	General	From our perspective it is therefore essential that, this time, there is adequate involvement of community optometry on the guideline committee including optometrists engaged in glaucoma care with both core and advanced skills.	Thank you for your comment. We plan to have 2 community optometrists and 1 hospital optometrist on the guideline committee.
38	SH	Optical Confederation + LOC Support Unit	4	1-4	LOCSU has developed a Glaucoma repeat readings & OHT monitoring pathway http://www.locsu.co.uk/community-services-pathways/glaucoma-and-oht/ We also collated all the evidence as part of our response to the Call to Action for Eye Health 2 years ago:	Thank you for your comment. We will take this pathway into consideration and will check your collated evidence report for references.

Glaucoma (update)

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					http://www.locsu.co.uk/uploads/call_to_action/copy_of_community_services_summary_september_2014_3.pdf	
39	SH	Optical Confederation + LOC Support Unit	12	19-23	The reason that recommendations for repeat measures & referral refinement in the NICE QS7 didn't fully resolve the problem is due to many CCGs not commissioning repeat readings services as advised in the NICE Commissioning Guide. Any possible amendments will still need resourcing to solve the problem.	Thank you for your comment. We hope that the updated guideline will be implemented by commissioners.
40	SH	Optical Confederation + LOC Support Unit	13	6	Instead of 'clarify the role of optometrists' we suggest 'take account of the role of community optometrists'	Thank you for your comment. We believe that clarifying the role is appropriate and that many optometrists would welcome a clear steer from the guideline.
41	SH	Optical Confederation + LOC Support Unit	13	8-13	It gives us no pleasure to note that, as we warned NICE in 2008, "an unintended consequence of publication of CG85 in 2009 was high levels of false-positive referrals to hospital eye services". This was entirely predictable but the influence of the community sector in CG85 was limited and the warnings ignored. We now face a situation in which the Royal College of Opthalmologists are warning (March 2016) that patients are losing their sight because of capacity pressures in hospitals. It is important that the work on these guidelines does not increase those pressures without evidence to justify referrals to hospital. Our exact response to the consultation is in the cell below; Currently a very large number of patients with intraocular pres-sure greater than 21 mm Hg, but with no other signs of glaucoma, are being successfully monitored by optometrists in the community with no evidence of visual loss occurring as a result. One of the	Thank you for your comment. We agree that the unintended flooding of the hospital eye service (HES) was unfortunate and that HES capacity issues are relevant. We anticipate that this update will remedy some of the adverse events from the previous guideline. NICE seeks to recommend excellent practice where evidence supports this, and will take into account implementation issues.

Glaucoma (update)

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					recommendations of the draft guidance is that OHT should be formally diagnosed for intraocular pressure greater than 21 mm Hg; a diagnosis requiring assessment of the anterior chamber angle by gonioscopy. Currently few optometrists are competent to perform gonioscopy (although all could be) and in order to conform with their legal and ethical obligations they will have no option but to refer all of these patients for a formal diagnosis before continuing to monitor them in the community. Unless the introduction of the guidelines is properly managed over a realistic timeframe many thousands of patients will be referred for a diagnosis over a very short period of time, overwhelming hospital eye departments with many false positive patients. We fear this sudden influx of very low risk, visually normal, patients will potentially disrupt the care of existing diagnosed patients, with a serious risk of unnecessary disease progression and visual impairment. If implemented we believe this guideline should be phased in, preferably over a 3 to 5 year timescale	

None of the stakeholders who comments on this clinical guideline have declared any links to the tobacco industry.