



The ROYAL COLLEGE of
OPHTHALMOLOGISTS

Ophthalmic Services Guidance:

Clinical Audit and Clinical Effectiveness in Ophthalmology

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1. Introduction

All doctors have a duty to understand, and participate in delivering quality, safety and clinical governance in modern healthcare as described in the General Medical Council's (GMC's) Good Medical Practice Domain 2.

This document aims to provide a simple overview of the principles and practice of clinical effectiveness and clinical audit for ophthalmologists, and should be read in conjunction with the College publication [Quality, safety and clinical governance in ophthalmology: an overview](#).

Clinical effectiveness is one of the three arms of healthcare quality defined by Lord Darzi in 2008 and can be defined as *“Care which provides good outcomes, that is good results or success of care for patients. This can be assessed both through clinical outcome measures, such as mortality/survival rates, complication rates, and through patient reported outcome measures (PROMs) such as a patient’s assessment of their own symptoms and quality of life measures”*. Clinical audit and the use of evidence based guidelines fall within this quality domain.

2. Clinical audit

Clinical audit is defined by the National Institute for Health and Care Excellence (NICE) as *“a quality improvement process that seeks to improve patient care and outcomes through systematic review of care against explicit criteria and the implementation of change.”* It differs from research in that, whereas research defines what is best practice where there is uncertainty and advances our knowledge, audit measures whether the already known best practice is actually occurring in clinic care and nearly always it should lead to change and reassessment later. The audit cycle describes this continuous process of review and implementation of change and involves the following steps:

1. Identify the topic and the question
2. Select standards – the audit criteria (audit criteria are simply the explicit standards against which care will be measured)
3. Measure performance/practice
4. Compare performance with standards and see where the standards are not achieved – these are the areas for improvement
5. Make improvements
6. Re-audit to ensure improvement has been achieved

For an audit to be worthwhile it requires careful planning. The choice of topic must be relevant to both the local situation and the patients and professionals involved. The aims and standards must be both realistic and valid. Data collection must be well thought out and undertaken accurately so that when data are analysed, a true and representative impression of practice is formed. The results must be carefully interpreted and any changes to practice implemented with full agreement of those involved or affected. Re-audit at a later time completes the audit cycle and should affirm adjustments to practice implemented in the earlier cycle(s) have had their desired effect and have not created other issues which need addressing. Most clinical audits that fail do so because they are undertaken as a tick box

exercise to fulfil a perceived duty and/or due to the failure to devote some thought and time to what is being done, and why and how it might help care and patients.

3. Why audit?

Apart from the fact that it is a professional and regulatory duty for providers and individual ophthalmologists to participate in clinical audit, it can, if done well, be very beneficial for the auditor, the unit and patients who can be reassured that good care is being provided.

Audits are broadly undertaken for two purposes:

1. Simple and brief quality assurance (QA) audits to ensure key areas reach a minimum standard e.g. annual audit of personal posterior capsular rupture rate in cataract surgery for annual appraisal.
2. Quality improvement (QI) audit.

Quality assurance audits allow you to:

- Demonstrate current best practice is in place
 - High quality
 - Low harm
- Provide evidence that there is good quality of care to
 - Patients
 - Regulators such as the Care Quality Commissioning
 - Peers
 - Professional bodies e.g. General Medical Council, The Royal College of Ophthalmologists
 - Commissioners
- Share your outcomes
 - Benchmarking for other units
 - Present at conferences and publish in journals
 - National ophthalmology audit
- Fulfil appraisal / revalidation

It is worth bearing in mind that these sorts of audits are likely to become more frequently required as the introduction of outcome based commissioning and specialised commissioning by the new Health and Social Care Act (2012) means that at least some of any provider's income will be based on the achievement of key standards of care which require an audit to assess.

There are certain areas where you would reasonably expect any provider or professional providing this care to perform regular QA audits:

Table 1 Quality assurance audits

Audit	Guidance adherence	Outcomes
Cataract surgery	College guidelines on cataract and cataract anaesthesia NICE (once published). College Quality Standards for Cataract Adherence to protocol if any extended roles for Health Care Practitioners (HCPs)	Posterior capsular rupture rate Visual Acuity (VA) results <i>Ideally via National Ophthalmalgia Database audit</i> Actual vs planned postop refraction Endophthalmitis rates Number wrong Intraocular Lenses
Medical retina	Adherence to NICE guidance on intravitreal injections College AMD guidelines College RVO guidelines College DRS guidelines College QS for MR Adherence to protocol if any extended roles HCPs	Injection endophthalmitis rates Other injection complications % eligible Certificate of Vision Impairment registered Number never events (wrong drug, wrong eye) injections Delays in follow up VA loss and gain after intravitreal injections in Age-related Macular Degeneration (AMD)
Vitreoretinal	College Quality Standards for vitreo retinal surgery	% reattachment primary retinal detachment surgery % closure macular hole surgery Macular hole VA outcomes Complications <i>Ideally via national VR dataset</i>
Adnexal	College Quality Standards for adnexal	
Paediatric & strabismus	College Quality Standards for Paediatric Ophthalmology College Retinopathy of Prematurity guidelines	

Neuro-ophthalmology	College Quality Standards for neuro-ophthalmology NICE TIA guidance	
Glaucoma	Adherence to NICE guidance on glaucoma care Adherence to protocol if any extended roles HCPs	% eligible CVI registered Delays in follow-up Success trabeculectomy and tube surgery
Cornea	College Quality Standards for cornea	% submission yellow forms corneal national audit % success/failure at 1 year for PK and lamellar grafts
Theatres	Use ophthalmic WHO checklist audit	Unexpected return to theatres Never events

Quality Improvement audits allow you to:

- Improve quality of care
- Reduce risk, harm and clinical mistakes
- Increase efficiency and effectiveness
- Direct resources or provide evidence for requirement of resources (e.g. in a business case) for staff, equipment, training

4. Key bodies

Healthcare Quality Improvement Partnership (HQIP) is an independent organisation led by the Academy of Medical Royal Colleges, The Royal College of Nursing and National Voices, established in 2008 to increase the impact of clinical audit on quality improvement. HQIP commissions, manages, supports and promotes national and local quality improvement and audit. This includes the national and local clinical audit programmes, the Clinical Outcome Review Programmes, the National Joint Registry and the Royal College of Ophthalmologists' National Ophthalmology Audit.

The Royal College of Ophthalmologists (RCOphth) provides advice and guidance on clinical audit in ophthalmology and also promotes audit via: its scientific publications; publication of various national audits or surveys; national ophthalmology datasets; the National Ophthalmology Database Audit; and presentations at the Annual Congress. At Congress, high quality audits are accepted as poster and oral presentations.

5. The National Ophthalmology Database (NOD) Audit and Ophthalmic Datasets

Previous efforts to establish a national electronic care record solution (Connecting for Health and the National Programme for IT) disappointingly failed to deliver, but the collection and analysis of comparable data as a by-product of routine clinical work across many ophthalmic units remains an achievable ambition through intraoperable specialty systems deployed at local level. Adherence to agreed data forms and formats are key to valid 'cross boundary' and 'through time' comparisons. The Cataract National Data set has paved the way for this in ophthalmology and generated multiple publications including a multicentre analysis of over 180,000 cataract operations. Such large volumes of data not only provide precise benchmarking estimates but also permit statistically powerful analyses of risk indicators which can then be used to risk adjust for the case complexity of individual surgeons, thus making comparisons against benchmarks and their confidence limits more meaningful. Of potentially immediate benefit to patients is the ability to routinely quantify risk strata preoperatively in order to ensure that higher risk operations are undertaken by the most experienced surgeons and consent discussions can be based on individualised risk rates.

The RCOphth has been commissioned by HQIP to provide the National Ophthalmology Database (NOD) Audit as part of the National Clinical Audit and Patient Outcomes Programme (NCAPOP). The NOD Audit will prospectively collect, collate and analyse the cataract surgery national dataset from all centres providing NHS cataract surgery in England and Wales to update benchmark standards of care and provide a powerful quality improvement tool. In addition to cataract surgery, electronic ophthalmology feasibility audits will be undertaken for glaucoma, retinal detachment surgery and age related macular degeneration (AMD).

The national cataract audit will utilise validated and risk (case complexity) adjusted measures of quality which discriminate between centres and surgeons. Initially these will be based on legacy (historic) EMR data up to the end of the 2014-15 NHS year. All EMR databases with national dataset compliant data will be eligible for data submission. The first prospective phase of the audit is due to report on surgery undertaken between 1 September 2015 and 31 August 2016. To facilitate participation centres will be provided with EMR data collection tools where needed, allowing both EMR and paper based centres to be included. In addition, there is a web based tool for optometrists to return visual acuity and refractive data directly back into the patient's EMR record. Following appropriate local information governance permissions data from electronically enabled units are remotely extracted to a secure server within the NHS firewall. Data are pseudonymised, checked for errors as far as possible and descriptive analyses produced. Summarised data are presented on the audit website, www.nodaudit.org.uk such that contributors are able to view data from their own centre in the context of data from all participating centres. Contributors are also able to use these data for personal audit with benefits in terms of appraisal and revalidation. Relevant aspects of the audit will be submitted for peer reviewed publication in medical journals and prospective results will in due course be publically available via annual reports and the NOD Audit website.

A number of non-cataract national datasets are available (e.g. retinal detachment, macular hole, strabismus, corneal cross linking, cosmetic surgery) and more details of these can be found on the [College website](#).

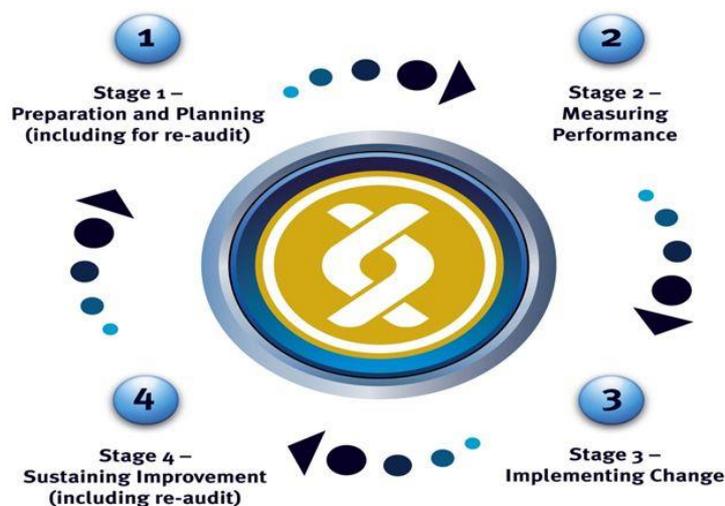
6. Who should do audit?

The Health and Social Care Act 2012 opened up competition to Any Qualified Provider of services and introduced commissioning by multiple GP-led Clinical Commissioning Groups (CCGs) and there has over recent years been a drive to deliver more care in community settings e.g. in optometric practices. Thus, increasingly, care is being delivered outside the traditional hospital ophthalmology unit setting. All medical ophthalmologists should be performing regular audit, both for quality improvement purposes within their department and for quality assurance of their personal practice as part of the annual appraisal process, to cover all major aspects of their practice over the 5 year revalidation cycle. Non-medical practitioners (HCPs) should also be involved in performing audit as part of the multidisciplinary team and this may become more of a formal requirement as revalidation is expanded beyond medical staff to nurses and HCPs. Audit should be integral to service delivery by any provider or unit and it would be reasonable to expect the use of standard audit methodologies and protocols by all providers of care to NHS patients in key areas. Concerns regarding differences in case mix between traditional and independent sector providers (“cherry picking”) have been expressed, the ability to risk adjust can now provide more comparable outcomes from units where selection of low risk cases is thought to be occurring. The new commissioning guidance from the College on glaucoma, cataract, the community ophthalmology framework and the primary eye care framework help set the expectations for appropriate audit and quality metrics in the commissioning and delivery of ophthalmic care in any setting.

7. Undertaking an audit

An audit is usually undertaken in clearly defined recognisable steps which form an Audit cycle:

The clinical audit cycle



HQIP
Healthcare Quality
Improvement Partnership

8. Identify a topic or a problem for audit

The first step is to identify the problem or topic that needs to be audited. At this stage it is important to define the exact focus and scope of the audit and detail the aims of the project. Decide whether this is a short quality assurance audit or one to drive improvement. Remember there is little to be gained from undertaking a time-consuming audit on a topic that does not examine an area which requires change to ultimately benefit patients and improve care. Certain factors should be considered when selecting a topic to ensure that the investment of time and effort lead to worthwhile improvement, either directly or indirectly, in the care provided for patients.

- Is the condition or event common? Does it affect a reasonable number of patients? Or are many patients at risk? What is the level of severity of the risk?
- Does the problem affect morbidity or important aspects of service organisation?
- Is there evidence that care could be improved (e.g. complaints or serious incidents)?
- Is the topic a national or regional priority? (e.g. indicated by the presence of NICE or other national guidance, national confidential enquiry (NCEPOD) issues, national safety alerts, national audits etc.)
- Is it an area of concern for clinical governance?
- Are local professionals (both clinical and other) interested in the topic and do they share the perception that a problem exists?
- Is the potential for benefit worth the effort and costs required for the audit?
- Is this a significant issue for the whole unit or the commissioners?
- Is it a second cycle?
- Is it a new type of care or service with uncertainties about success?
- Is it on your unit's or organisation's annual audit plan?

9. The team

It is important to put together a suitable audit group which should be multidisciplinary, include representatives of everyone involved in the service or who might have an insight into issues or the area, or whose work might need to change. For instance, if the audit is likely to show there is a problem with booking patients into clinic, it is crucial to involve the administrative or reception staff who may understand what the issues are and ensure you collect the data which will allow you to decide what to change. Many in the group will be purely advisory or simply to be kept informed, others will have key roles to perform and a smaller number will decide the exact methodology and perform the analysis.

It is also worth thinking about the involvement of patients and carers where relevant and this is encouraged at a national level. It is absolutely crucial to involve patients in some way where you are developing a patient questionnaire or directly assessing the patient

experience as part of the audit. Do not forget to involve and use staff from your own clinical audit department.

Ophthalmologists in training often move posts or attachments and this is one of the commonest reasons why audits are not finished. Ensure there is a permanent member of staff on the team or someone to hand over the project to if the audit lead is likely to move on.

In planning an audit, it is necessary to identify the resources required and to check that these are available. Considerations for this should include:

- Clinicians time
- Support staff requirements
- IT requirements
- Data handling and analysis support

10. Identify standards

The standards to be reached for the audit must be set prior to data collection and it is vital that all those involved in the project agree with them. They need to be explicit (that is clearly defined including exclusions), objective and measurable, and the achievement level must be stated and be realistic – it may not always be possible to achieve 100% success or the success achieved in a clinical trial, even in best practice in real life clinical settings and benchmark standards may be required. All standards should be considered carefully to ensure their applicability to your local population, case mix, and practice.

Standards for audit should be based on the best available evidence or guidelines, and agreed and widely accepted. Good sources of standards include:

- The Royal College of Ophthalmologists and other national audits and national databases
- The Royal College of Ophthalmologists Clinical and Ophthalmic Service Guidelines
- NICE guidance
- National service frameworks (e.g. diabetes, paediatrics)
- National Confidential Enquiries
- CQC and NHSLA
- American Academy of Ophthalmology and similar respected international professional and specialty body guidance
- Major published treatment trials
- Cochrane Library – Cochrane Eyes and Vision Group
- Effectiveness Bulletins Centre for Reviews and Dissemination, University of York

The references section has a list of relevant guidelines, quality standards and journal publications which may be used to identify audit standards but many more are available and these will change as new publications emerge.

Prior to undertaking an audit, it is good practice to research the published literature using:

- NHS Evidence (<http://www.nice.org.uk/#tab1>)
- Cochrane Eyes and Vision Group www.cochrane.org
- Scottish Inter-Collegiate Guideline Network (SIGN) www.sign.ac.uk
- Pubmed / Medline (<http://www.ncbi.nlm.nih.gov/sites/entrez?db=pubmed>)
- Embase; Healthstar

Remember – clinical guidelines and relevant literature may need to be adapted so that they are applicable to the local patient population and local service provision.

11. What exactly to measure and methodology

It is important to define what exactly needs to be measured to assess whether the agreed standards are being achieved. The choices are broadly categorised as:

- Structure – the establishment in which you are working e.g.
 - staff available / staff training
 - equipment
 - physical environment
 - time allowed
- *Process* – *does* what you do comply with guidelines and protocols to deliver the right things to the right patient at the right time e.g.
 - Record keeping
 - History and examination
 - Interventions
 - Investigations
 - Drugs / surgery, procedures
- *Outcome* – what is the result of your care for the patient e.g.
 - better health/vision, quality of life, longer life, reduced symptoms
 - fewer adverse events such as loss of vision, complications, failure of surgery

It is often much easier to measure structure and process as it is quick and simple and the assumption is that doing the right thing (adhering to good practice guidance) with the right staff, equipment and facilities will inevitably lead to good results for patients (outcomes). Measuring outcomes, that is what results the care achieved for patients, can be harder as it can be difficult to measure, or the results may take time to be apparent. For instance, it is much easier to measure whether a glaucoma patient received appropriate examination and drugs at the right time than to measure whether your care meant they retained their visual field so that they could continue to drive. However, outcomes are what really matter to patients.

Methods of data collection and analysis must then be designed. Consider whether data should be collected about events that are about to happen (prospective audit) or events that have already taken place (retrospective audit). Prospective audit has the advantage of allowing all the relevant data to be collected, the disadvantage being that the knowledge that data are being collected can influence people's usual behaviour and it is likely to take longer to finish. Retrospective audit is the most common form of clinical audit, and usually examines what has been recorded in patient notes. This has the advantage that the data collected are not influenced by a knowledge that the audit is taking place, but a limitation is that only routinely collected data are available for analysis. Any missing data are usually unobtainable and can lead in bias in the results.

12. Sampling

In the absence of full electronic working it is rarely practical to collect data on all patients or events for an audit. Thus it is important to ensure that those included in the audit are representative of the underlying population.

The two key issues associated with obtaining a representative sample are:

- Patient selection
- Sample size

Selecting a sample can be complicated and if necessary it may be advisable to obtain some help in deciding how to do this and how many patients to include. The principles of random selection and sufficient sample size must be respected and decided upon before data collection begins. Choosing the next or last ten patients rarely provides a true representation of the underlying patient population or routine clinical practice. Sample sizes of around 100 are often sufficient for audits of common conditions or events. Where specific precision for estimates is required a formal power calculation can be performed with the help of a statistician.

13. Data collection

Data collection tools should be as brief, simple and user friendly as possible. When designing a proforma or questionnaire it is useful to consider the following points:

- Are all variables of interest identified?
- Are all variables necessary?
- Are the sections / questions in logical order
- Are all the questions appropriate?
- Are there question which tell you not only whether or not the standard is achieved but why this might be the case if not?

- Are all the questions worded in a clear, concise and unambiguous way
- Is the layout attractive? Is it compact without being cramped and is there enough space to write? Can you use tick boxes or Yes/No answers for easier data collection?

If using a questionnaire for patients, ensure the language is suitable and test it out with patient input and with your patient experience lead. Ensure whoever collects the data and fills in the form understands it and has the knowledge to understand and enter the data. If there is more than one data collector, ensure that they will be consistent in their approach.

14. Always do a pilot!

Test out your audit tool and do a mini-analysis on a few cases to see if the form works, is usable and if it is providing you with the data and answers you need. It is much better to undertake a pilot, make any necessary changes, and then commence data collection, than to collect a lot of data and then to realise that you did not get the information required.

15. Data analysis

This should be kept simple, and should be appropriate to answering the audit questions. Clinical audits seldom require complicated statistical analysis, but if in doubt ask for advice if required before you start the audit. More often than not simply identifying proportions of events or patients will be sufficient to inform the majority of audits. Standards are frequently expressed as percentages, for example success rates or complication rates. It is good practice to provide confidence intervals (95%) for percentages and averages as this aids understanding of the precision of the estimate under consideration. Always include in your audit documents and reports the numbers as well as the percentages which is particularly helpful when someone else comes to re-audit. Explain your calculation methods, e.g. what are you going to do with missing data or 'non-responses'?

Data for 67 cases: 32 met the criterion, 16 did not and 19 did not provide a response

Calculation of success might be

① $32/67 = 48\%$

② $32/(67-19) = 67\%$

Compliance with standards is:

Number of people whose care is consistent with the criterion / Number of people to whom the measure applies (total – exceptions) X100

Remember – data collection forms or spreadsheets which have patient identifiable information are confidential and will need to be stored in line with information governance

(IG) requirements and such data must remain within the trust firewall at all times. Avoid patient details being included in the data analysis file. A decoding file with the relationship between audit ID number and patient ID can be held securely and separately from the data analysis file. This minimises IG risk but provides a mechanism for returning back to the patient in the event of a serious issue arising which needs to be addressed.

16. Identify changes required – action planning

If practice does not meet the standards it will usually be necessary to make some changes. Discussion between all those affected by proposed changes in practice is required, presenting the findings, discussion of issues and possible causes, and deciding what actions are needed. This may involve presenting and discussion in more than one meeting. Resource implications should be taken into account. Unanimous agreement with the changes from key players is essential, otherwise improvement is unlikely, and things could carry on being done in the same unsatisfactory way as before. Changes do not have to be complicated, but should be achievable. If the standards have been met this indicates that performance is at a satisfactory level. The opportunity should still be taken to consider if there are possibilities for improvements.

The implementation of agreed changes may involve other people (e.g. other professionals, managers or commissioners) and it is important to inform and involve all those affected. A clear timetable should be agreed to facilitate a successful implementation. Ideally an action plan should include several actions presented in the following way:

Issue	Action needed	By whom (action lead)	By when (timescale)
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17. Presentation of audit

Presentation of an audit should cover the steps described above with the following headings in an audit report and/or an audit PowerPoint presentation. Where presentation is in written report form a structured abstract or summary is helpful:

- Title
- Audit team
- Background
- Aim/objectives
- Setting or service
- Evidence base
- Standards
- Methods (copy of data collection form in appendix)
- Results
- Interpretation of findings/conclusions
- Action plan
- Date for re-audit

HQIP have lots of resources on their website including detailed guidance to undertaking audits and template audit reports: <http://www.hqip.org.uk/resources/>.

18. Re-audit

The re-assessment of quality is the final stage of the audit and is often referred to as 'closing the loop'. This entails returning to the topic after an appropriate length of time to re-measure the quality of practice to ensure that the actions have been implemented and that standards have improved as a result of the changes in practice; and that the changes have not thrown up other issues which need addressing. Occasionally initial audit will have confirmed excellent practice with no adjustments necessary. In this instance, a re-audit may be considered unnecessary.

19. Clinical guidelines and national guidance

Clinical guidelines are defined as systematically derived statements that help practitioners to make decisions about care in specific clinical circumstances and should be research or evidence based. The use of evidence-based medicine is essential in maintaining a high standard of care and guidelines are often the most effective way of ensuring practice is consistent, evidence based and supported by a consensus of experts. Keeping up-to-date with recent clinical guidelines is a requirement of the GMC "Duties of a Doctor" and guidelines provide standards against which current clinical practice can be audited. Guidelines do allow deviation from the prescribed pathway according to individual circumstances and where reasons can be clearly demonstrated and documented. In other words, they do not have to be slavishly followed where there is good reason to do otherwise. The NICE approach is that their clinical guidelines are intended to apply to 80% of people on 80% of occasions. A number of other guides exist which may influence clinical practice.

Policy documents take the form of formal written statements detailing particular actions to be taken in particular situations and are contractually binding. A policy assists management and staff to make correct decisions; deal effectively with and comply with relevant legislation, organisational rules and good practice. A policy document should be regarded as mandatory, with deviation only in exceptional circumstances. Policies in hospitals are primarily operational tools for example a sick leave policy, or a 'did not attend' policy.

Procedure documents take the form of a set of detailed step by step instructions that describe the appropriate method for carrying out simple tasks or activities to maintain high quality and to ensure efficiency, consistency and safety, e.g. a biometry procedure, or a venepuncture procedure.

Protocols are rigid statements which set out a precise sequence of activities to be adhered to in the management of a specific clinical condition. These allow little or no flexibility or variation, e.g. protocol for technicians seeing patients in a glaucoma clinic, diabetic retinopathy screening imaging protocol.

20. Key bodies

National Institute for Health and Care Excellence (NICE)

The role of NICE is to improve outcomes for people using the NHS and other public health and social care services by producing evidence based guidance and advice, developing quality standards and metrics for services and providing a range of information services for commissioners, practitioners and managers across the spectrum of health and social care.

NICE issues guidance in five categories:

- NICE guidelines
- Technology appraisals guidance (mostly drugs)
- Interventional procedures guidance
- Medical technologies and diagnostics guidance

They produce the following performance standards:

- Quality standards
- Quality outcomes frameworks
- Clinical commissioning group outcomes indicator

They also run NICE evidence, an online search engine for guidance, medicines and prescribing support and the BNF.

NICE guidelines include clinical guidelines, and guidelines for public health, social care, safe staffing and medicines practice. There are a number of NICE clinical guidelines that focus primarily on ophthalmic practice and these are:

- Glaucoma (CG85) [Limited update in development – publication expected mid 2017]
- Cataracts in Adults (Guideline in development – publication expected mid 2017)
- Macular Degeneration (Guideline in development – publication expected mid 2017)

However, there are many other guidelines which have relevance for the ophthalmologist such as those concerned with diabetic care.

Technology appraisals guidance assess the clinical and cost effectiveness of health technologies, such as new pharmaceutical and biopharmaceutical products, but also include procedures, devices and diagnostic agents, hoping to ensure equitable access to the most

clinically and cost-effective treatments that are available. There are a number of TAs which are directly relevant to ophthalmology for example:

- Choroidal neovascularisation (pathological myopic) – Ranibizumab (TA298)
- Dry eye disease – Ciclosporin (TA369)
- Macular degeneration (age-related) – Aflibercept (TA294)
- Macular oedema (retinal vein occlusion) – Dexamethasone (TA229)
- Vitreomacular traction – Ocriplasmin (TA 297)

Interventional procedures guidance cover procedures used for diagnosis or for treatments that involve gaining access into the body (e.g. surgery, endoscopy), or using electromagnetic radiation (e.g. X-rays, lasers) and examine safety, whether efficacy is sufficient for routine use and whether special consenting is needed. They essentially cover new innovative therapies allowing them to be safely and cautiously introduced into routine care.

Ophthalmology is a rapidly changing highly technical surgical field so, not surprisingly, there are many IPGs which are relevant for example:

- Adnexal and Lacrimal – Endoscopic dacryocystorhinostomy (IPG113)
- Corneal and Refractive – Accommodating intraocular lenses for cataract (IPG209)
- Corneal and Refractive – Collagen cross-linkage using riboflavin and ultraviolet A for keratoconus and keratectasia (IPG466)
- Glaucoma – Trabecular stent bypass micro-surgery (IPG396)
- Macular Degeneration (age-related) – Macular translocation with 360° retinotomy (IPG340)
- Macular Degeneration (age-related) – Miniature lens systems (IPG272)
- Medical Retina – Insertion of a subretinal prosthesis system for retinitis pigmentosa (IPG537)
- Strabismus – Tenotomy of horizontal eye muscles for nystagmus (IPG299)

NICE medical technologies and diagnostics guidance addresses specific technologies and diagnostic tests notified to NICE by manufacturers and developers who examine the ‘case for adoption’ based on the claimed advantages of introducing the innovation compared with current management of the condition aiming to ensure the NHS is able to adopt clinically and cost effective technologies and diagnostics rapidly and consistently.

Quality standards are concise sets of statements, with accompanying metrics, to measure priority quality improvements within a particular area of care and are usually derived from NICE’s guidance. These are very useful tools to decide whether or not care is compliant with the guidance and to use for clear audit standards.

The Royal College of Ophthalmologists

The Royal College of Ophthalmologists maintains its own guideline development programme and over the past decade has produced guideline statements on many major ophthalmological conditions and areas which are available on the college website.

Clinical Guidelines Where NICE guidance is available it is College policy to adopt such guidance and avoid duplication. Occasionally supplementary College guidance may be necessary to clarify specific issues, the College is however mindful to not contradict guidance issued by NICE. For more recent clinical guidelines, the College has attempted to adopt the methodology and rigour of the NICE approach, with more robust though fewer guidelines produced and concentration on major areas of care. Although the College does not possess the infrastructure and resource needed to work to the same standards as NICE, more recent guidelines have been widely consulted on and are better evidence based.

Examples of currently available College clinical guidelines include:

- Cataract Surgery Guidelines 2010 (will be superseded by NICE guideline)
- Age-Related Macular Degeneration: Guidelines for Management 2013 (will be superseded by NICE guideline)
- Diabetic Retinopathy Guidelines 2012
- Retinal Vein Occlusion 2015
- Local Anaesthesia in Ophthalmic Surgery 2012
- Abusive Head Trauma and the Eye in Infancy 2013
- Retinopathy of Prematurity Guideline 2008

Ophthalmic services guidance is intended to inform both ophthalmologists and those managing eye services what the expected standards of practice are and how these should be achieved through adequate staffing levels, proper facilities and appropriate managerial support as well as clinical input. These are based on published evidence as far much as is possible but, in the absence of high quality published evidence for some areas of practice, expert consensus is also used to make recommendations.

Examples of these include:

- Ophthalmic day care and inpatient facilities 2012
- Managing an outbreak of postoperative endophthalmitis 2016
- Ophthalmic imaging 2016
- Ophthalmic services for children 2012
- Ophthalmic pathology 2016

Quality Standards are a set of simple self-assessment tools for a number of clinical services including subspecialty care (cataract, glaucoma, adnexal, medical retina (including age-related macular degeneration [AMD]), diabetic retinopathy, vitreoretinal surgery, neuro-ophthalmology) and care for specific groups (children and young adults and adults with

learning difficulties, adults with sight loss and dementia). The tools focus on service provision not outcomes, and do not attempt to assess every aspect of service but try to focus on a small number of key areas. It is not expected that most clinical services will achieve a perfect score, and the results should be used in conjunction with other methods of quality assessment to support learning and improvement.

Commissioning Guidance The College process for development of commissioning guidelines has gained NICE approval and the College has issued NICE accredited commissioning guidance for services in the areas of glaucoma, cataract, as well as frameworks for community ophthalmology and primary eye care.

The National Guideline Centre

Previously the National Clinical Guideline Centre (NCGC), the National Guideline Centre was formed in 2009 and is one of the largest clinical guideline development organisations in the world. The work of the NGC is overseen by a governance partnership between the Royal Colleges of General Practitioners, Nursing, Physicians and Surgeons. Each college is represented on the NGC management board, alongside representatives from the Royal College of Physicians Patient and Carer Network, the UK Cochrane Centre, and NHS England. It is a multi-disciplinary health service research team which produces and publishes guidelines on behalf of NICE for use in England and Wales.

National Guideline Clearinghouse

www.guideline.gov

This is the largest database of appraised guidelines in the world. It is biased towards US guidance but it does include guidelines from other countries.

Scottish Intercollegiate Guidelines Network (SIGN)

www.sign.ac.uk

SIGN develops and publishes clinical guidelines for use in Scotland.

The Guidelines and Audit Implementation Network (GAIN)

This is the clinical and social care regional audit and guidelines body for Northern Ireland, formed after the amalgamation of CREST (Clinical Resource Efficiency Support Team with the Regional Multi-professional Audit Group (RMAG) and the Northern Ireland Audit Advisory Committee (NIRAAC).

Cochrane

Cochrane is a global independent network of researchers, clinical professionals, patients and carers with 37,000 contributors from more than 130 countries producing the **Cochrane Reviews**, a database of systematic reviews and meta-analyses which summarise and interpret the results of medical research, particularly well-conducted controlled trials

considered free from commercial sponsorship and other conflicts of interest. This is a huge and important resource for gold standard detailed evidence based information.

21. Conclusions

There is a wealth of evidence, guidance and standards available for ophthalmologists on practice and on how to measure whether care is safe and of a high quality. There is a huge amount of material available particularly from the College and from NICE websites. All ophthalmologists have a duty to be involved in providing clinically effective care both personally and within their teams and units and need to make use of guidelines and clinical audit, which are powerful and useful tools if used well.

22. Authors for 2016 revision

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23. Previous Versions

Original Paper 2002

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Revisions 2005, 2008, 2012

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24. Resources

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- Quality, safety and clinical governance in ophthalmology: an overview. Royal College of Ophthalmologists 2016. <https://www.rcophth.ac.uk/standards-publications-research/>

- High Quality Care for All: the next stage review final report. “The Darzi report” Crown Copyright 2008
https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/228836/7432.pdf
- Principles for Best Practice in Clinical Audit, NICE/CHI (2002)
- HQIP website. <http://www.hqip.org.uk/>
- National Ophthalmology Database Audit <https://www.nodaudit.org.uk/>
- The Health and Social Care Act 2012. <http://services.parliament.uk/bills/2010-12/healthandsocialcare.html>
- Commissioning guide: Cataract surgery. Royal College of Ophthalmologists Clinical Council for Eye Health Commissioning 2016.
<https://www.rcophth.ac.uk/standards-publications-research/commissioning-in-ophthalmology/>
- Commissioning guide: Glaucoma. RCOphth, Clinical Council for Eye Health Commissioning, 2016. <https://www.rcophth.ac.uk/standards-publications-research/commissioning-in-ophthalmology/>
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- NICE <http://www.nice.org.uk>
- National Clinical Guideline Centre (NCGC) www.ncng.ac.uk
- Cochrane <http://www.cochranelibrary.com/>

25. Papers for possible audit standards

Age-related Macular Degeneration

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Diabetic Retinopathy

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Glaucoma Surgery

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Glaucoma Visual Loss

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26. Guideline resources for possible audit standards

The Royal College of Ophthalmologists

Clinical Guidelines and Ophthalmic Services Guidance

Cataract Surgery

- [Cataract Surgery Guidelines 2010](#)
- [Cataract Surgery Commissioning Guide 2015](#)

Glaucoma

- [Glaucoma Commissioning Guide](#)

Medical Retina

- [Age-Related Macular Degeneration: Guidelines for Management 2013](#)
- [Age-related macular degeneration: Commissioning better eye care](#)
- [Delivery of Diabetic Eye Care 2009](#)
- [Diabetic Retinopathy Guidelines 2012](#)
- [Diabetic Retinopathy Screening \(DRS\) and the Ophthalmology Clinic set up in England 2010](#)
- [Maximising Capacity in AMD Services](#)
- [Retinal Vein Occlusion 2015](#)

Ophthalmic Surgery

- [Local Anaesthesia in Ophthalmic Surgery 2012](#)
- [Intra-ocular injections by non-medical health care professionals 2013](#)
- [Managing an outbreak of postoperative endophthalmitis](#)
- [Prevention of transmission of blood-borne viruses in ophthalmic surgery](#)
- [Standards for the Retrieval of Human Ocular Tissue used in Transplantation, Research and Training 2013](#)
- [Theatres](#)

Paediatric Ophthalmology

- [Abusive Head Trauma and the Eye in Infancy 2013](#)
- [Adalimumab for children with uveitis](#)
- [Management of Strabismus in Childhood 2012](#)
- [Ophthalmic Services for Children](#)
- [Recording Ophth features of suspected paediatric head trauma](#)
- [Retinopathy of Prematurity Guideline](#)
- [Vision screening for children](#)

Vitreous Retinal

- [Management of Retinal Detachment](#)

Other Clinical Guidelines

- [Emergency Eye Care](#)
- [Eye Care Services for Adults with Learning Disabilities 2015](#)
- [Management of visual problems in people with learning disabilities](#)
- [Management of patients with Grave's orbitopathy: initial assessment, management outside specialised centres and referral pathways](#)
- [Ocular Pathology](#)
- [Primary Care Ophthalmology](#)
- [Referral guidelines for adult ocular tumours including choroidal naevi 2009](#)
- [Review of the Ocular side effects of Topiramate 2010](#)
- [The Ocular Side-Effects of Vigabatrin \(Sabril\) Information and Guidance for Screening 2008](#)
- [UK guidelines for the management of Stevens-Johnson syndrome/toxic epidermal necrolysis 2016](#)
- [Vision Standards for Driving](#)

Ophthalmic Service Guidelines

- [Audit & Clinical Effectiveness Information for Ophthalmologists](#)
- [Informatics \(update due 2017\)](#)
- [Ophthalmic Day care and Inpatient Facilities](#)
- [Ophthalmic Imaging](#)
- [Ophthalmic Instrument Decontamination](#)
- [Ophthalmic Outpatient Department](#)
- [Patient Safety in Ophthalmology](#)
- [Quality safety and clinical governance in ophthalmology: an overview](#)
- [Sustainability in Ophthalmology May 2013](#)
- [Quality Standards:](#)
 - [Quality Standards for Services to Patients with Learning Disabilities](#)
 - [Quality Standards & Quality Indicators for Ophthalmic Care and Services for Children and Young People](#)
 - [Quality Standards for Oculoplastic Surgery Services](#)
 - [Quality standards for diabetic retinopathy services in NHS Scotland](#)
 - [Quality standards for diabetic retinopathy services for England, Wales and Northern Ireland](#)
 - [Quality Assurance Self Test for AMD Services](#)
 - [Quality standard for people with sight loss and dementia in an ophthalmology department](#)
 - [Quality Standard for Adnexal Services](#)
 - [Quality Standard for Cataract Services](#)
 - [Quality Standards for Cornea Services](#)
 - [Quality Standard for Glaucoma Services](#)
 - [Quality Standard for Medical Retina Disease Services](#)
 - [Quality Standard for Neuro-ophthalmology Services](#)

- [Quality Standard for Vitreoretinal Services](#)
- [Refractive Surgery Standards](#)

National Institute for Health and Care Excellence

Clinical Guidelines

- [Glaucoma \(CG85\)](#) [*Limited update in development - publication expected mid 2017*]
- [Cataracts in Adults](#) (*Guideline in development - publication expected mid 2017*)
- [Macular Degeneration](#) (*Guideline in development - publication expected mid 2017*)

Technology Appraisals

- [Choroidal neovascularisation \(pathological myopic\) - Ranibizumab \(TA298\)](#)
- [Dry eye disease - Ciclosporin \(TA369\)](#)
- [Macular degeneration \(age-related\) - Aflibercept \(TA294\)](#)
- [Macular degeneration \(age-related\) - Photodynamic Therapy \(TA68\)](#)
- [Macular degeneration \(age-related\) - Ranibizumab and Pegaptanib \(TA155\)](#)
- [Macular oedema \(retinal vein occlusion\) - Dexamethasone \(TA229\)](#)
- [Macular oedema \(retinal vein occlusion\) - Aflibercept \(TA305\)](#)
- [Macular oedema \(retinal vein occlusion\) - Ranibizumab \(TA283\)](#)
- [Macular oedema \(diabetic\) - Aflibercept \(TA346\)](#)
- [Macular oedema \(diabetic\) - Dexamethasone \(TA349\)](#)
- [Macular oedema \(diabetic\) – Fluocinolone \(TA301\)](#)
- [Macular oedema \(diabetic\) - Ranibizumab \(TA274\)](#)
- [Vitreomacular traction - Ocriplasmin \(TA297\)](#)

Interventional Procedures

- [Adnexal & Lacrimal - Endoscopic dacryocystorhinostomy \(IPG113\)](#)
- [Adnexal & Lacrimal - Retrobulbar irradiation for thyroid eye disease \(IPG148\)](#)
- [Corneal & Refractive - Accommodating intraocular lenses for cataract \(IPG209\)](#)
- [Corneal & Refractive - Collagen cross-linkage using riboflavin and ultraviolet A for keratoconus and keratectasia \(IPG466\)](#)
- [Corneal & Refractive - Corneal graft–keratoprosthesis for severe corneal opacity in wet blinking eyes \(IPG534\)](#)
- [Corneal & Refractive - Corneal implants for keratoconus \(IPG227\)](#)
- [Corneal & Refractive - Corneal implants for refractive error \(IPG225\)](#)
- [Corneal & Refractive - Corneal inlay implantation for presbyopia \(IPG455\)](#)
- [Corneal & Refractive - Endothelial transplantation \(IPG304\)](#)
- [Corneal & Refractive - Hydrogel keratoprosthesis \(IPG69\)](#)
- [Corneal & Refractive - Intraocular lens insertion for refractive error, with preservation of the natural lens \(IPG289\)](#)
- [Corneal & Refractive - Laser correction of refractive error following non-refractive ophthalmic surgery \(IPG385\)](#)

- Corneal & Refractive - Multifocal (non-accommodative) intraocular lenses during cataract surgery (IPG264)
- Corneal & Refractive - Photorefractive (laser) (IPG164)
- Corneal & Refractive - Phototherapeutic laser keratectomy for corneal surface irregularities (IPG358)
- Corneal & Refractive - Scleral expansion surgery for presbyopia (IPG70)
- Corneal & Refractive - Tissue-cultured limbal stem cell allograft transplantation for regrowth of corneal epithelium (IPG216)
- Glaucoma - Canaloplasty (IPG260)
- Glaucoma - Trabecular stent bypass micro-surgery (IPG396)
- Glaucoma - Trabeculotomy ab interno (IPG397)
- Macular Degeneration (age-related) - Epiretinal brachytherapy (IPG415)
- Macular Degeneration (age-related) - Limited macular translocation (IPG339)
- Macular Degeneration (age-related) - Macular translocation with 360° retinotomy (IPG340)
- Macular Degeneration (age-related) - Miniature lens system implantation for advanced age-related macular degeneration (IPG565)
- Macular Degeneration (age-related) - Radiotherapy (IPG49)
- Macular Degeneration (age-related) - Transpupillary thermotherapy (IPG58)
- Medical Retina - Arteriovenous crossing sheathotomy for branch retinal vein occlusion (IPG334)
- Medical Retina - Insertion of a subretinal prosthesis system for retinitis pigmentosa (IPG537)
- Medical Retina - Insertion of an epiretinal prosthesis for retinitis pigmentosa (IPG519)
- Strabismus - Opaque intraocular lens for intractable double vision (IPG293)
- Strabismus - Tenotomy of horizontal eye muscles for nystagmus (IPG299)

NICE Quality Standards

- Diabetes in adults (QS6)
- Glaucoma (QS7)