The Royal College of Ophthalmologists

Ophthalmic Services Guidance

Audit and Clinical Effectiveness Information for Ophthalmologists

Introduction and General advice on Audit

Quality assurance remains an important priority in the Hospital Eye Service and audit activity is expected as an integral component of all NHS care. Since the formal introduction of medical audit in 1989 there has been continuous evolution in the approach to quality improvement. Developments have occurred in technology, methodology, the professionals involved, and in the role which audit plays within the wider context of clinical effectiveness, clinical governance and accountability. During the 1990's provision for national audits was through professional bodies and The Royal College of Ophthalmologists developed a broad portfolio of benchmark setting 'survey audits' encompassing many common ophthalmological conditions and procedures.

Following the formation of the National Institute for Health and Clinical Excellence (NICE) national audit budgets were withdrawn and used to fund National Collaborating Centres (NCC's) for Clinical Guideline Development. The Royal College of Ophthalmologists was one of four key members with full representation on the management board of the NCC for Acute Care which opened in April 2001. Although there have been subsequent reorganisations of the centres the brief of the NCC's remains to develop evidence based NICE Clinical Guidelines using rigorous methodology. Also under the NICE umbrella are groupings which develop Health Technology Appraisals (HTA's) and Interventional Procedures (PI) guidance. More recently the NICE remit has expanded to include Quality Standards and Outcome Indicators (Commissioning Outcomes Framework).

The Royal College of Ophthalmologists maintains its own guideline development programme and over the past decade has produced guideline statements on most major ophthalmological conditions. These are available to all College members on the College website. Where topics have previously been covered by NICE guidance the College has chosen to either 'adopt' such guidance, or issue supplementary guidance as deemed appropriate. Guideline statements and published national and multicentre audits underpin many of the local clinical audits routinely undertaken up and down the country.

Connecting for Health and the National Programme for IT disappointingly failed to deliver serviceable electronic care record solutions but the collection and collation 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, and the Cataract National Data set has shown the way to simplified NHS Information Standards Board approval through a modified procedure for existing 'inherited data sets'. The potential of working in this way has been illustrated by a multicentre analysis of 55,567 cataract operations with updating of cataract surgery benchmarks nationally and internationally (see audit resources below). Following on from this work the College facilitated National Ophthalmology Database (NOD) project is developing resources for extraction, aggregation and analysis of multicentre data, with data volumes currently approaching 400,000 extracted records from 30 NHS Trusts,

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including some 240,000 cataract operations. Contributing ophthalmologists and centres are already able to view their own data in the context of their peers and future developments are planned to provide regular updates through periodic refreshing of extractions. As illustrated in the recent cataract analysis 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. From the point of view of training the opposite should apply with only the most straightforward cases operated upon by junior trainees, an approach already widely practiced though until recently without empirically robust risk stratification.

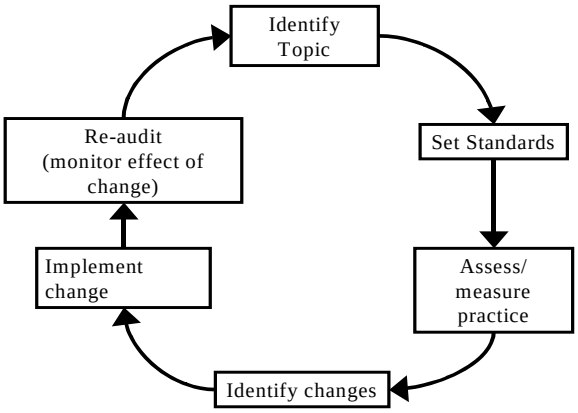
Of ongoing concern to NHS based ophthalmologists is the question of routine quality control and ‘cherry picking’ among Independent Sector Providers. Audit should be integral to service delivery by these units and it would be reasonable to expect the use of standard audit methodologies and protocols by all providers. Concerns regarding case mix have been expressed and it is of interest that the ability to risk adjust can now provide comparable outcomes from units where selection of low risk cases is thought to be occurring.

The College continues to promote audit at its Annual Congress, with a regular poster category for audit and relevant ‘occasional’ symposia. 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. Re-audit at a later time completes the audit cycle and should affirm adjustments to practice implemented in the earlier cycle(s). With the support of ophthalmologists and trust audit staff across the UK, The Royal College of Ophthalmologists national audits have been successful in describing practice and outcomes for a range of key ophthalmic conditions and procedures. The value of surveys of this kind is well illustrated by the numerous presentations of local audits submitted to the College Annual Congress each year which have used published data from these surveys to establish and monitor local standards. College guideline statements likewise acknowledge these national audits as important contributions to the clinical evidence base.

This chapter intends to briefly describe the main aspects of undertaking an audit and indicate what resources are available either as a result of The Royal College of Ophthalmologists audit and guidelines work or otherwise.

Undertaking an Audit

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



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.

There is little to be gained from undertaking an audit on a topic which will not ultimately benefit patients. Certain criteria 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?
- Is the topic a national or regional priority?
- 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?

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Identify Standards

The standards to be reached for the audit activity should be set prior to data collection. They should be evidence based, and it is vital that all those involved in the project agree with them. It may be possible to use some previously developed standards. However, all

standards should be studied carefully to ensure their applicability to your local population, case mix, and practice.

Standards for audit should be based on the best available evidence. Published Royal College of Ophthalmologists National Audits and Clinical Guideline statements frequently provide a good basis for defining standards for local audit.

Resources and Bibliography

The Royal College of Ophthalmologists
(See members area of the website for regularly updated information http://www.rcophth.ac.uk/)

Guidelines

- Interim Guidelines for Management of Retinal Vein Occlusion 2010
- The Intravitreal use of bevacizumab Avastin in AMD - update
- Age-Related Macular Degeneration 2009 Guidelines for Management - Update
- RVO December 2010 Guideline Appendix A - NHS Evidence 2010 Annual Evidence Update on Retinal Vein Occlusion
- RVO December 2010 Guideline Appendix B - NHS Evidence RVO Annual Evidence Update 2010 Search History
- Diabetic Retinopathy Screening Preferred Practice Guidance 2010
- Cataract Surgery Guidelines 2010
- Maximising Capacity in AMD Services
- Ocular Toxicity and Hydroxychloroquine: Guidelines for Screening 2009
- Referral Guidelines for Adult Ocular Tumors Including Choroidal Naevi 2009
- Guidelines for Intravitreal Injections Procedure 2009
- AMD Consent Form
- Standards for the Retrieval of Ocular Tissue used in Transplantation, Research and Training
- Revised statement on N Acetyl Carnosine for Cataracts August 2008
- Guidelines for Ranibizumab
- The Ocular Side-Effects of Vigabatrin
- UK Retinopathy of Prematurity Guideline May 2008
- Retinopathy of Prematurity Appendix A - Standardised Sheet for Recording Screening Results

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- Retinopathy of Prematurity Appendix A – Standardised Sheet for Recording Screening Results
- Retinopathy of Prematurity Appendix B - Algorithm for Ophthalmic Observations
- Retinopathy of Prematurity Appendix C - Information Leaflet for Parents
- Guidelines - Declaration of Interest 2008
- Commissioning Contemporary AMD Services
- Ocular Side Effects of Topiramate - Frequently Asked Questions 2006
- Guidelines for Diabetic Retinopathy 2005
- Guidelines for Diabetic Retinopathy 2005 - Legends
- Guidelines for Diabetic Retinopathy 2005 - Figures
- Commissioning Cataract Surgery - An Outline of Good Practice
- Guidelines for the Management of Open Angle Glaucoma and Ocular Hypertension 2004
- Local Anaesthesia for Intraocular Surgery Published jointly with The Royal College of Anaesthetists July 2001

Information from the Paediatric Sub-Committee for Healthcare Professionals

- Record of Disorder (s) resulting in Visual Impairment (CVI Form). Paediatric patients
- Is It Necessary to Screen Children for Ethambutol Toxicity? October 2010
- Review of the Ocular Side Effects of Topiramate October 2010
- Ocular side effects of Topiramate FAQs
- 2010 Annual Evidence Update on Amblyopia
- Statement on Visual Screening in Children and Young People
- Squint Surgery Care Pathway Example
- Reading and the Visual System
- Juvenile Arthritis
- Procedures for the Ophthalmologist who Suspects Child Abuse
- Update from the Ophthalmology Child Abuse Working Party

College Service Quality Standards

http://www.rcophth.ac.uk/page.asp?section=444&sectionTitle=Quality+Standards

These tools are primarily for service evaluation and are not focused on personal or surgeon based audits. For certain clinical topics however team based outcomes remain the most appropriate method for auditing individuals involved in the delivery of such care.

- 20/20 QIPP Quality Assurance Self Test for AMD Services
- Quality Standards for Cataract Services
- Quality Standards & Quality Indicators for Ophthalmic Care and Services for Children and Young People
- VR Quality Standards
- Quality Standards for Glaucoma Services
- Quality Standards for Oculoplastics
- Quality Standards for Diabetic Retinopathy_SCOTLAND
- Quality Standards for Diabetic Retinopathy_Eng_Wales_NI

- Quality Standards Development Tools Feedback Form

The National Ophthalmological Database (NOD)
(https://nod.nhs.uk)
The NOD aims to extract electronically collected care record data from participating units and to present a range of information back to contributors in useful summary forms showing personal / unit level results against a backdrop of their anonymised NHS peers. This is a Royal College of Ophthalmologists facilitated project, the College being the official data controller. The content of the database can be derived from any NHS electronic care record with standardised data formats and the NOD project intends to provide increasingly sophisticated service and audit data of relevance to audit in ophthalmology. Access is available from any NHS N3 connected computer and anyone with an NHS Email address may register on the site. Contributing ophthalmologists and centres are able to view their own personal and /or local service data in the context of multicentre aggregated data. For example a contributing surgeon can currently view his or her own cataract surgery capsule rupture rate in the context of all contributing surgeons in a funnel plot presentation. Non-contributing surgeons are able to view aggregated data from surgical peers and can set their own (self calculated) result in the context of surgical colleagues. It is anticipated that the clinical coverage of this database will increase as electronic working in ophthalmology becomes the norm within the NHS, and that this will become a major audit facility for UK ophthalmologists. At the initial data extract from 30 NHS Trusts around 400,000 clinical episodes were extracted including around 240,000 cataract operations. All NHS ophthalmologists are encouraged to take advantage of this facility.

NICE Guidance of direct relevance to Ophthalmologists
(See website for regularly updated information (http://www.nice.org.uk/)

Clinical Guideline
- Glaucoma (CG85)

Technology Appraisals
- Macular degeneration (age-related) - photodynamic therapy (TA68)
- Macular degeneration (age-related) - ranibizumab and pegaptanib (TA155)
- Macular oedema (retinal vein occlusion) - dexamethasone (TA229)
- Macular oedema (diabetic) - ranibizumab (TA237)

Interventional Procedures
- Radiotherapy for age-related macular degeneration (IPG49)
- Transpupillary thermotherapy for age-related macular degeneration (IPG58)
- Insertion of hydrogel keratoprosthesis (IPG69)
- Scleral expansion surgery for presbyopia (IPG70)
- Endoscopic dacryocystorhinostomy (IPG113)
- Photorefractive (laser) surgery for the correction of refractive error (IPG164)
- Implantation of accommodating intraocular lenses for cataract (IPG209)
- Tissue-cultured limbal stem cell allograft transplantation for regrowth of corneal epithelium (IPG216)

- Corneal implants for the correction of refractive error (IPG225)
- Corneal implants for keratoconus (IPG227)
- Canaloplasty for primary open-angle glaucoma (IPG260)
- Implantation of multifocal (non-accommodative) intraocular lenses during cataract surgery (IPG264)
- Implantation of miniature lens systems for advanced age-related macular degeneration (IPG272)
- Intraocular lens insertion for correction of refractive error, with preservation of the natural lens (IPG289)
- Implantation of an opaque intraocular lens for intractable double vision (IPG293)
- Tenotomy of horizontal eye muscles for nystagmus (with reattachment at their original insertions) (IPG299)
- Corneal endothelial transplantation (IPG304)
- Photochemical corneal collagen cross-linkage using riboflavin and ultraviolet A for keratoconus (IPG320)
- Arteriovenous crossing sheathotomy for branch retinal vein occlusion (IPG334)
- Limited macular translocation for wet age-related macular degeneration (IPG339)
- Macular translocation with 360° retinotomy for wet age related macular degeneration (IPG340)
- Phototherapeutic laser keratectomy for corneal surface irregularities (IPG358)
- Laser correction of refractive error following non-refractive ophthalmic surgery (IPG385)
- Trabecular stent bypass micro-surgery for open angle glaucoma (IPG396)
- Trabeculotomy ab interno for open angle glaucoma (IPG397)
- Epiretinal brachytherapy for wet age related macular degeneration (IPG415)
- Type 2 diabetes - retinopathy (E replaced by CG66)

NICE Quality Standards

- Glaucoma
  http://www.nice.org.uk/guidance/qualitystandards/glaucoma/Home.jsp
- Diabetes in adults
  http://www.nice.org.uk/guidance/qualitystandards/diabetesinadults/diabetesinadultsqualitystandard.jsp

Journal Publications

AMD

- Ranibizumab and bevacizumab for neovascular age-related macular degeneration. CATT Research Group, Martin DF, Maguire MG, Ying GS, Grunwald JE, Fine SL, Jaffe GJ. N Engl J Med. 2011 May 19;364(20):1897-908.
- Regillo CD, Brown DM, Abraham P, Yue H, Ianchulev T, Schneider S, Shams N; The PIER Study Group. Randomized, Double-Masked, Sham-Controlled Trial of ranibizumab for Neovascular Age-related Macular Degeneration: PIER Study Year 1. Am J Ophthalmol. 2008 Feb;145(2):239-248.

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Cataract Surgery

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Biometry in Cataract Surgery

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target refraction in cataract surgery: Swedish National Cataract Register study. J Cataract Refract Surg 2008;34:1935-9.

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- El-Hindy N, Johnston RL, Jaycock P, Eke T, Braga AJ, Tole DM, Galloway P, Sparrow JM. The Cataract National Dataset Electronic Multi-centre Audit of 55,567 operations: anaesthetic techniques and complications. Eye 2009;23:50-5.
- Eke T, Thompson JR. Serious complications of local anaesthesia for cataract surgery: a 1 year national survey in the United Kingdom. Br J Ophthalmol 2007;91:470-5.
- Eke T, Thompson JR The National Survey of Local Anaesthesia for Ocular Surgery: I Survey methodology and current practice Eye 1999:13:189-195
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Glaucoma Drainage Surgery

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- Gedde SJ, Schiffman JC, Feuer WJ, Herndon LW, Brandt JD, Budenz DL. Three-year follow-up of the tube versus trabeculectomy study. Am J Ophthalmol 2009;148:670-84.
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- Molteno AC, Bosma NJ, Kittelson JM. Otago glaucoma surgery outcome study: long-term results of trabeculectomy--1976 to 1995. Ophthalmology 1999;106:1742-50.
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Postoperative Endophthalmitis

- Arshinoff SA, Bastianelli PA. Incidence of postoperative endophthalmitis after immediate sequential bilateral cataract surgery. J Cataract Refract Surg 2011;37:2105-14.
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Diabetic Retinopathy Laser Treatment Audit

- Bailey CC, Sparrow JM, Grey RHB, Cheng H Diabetic Retinopathy Laser Treatment: 1 Maculopathy Eye 1998:12:69-76
- Bailey CC, Sparrow JM, Grey RHB, Cheng H Diabetic Retinopathy Laser Treatment: II Proliferative retinopathy Eye 1998:12:77-84
- Bailey CC, Sparrow JM, Grey RHB, Cheng H Diabetic Retinopathy Laser Treatment: III Clinical outcomes Eye 1999:13:151-159

Diabetic Retinopathy Screening Audit

- UK National Screening Committee 2011 Key Performance Indicators for Screening, Version 1.7 (accessed 22.01.12) http://www.screening.nhs.uk/kpi
- DESP Quality Assurance Standards Release 7 Version 1.3, 23 January 2012 (accessed 23.01.12) http://diabeticeye.screening.nhs.uk

Ocular Trauma

- Man CY, Steel D. Visual outcome after open globe injury: a comparison of two prognostic models--the Ocular Trauma Score and the Classification and Regression Tree. Eye 2010;24:84-9.
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Retinal Detachment Surgery

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Alternative information sources can also be used to inform standards:

Cochrane Library – Cochrane Eyes and Vision Group
Effectiveness bulletins Centre for Reviews and dissemination, University of York.

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

Clinical guidelines and relevant literature need to be considered and adapted so that they are applicable to the local patient population and local service provision.

Define Outcome Measures and Methodology

It is important to define what needs to be measured to assess whether the agreed standards are being achieved. 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. 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.

Sampling

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.

Proforma and Questionnaire Design

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 the sections / questions in logical order
- Are all the questions necessary and appropriate
- Are all the questions worded in a clear, concise and unambiguous way
- Is the layout attractive? Is it compact without being crammed

Data Analysis

Data analysis should be kept simple, and should be appropriate to answering the audit questions. Again it may be necessary to obtain some advice as to the best approach. It is wise to do this before data collection starts to ensure that it is possible to answer all the audit questions with the variables included in 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.

Identify Changes Required

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, and resource implications should be taken into account. Unanimous agreement with the changes 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.

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 standards have improved as a result of the changes in practice. Occasionally initial audit will have confirmed good practice with no adjustments necessary. In this instance a re-audit may be unnecessary.

Resource Requirements

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

Presentation of Audit

Presentation of an audit should cover the steps described in this paper. Where presentation is in written form a Structured Abstract is helpful to summarise key points which should include:

- Title
- Background
- Aim
- Setting
- Standards
- Method (including approach to sampling)
- Results
- Interpretation of findings
- Adjustments to practice
- Date for re-audit

Contributors

Original Paper 2002
John Sparrow, Audit and Clinical Effectiveness Lead, The Royal College of Ophthalmologists

Richard Wormald, Consultant Ophthalmologist, Moorfields Eye Hospital
John Thompson, Epidemiologist, Leicester Royal Infirmary
Barny Foot, Audit Fellow, The Royal College of Ophthalmologists

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John Sparrow, Audit and Clinical Effectiveness Lead, The Royal College of Ophthalmologists

Author: John M Sparrow

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