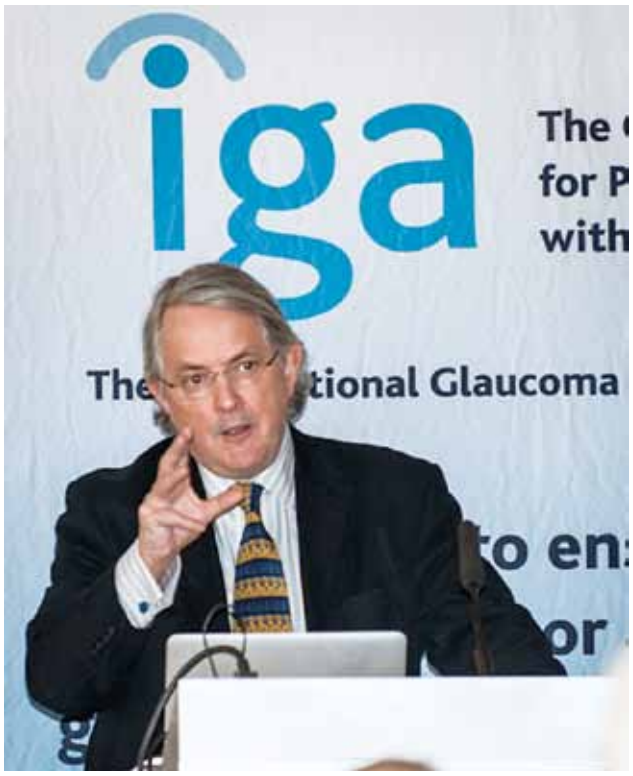
Janice Krushner Memorial Lecture 2012

Patient involvement in standards of care, outcomes and research

Mr Richard Wormald MA MSc (Epid) FRCS FRCOphth
Consultant Ophthalmologist, Moorfields Eye Hospital

Richard Wormald is a consultant at Moorfields Eye Hospital and an Honorary Senior Lecturer for the London School of Hygiene and Tropical Medicine, and University College London. He specialises in glaucoma, blepharitis and cataracts, and has worked at Moorfields since 1994.



My background that is relevant to my talk this afternoon is my role as the coordinating editor of the Cochrane Eyes and Vision Group. The Cochrane Collaboration is all about producing evidence for practice, and the best possible evidence is produced in a systematic review of everything we know (and quite often everything we don't know). I'm funded by a grant that goes to Moorfields from the Biomedical Research Centre for the National Institute for Health research (NIHR) and I like to acknowledge them in everything I say. The Cochrane Collaboration itself is funded by a whole lot of different agencies, but particularly in the UK by the NIHR as well as the National Health Service (NHS). The NHS wants to have the best possible information it can get to make decisions about how it should or should not be spending its money.

Did anybody hear the obituary for the founder of the International Glaucoma Association (IGA) and its first Chairman, Mr Ronald Pitts Crick, on Last Word some time ago? It was back in July 2009 and, in the programme, Peter White emphasised the importance of the role of the IGA to look after the

needs of patients, to help patients manage their own problem. He also referred to ophthalmologists as being rather 'Olympian' in their attitude, implying they are up there, on top of a mountain somewhere, and they're not really particularly in touch or in contact with their patients and they're not the greatest communicators. But Ronald, of course, was totally different, and the whole point of the IGA was to empower patients with a better understanding of their disease. That's very much really what I'm talking about this afternoon.

So, whose disease is it anyway?

It's your disease! It's not my disease, it's your disease, but I (as your ophthalmologist) gave it to you. Right?

You have had the benefit of my gift of a disease that gave you no symptoms, of which you had no knowledge and yet I'm telling you that you've got something which, if you don't do something about it, will make you go blind!

So this is a very very particular kind of problem: glaucoma, which creates huge challenges for you and for me especially in terms of our communication. We want to detect glaucoma long before you know you've got it, because we think that early detection will improve the outcome. There's a constantly repeated mantra about the importance of early diagnosis, because of the belief that if we get it early, we can stop people losing their sight in the long-term.

Very often there is a gap between hard scientific evidence and a belief that a treatment or management regime works. Indeed, glaucoma was treated for well over 100 years before we had scientific evidence to support the treatment (we have it now), but there was the evidence of experience and the evidence of inference on which to base our efforts. In the case of early detection leading to an improved long term outcome, I think that the real evidence to support that statement comes from an indirect association with the fact that we know if people come too late, then they have a poor prognosis. However, it doesn't necessarily follow then that everybody has to be 'given' the disease at an earlier and earlier stage, and it has been suggested that this leads to a lot of over diagnosis of glaucoma.

There is an enormous potential for over diagnosis, especially as we can now see abnormalities of structure of the optic nerve head long before there is any functional abnormality that we can detect. Does such an abnormality really constitute disease? Should we be putting structural abnormality as part of the case definition of glaucoma? Where is the

dividing line between a suspicion of glaucoma, which should, perhaps, be monitored to make sure that it is really there, and the definite disease, which needs all our resources? Even the National Institute for Health and Clinical Excellence (NICE), whose whole remit is based on 'evidence', couldn't really make a decision about where that line falls and the question remains unresolved at present.

So, when do you get the 'glaucoma' label and when are you just 'under suspicion'?

In my opinion we shouldn't give the 'glaucoma' label to anybody until we are completely sure that this is a progressive problem that we've got to treat. Quite a lot of people have an abnormal looking optic disc, some have a slightly raised intraocular pressure (IOP) and some possibly have a visual field defect, but the critical question is: 'is it getting worse?' We can't know until we've tested over a period of time.

There is a scary, often forgotten, fact about outcomes from a very old survey of eye disease in the United States, in which researchers were trying to estimate the prevalence of glaucoma in European ancestry population in Wisconsin. They had pretty robust case definition for glaucoma and they found out of 108 people who already had a diagnosis of glaucoma only 10 people actually had the condition, and the vast majority of the people who had been told they had the disease when they didn't in fact have it were women.

In America, of course, you have a health system that's running on profits and in such a case it could be argued that glaucoma's a gift because in glaucoma it is recognised practice to treat the condition before it has any symptoms, so the patient cannot know if they do or do not have the condition. However, even within the NHS there is probably quite a lot of over diagnosis. I spend a lot of time in my clinic in Moorfields saying to people 'You've been coming for 10 years and the good news is you haven't got glaucoma.' They are, of course, very surprised and usually want to know why they have been coming for 10 years if there's nothing wrong with them. The fact is that it can take a very long time to be sure. We have to examine people many times to be absolutely certain, and absolute certainty is essential because, as we all know, we can't give back sight that has been lost to glaucoma.

Does being involved more matter?

The received wisdom is to get involved – for you to 'own your disease', to be in control because you'll get a better outcome, but what's the evidence for that? Not everybody thinks this is a great idea, particularly

in terms of self-monitoring your own IOP for instance. There's no research to tell us either way if it is improving outcomes. Some doctors hate the idea; they are worried that they are going to have phone calls in the middle of the night from people saying 'My pressure's gone up to 23! What am I going to do about it?'

Self monitoring has been proposed for many chronic conditions: for heart failure, for the management of anti-coagulation in people who've had strokes or who have atrial fibrillation, and in the management of thyroid disease, thyroid deficiency. For maturity onset diabetes self monitoring is well established and there are five randomised controlled trials in which patients were randomised to testing their own blood glucose or not, and two of those randomised controlled trials, large trials, showed that patients who were monitoring their own blood glucose had lower levels of something called haemoglobin A1C. Haemoglobin A1C is a good marker for the risk of getting the long term complications of diabetes. So this suggests that giving patients the power to monitor their own blood sugar had a positive impact.

This is therefore one research question that is worth asking: 'Does self-monitoring of IOP improve outcomes?' At the moment, we simply don't know the answer and only large scale randomised controlled trials can give it to us providing that reliable technology exists to allow self measurement of IOP. Several devices have been tried, with the first being tried some 20 years ago. However, there are problems. I tried one of the new devices out on myself at a recent ophthalmological conference. You had to hold the device against your forehead and a little plastic probe bounces off your cornea between 6 and 12 times. You can feel it but it doesn't hurt and you don't need drops. It is actually quite clever because it records the readings electronically and downloads them onto a computer on which you can store your information over time. It is not ideal because you have to be able to be stand up perpendicularly upright. You can't be leaning forward or back, and if you've got a tremor in your hand then you can't use it, but it might be good for some people.

It might also be good for the NHS because we still have to admit some people for up to 24 hours to measure their pressure again and again (known as phasing), and that costs the NHS an awful lot of money. If we were able to have people measure their own pressure repeatedly over 24 hours (just as people do with their blood pressure and blood sugar) it may be quite an important step forward for us in our understanding of what's going on over time.

Standards of care

So, let's move on to standards of care. What are they? What are they for? Who sets them? Who monitors them? Are patients involved?
The first thing I want to talk about is the NICE Guideline for Glaucoma (CG85) and the NICE Quality Standards for Glaucoma. Your Chief Executive, David Wright, was a member of both development groups, together with one patient member of the IGA. I don't want to bore you if you already know all about these standards, but I think it would be good to discuss them a little bit and also, perhaps, get your views on them.

I'm just going to read you a little of what they said:

'Chronic open angle glaucoma, suspected chronic open angle glaucoma and ocular hypertension are common conditions which, if not diagnosed and managed correctly, can lead to partial-sightedness, sight impairment and blindness, severe sight impairment. This quality standard describes markers of high quality, cost effective that, when delivered collectively, should contribute to improving the effectiveness, safety and experience of care for people with chronic open angle glaucoma, suspected chronic open angle glaucoma or with ocular hypertension.'

Overview of statements:

The recommendations came from glaucoma, diagnosis and management of chronic open angle glaucoma, ocular hypertension, NICE clinical guideline 85 published in April 2009 (Ref 1-3), I had the mixed benefit or disbenefit of being on that guideline development group, as did David Wright.

These recommendations were developed into nine draft quality statements by the topic expert group, which also involved David Wright. A further three draft quality statements were developed from the College of Optometrists and the Royal College of Ophthalmologists, joint guidance (Ref 4) and a National Patient Safety Agency (NPSA) rapid response report about the way peoples' appointments get deferred when clinics get too full (Ref 5).

People at increased risk of developing open angle glaucoma include those over 40 years of age, those with ocular hypertension, those with a family history of glaucoma, those of African or African Caribbean origin, those with diabetes and those with moderate or high myopia. There's some question about the level of increased risk caused by some of those risk factors, but they're making a very clear statement about equity of access. This remains, I think, a big challenge to preventing blindness from glaucoma in the NHS because

people's access to sight tests is not equitable. Firstly, you have to pay for a sight test (unless you qualify for an NHS funded sight test or take advantage of one of the companies offering free testing) and if you don't know about the importance of sight testing, you are unlikely to be aware of the provisions for 'free' testing. There is also a perception that by taking a test, you are at risk of having to spend a lot of money on an expensive pair of glasses (this is, of course, not true – firstly, no one can make you decide to have spectacles and secondly, you are at liberty to take your prescription and have it made up at any optician, not necessarily the one that tested your eyes), but these are still disincentives to go for a sight test.

The quality standard for glaucoma in adults requires that the services should be commissioned and coordinated across all relevant agencies, encompassing the whole glaucoma care pathway including primary, secondary and social care. An integrated approach to provision of services is fundamental to the delivery of high-quality care to people with glaucoma.

A local register of glaucoma-related conditions, organised according to diagnosis, for example could facilitate such integration. That's an interesting idea but not everyone here would like to be on such a register, so while it would make a difference to the management of the health and social care services as a whole, it could be difficult to implement.

The Quality Standards:

1. People are referred to a consultant Ophthalmologist for further assessment and definite diagnosis, if the Optometrist or other healthcare professional suspects glaucoma.

There are local agreements in place for referral refinement, but what that is saying is the person who gives you the label has got to be qualified to do it. But it's a great responsibility to say to someone, 'you've got this disease and if you don't take treatment for the rest of your life, your sight is threatened'. You only have to say to a patient once 'oh you might have glaucoma' and it doesn't matter how many times afterwards, we say 'no, you haven't got glaucoma', at the back of their mind, they're thinking well, why did somebody say I had glaucoma? They're always going to have that doubt. So that's why it is so important to get the right label on the right person.

2. People with elevated IOP alone are referred to an appropriately qualified health care professional for further assessment on the basis of perceived risk of progression to open angle glaucoma. There are

agreements in place for repeat measures.

So this is talking about referral – 'don't send everyone to the hospital if they haven't got any other problem'. Refine the referral – don't clog up the system with people who don't need to be there.

3. People referred for definitive diagnosis, in the context of possible open angle glaucoma, or with ocular hypertension receive all relevant tests in accordance with the NICE guidance.

The standards in the NICE guidance are bottom line basic standards. They are nothing fancy, but you have got to have the pressure measured properly, you've got to have a proper standard automated perimetry field test, and gonioscopy and a good quality assessment of the condition of your optic nerve head. These are the absolute minimums for a diagnosis to be made.

4. People with glaucoma, suspected glaucoma or with ocular hypertension are diagnosed and have a management plan formulated by a suitably trained healthcare professional with competencies and experience in accordance with NICE guidance.

This standard guarantees that you will have an individual management plan drawn up by an experienced and properly qualified person to ensure that your condition is controlled as well as possible.

5. People diagnosed with glaucoma, suspected glaucoma, ocular hypertension are monitored at intervals according to their risk of progressive loss of vision in accordance with NICE guidance.

Here's a statement that says 'you can't keep having your appointment cancelled or deferred if you're at a certain level of risk'. It's got to be within a time-frame that's laid down in the NICE guideline.

6. People with suspected glaucoma, ocular hypertension, are managed based on an estimated risk of conversion.

So, again, it's the same thing. If someone is at low risk of conversion from ocular hypertension to glaucoma, they don't need to be seen frequently, but if they're at high risk, we must see them more frequently. Those intervals are given in the guidance.

7. People with open angle glaucoma, suspected open angle glaucoma, ocular hypertension, have regular reviews of management options with their healthcare professional, taking into account co-morbidity in other changed circumstances,

including a discussion of the benefits and risks of stopping treatment for those at low risk of progressing to visual impairment.

So, not being treated or stopping is also an option.

8. People diagnosed with glaucoma... have access to timely follow-up appointments and special investigation at intervals in accordance with NICE guidelines.

So this is the national patient safety agency coming in again. You can't have your appointments deferred and it says 'sufficient capacity is put in place to provide this service and systems are developed to identify people needing clinical priority if appointments are cancelled, delayed or missed'. This is a strong message to Commissioners. They have to commission adequate capacity to meet the need, the number of the people on that register in the local area or local authority.

9. Health care professionals involved in the care of a person with glaucoma, suspected glaucoma... have appropriate documentation and records available at each clinical encounter in accordance with NICE guidance. They're not allowed to have missing notes.

Now, of course, one of the greatest challenges, one of the most exciting things that's going to happen to glaucoma care in the future, is the electronic patient record that enables us to summarise the patient's experience and access that information a lot more efficiently, reliably and quickly, but even before this is universally available, the standard demands that the records are available at every consultation.

10. People with glaucoma who are progressing to loss of vision despite treatment or who present with advanced visual loss are offered surgery with pharmacological augmentation as indicated and information on the risks and benefits associated with surgery is properly provided.

So, surgery has got to be offered at the appropriate time, and actually the NICE guidance recommends the offer of surgery when two drugs are insufficient to control the pressure. So not multiple medications: it should be if two drugs are insufficient to control, then surgery should be offered. It doesn't have to be accepted, but it should be offered.

11. People with glaucoma...are given the opportunity to discuss their diagnosis, prognosis and management and are provided with relevant and accessible information and advice at initial and subsequent visits in accordance to NICE guidance.

That's really important. You've got to be told what's going on and what's going to happen to you, and you've got to be allowed to ask and you've got to be allowed to get an answer.

12. People with suspected glaucoma or with ocular hypertension who are not recommended for treatment and whose condition is considered stable are discharged from formal monitoring with a patient held management plan.

And the last one is if you haven't got glaucoma, you haven't got to be dragged back to clinic for the next ten years of your life; you can be discharged with a management plan telling you that you're OK but to get a check up each year with your local optometrist.

So, those are the 12 commandments which are out there and in this guidance, in the appendices; they are the actual bits of the NICE guideline that tell you what the follow up intervals should be and so on, and the thresholds of treatment.

Outcome measures (saving sight)

Now I want to go on to talk a little bit about outcomes because there's not much in the Quality Standard about the outcomes of your treatment. It's all really about the process of your treatment, but what really matters is 'are you doing well?'

How do we measure the quality of your care in glaucoma in terms of outcome measures?

We as ophthalmologists desperately need good outcome measures, so that we can measure the effectiveness of our treatment, so that we can say to NICE, or to the Government, 'look, we can show what we're achieving for the money you're giving us in terms of saving sight'.

It would be wonderful if we could say how many people we've cured of glaucoma, but I'm afraid that's not an option yet. It would be great if we could measure an improvement – can we say we're making people better? Not yet. Maybe one day. Prevention of progression – now that's different – we can be definite about that – we can prevent progression. We've got good evidence that we can prevent people getting worse by lowering the pressure. But progression can still occur with people on treatment, and progression doesn't always occur with people who have quite high pressure. So pressure is not an absolutely reliable connection to the thing that really matters to you and to me, which is whether or not there's evidence of progression.

However, there really doesn't seem to be any other option for treatment at the moment except lowering the intraocular pressure. We want to

know how we can save nerve fibres, working in a way that's independent from lowering pressure and there is much research under way across the world looking for neuro protective drugs, but as yet the evidence is weak, except for pressure lowering medications.

If we accept that the most important outcome is the prevention of progression, it is understandable that there's a lot of interest in how we can measure progression, which depends on doing the visual field tests and probably doing them more often. Are there other structural changes that we could be looking for in the optic nerve or in the retina? Retinal nerve fibre layer thickness perhaps?

There's a lot of interest in this with the new OCT devices, but how reliable are they in measuring progression? That's the thing we really need to know, and only time and experience over the long term will tell us. Making the diagnosis is one thing (we know they are very helpful at that important task), but measuring change over time is the subject of a lot of research that the IGA Professor, Ted Garway-Heath, does at Moorfields, trying to find out the repeatability and the validity of changes that are observed in these things and how they actually relate to real progression of the disease.

What has taken us a long time to realise – what is really, really important to you – is your quality of life and the impact of this condition and its treatment is having on that quality of life. There are quite a lot of measures of quality of life in people with glaucoma out there and they've been evaluated systematically but none of them are all that robust.

One of the most important things for many people is, of course, driving. I had a patient on Monday who came to me because he'd lost his driving licence, and he was utterly, utterly shattered. His quality of life was ruined. The committee that sets the driving standard has produced a standard that is not based on actuarial risk but rather on a perception of risk.

The thing is that insurance companies have actuarial risk data on what your likelihood is of having an accident and how bad an accident is likely to be according to your disease and all sorts of other information, but that information is not available to us, because it's commercially sensitive.

There is research that's been done by Professor David Crabb and others who have looked at people who have got field loss and the way they try to compensate for missing parts of the visual field when they're driving (in simulated driving conditions) but the results of this research (and of others looking into similar questions) have

not yet been accepted and, because everyone drives differently, it may be very difficult to define a set of criteria based on such evidence.

Setting driving aside for a moment, there is some measure of disability that is the effect of glaucoma, some threshold that you go past, with a chronic progression of this condition which is the place we want to stop people arriving at. We don't quite know what that is and we would like to know from you what you think that is. At what point has it gone too far? Now, quite of lot of people get the diagnosis when it's already gone too far, and that's pretty straight forward. But where do we say 'right, that's enough. It shouldn't have got this bad'. Because if we had a way of looking at the effectiveness of our interventions, one outcome measure would be:

How many people reach that threshold under this treatment, and how many people reach that threshold under another treatment?

That would help us decide which is the better way of delivering treatment.

Getting involved in research

So, this is the last bit of the talk, 'getting involved in research'.

I think I've made the case that there is a lot you can do to help with research, but still in the minds of many it's an extremely unattractive idea. Why be a guinea pig? Why would you want to be experimented on when God knows what might happen?

Well, the answer is that you've got an awful lot to contribute!

It's become a requirement for all National Institute of Health Research (NIHR) funded studies to have something about how you've involved your patients in developing the proposal. If you haven't ticked that box, they're not likely to get the money.

I've got a nice picture of someone wearing a T-shirt saying 'when I want your opinion I will give it you'. It is not about that, it's about giving us your opinion in a way that actually affects outcome and affects the quality of the research.

I told you that I'm coming from a background with the Cochrane Collaboration which is all about systematic reviews and evidence based health care. We've involved consumers in developing these systematic reviews since 1994. The most common thing consumers do, as they were called in the collaboration, is to comment on pre-published systematic reviews, best evidence or health care interventions and to comment on the protocols, on the way we go about collecting information and synthesising and

disseminating it (the road map on how the review is done, effectively). This means commenting on the summaries of reviews in plain English and producing those summaries and also actually being involved in raising awareness of the need for evidence in day to day health care delivery and many other areas of involvement.

Here's quite a nice quote from a consumer advocate for the collaboration back in 1994: she said 'The notion of collaboration between professionals and consumers is a complex one. My dictionary reminds me that one of the meanings of collaborating is cooperating treacherously with the enemy'.

Actually, we may laugh, but there is sometimes that kind of relationship between patients and doctors, and there's a similar attitude behind the concerns about giving you the disease to control. We're scared about what's going to happen.

One of the great things that the Cochrane Review, especially the Cochrane Eyes and Vision Reviews, does is to point to areas of uncertainty of the effectiveness of eye health interventions and the example I should like to use here is laser trabeculoplasty treatment in glaucoma.

It's quite a nice treatment, laser trabeculoplasty. It's been around for quite a long time. It looks like it works, but not a lot of people use it. There's an uncertainty about whether it really does work or whether its effect lasts. Why is there uncertainty? Because the studies haven't been done.

We've had selective laser trabeculoplasty around for at least 12 years, but there have been very few good quality studies that tell us whether or not it's safe and effective in the longer term. Why? It's possible to market these machines. It's possible to sell them without people actually knowing how well they actually work, because they're not a drug. They're a device. And you can use devices without any kind of regulatory control, unlike drugs. Now is that good enough?

There's a database on the NHS evidence website of the uncertainties of the effects of treatments, called DUETS and you can look under eyes and vision and there's a long list of uncertainties, questions about the effectiveness of health care interventions that have not been properly answered. The man who set up the Cochrane Collaboration went on from setting up this database of systematic reviews and database of uncertainties, to a thing called the James Lind Alliance (JLA), and I hope this is something that the IGA are going to hear a lot more about in the next year or so. (See the centre pages of this edition of IGA News)

This is an alliance of health care

professionals and patients and other clinicians who want to involve patients and their carers in prioritising research questions. Setting the research agenda, you as the potential beneficiaries of research saying 'these are the questions we want to get answers to'. It's been very exciting: the JLA started three or four years ago, perhaps a bit more; I think they started out with asthma and they identified a whole lot of questions that nobody would have thought of doing research on and answering.

So, for sight loss and vision, the James Lind Alliance has agreed to help us in collaboration with Vision 2020 UK and Fight for Sight, and the IGA will certainly be involved in asking questions around interventions for glaucoma, and research questions in glaucoma.

So, I hope I've primed you a bit for the opportunity to think about the questions you think you'd like to see the subject of prioritised research. The point is to get more funding into eye research and to get questions answered that are relevant to patients, their carers and the public.

There are the resources on the web. There's an organisation called Involve, and they provide information about how to learn more about being involved in research. So if you search on Involve on Google, you'll find out about it.

There are a number of different publications. So you can make sure that researchers ask the right questions, keep research on track so that it stays relevant. Make sure the people being researched are approached in the right way, and dealt with with sympathy and courtesy, and improve the quality of the research by adding another point of view on the design and conduct. It means that you might well be invited to participate in randomised controlled trials. You have to think about how you feel about being randomised to a new intervention or an old intervention or no treatment, but that's all part of contributing to the evidence base, but also in studies on screening and diagnostic accuracy and so on and so on.

So, to finish, glaucoma is a condition that we give to you. You don't have any symptoms. We give you a sword of Damocles to hang over your head for the rest of your life. I believe that giving you ownership: not just the sword of Damocles, but the way to monitor how thin that string is getting, and what you can do about wearing a helmet, is very, very important to improve your quality of life.

Francis Bacon said knowledge is power. I'm sure it's true in this case, as is sharing the knowledge in proper communication between patients and their carers.

Thank you very much.

References:

http://guidance.nice.org.uk/CG85/Guidance/pdf/English Full text NICE Guidance downloadable pdf

http://guidance.nice.org.uk/CG85/QuickRefGuide/pdf/English Quick reference guide - downloadable pdf

http://guidance.nice.org.uk/CG85/PublicInfo Patient Guide downloadable pdf

http://www.college-optometrists.org/en/utilities/document-summary.cfm?docid=14D0AC7E-06FC-4453-BAFBEEC13E236C21 College of Optometrists and Royal College of Ophthalmologists Joint Guidance on Glaucoma (reference NICE CG85) downloadable pdf

http://www.nrls.npsa.nhs.uk/resources/type/alerts/?entryid45=61908 Rapid Response Report Glaucoma

http://www.invo.org.uk/Involve

http://www.cochrane.org/