



The ROYAL COLLEGE of
OPHTHALMOLOGISTS

Process Manual

Guideline Process Manual

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Contents

Section	page
1 Introduction	3
1.1 Clinical Guidelines	3
1.2 Commissioning Guidance	3
1.3 Key Terms	4
2 Objectives	4
2.1 Clinical Guideline	4
2.2 Commissioning guidance	4
3 Method	5
4 Topic Selection	5
4.1 Clinical Guidelines	5
4.2 Commissioning Guidance	6
4.3 Updating Published Guidelines	7
4.4 Selecting guidelines for updating	7
5 The Guideline Development Group (GDG)	7
5.1 Guideline Development Group Chair	8
5.2 Guideline Development Group members	8
6 Developing the Guideline	9
6.1 Defining Key Review Questions	10
6.2 Search Strategy	11
6.3 Electronic search for identifying the literature	11
6.4 Search Results	12
6.5 Evaluating the Evidence	12
6.6 Considering the Quality of the Evidence	12
6.7 Recording the Search	13
6.8 Search reruns	13
6.9 Uncertainties	13
7 Grading the level of evidence	13
8 Making Recommendations	14
Key Recommendations	16
9 Guideline Document	16
10 External Peer Review	16
11 Dissemination of Clinical Guidelines	17
12. Evaluation and Impact Assessment	17
13 Editorial Independence	18
14 Funding of Clinical Guidelines	18
Appendix 1 Guideline Proposal Form	19
Appendix 2 Terms of Reference Template for Guideline Development Groups	22
Appendix 3 Template for a Clinical Guideline	24
Appendix 4 Template for the Quick Reference Guide for [Guideline Title]	25
Appendix 5 Template for Commissioning Guidance	26

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Approved by Professional Standards and Scientific Committees

1 Introduction

The Royal College of Ophthalmologists (RCOphth) provides a range of advice, standards and guidelines on the delivery of eye care services. This process manual details the RCOphth guideline development process to ensure consistency and provide users with assurance that the appropriate methodologies and strategies are followed. It is used to develop two main RCOphth products:

- Clinical Guidelines
- Commissioning Guidance

Whilst both products follow a comparable development process, they differ in purpose, focus and intended audience. The objectives for each product are described below.

1.1 Clinical Guidelines

Systematically developed to support clinicians to make better decisions about appropriate healthcare for specific eye disorders, to enhance clinician and patient decision making by clearly describing and appraising the scientific evidence and reasoning (the likely benefits and harms) behind clinical recommendations. The link between a set of guidelines and the scientific evidence must be explicit, and high quality scientific and clinical evidence must take precedence over expert judgment. They aim to make recommendations about appropriate health care for specific clinical situations for the majority of clinical situations, thereby reducing unwarranted variations in practice. They are an aid to clinical judgment not a replacement for it. Guidelines do not provide the answers to every clinical question, nor guarantee a successful outcome in every case. The ultimate decision about a particular clinical procedure or treatment will always depend on each individual patient's condition, circumstances and wishes, and the clinical judgment of the healthcare team.

The aim of clinical guidelines is to systematically identify the best medical evidence, set standards of patient care and ensure patient safety, and provide a benchmark for outcomes within which high quality Ophthalmology is practiced.

1.2 Commissioning Guidance

Systematically developed tools designed to help Clinical Commissioning Groups (CCGs) and other commissioning organisations make better decisions about appropriate healthcare for specific eye disorders. This should enable them to fulfil their obligation to commission healthcare for their population that meets the requirements of the NHS Outcomes Framework Indicators and the Government's mandate for the NHS.

In addition, they aim to fulfil their obligation to the five domains in the NHS Outcomes Framework:

- Domain 1: Preventing people from dying prematurely.
- Domain 2: Enhancing quality of life for people with long-term conditions.
- Domain 3: Helping people to recover from episodes of ill health or following injury.
- Domain 4: Ensuring that people have a positive experience of care.
- Domain 5: Treating and caring for people in a safe environment and protecting them from avoidable harm.

The topics selected are set within the context of vision, eyes and blindness. There is a broad overarching aim of health promotion, preventing ocular disease, prolonging eye health and

improving quality of life. This will continue the RCOphth commitment of the highest quality eye care in the context of modern delivery.

This document is primarily aimed those who develop and prepare the guideline products. It only relates to products produced by the RCOphth. The advice in this document draws on international guideline development methodology from Cochrane, the Scottish Intercollegiate Guidelines Network (SIGN) and the National Institute for Health and Clinical Excellence (NICE).

Whilst the principal audiences for guidelines developed by RCOphth are ophthalmologists and commissioners, eye care in the United Kingdom is delivered by a range of professionals in the primary and secondary healthcare sectors and so all guidelines may also be relevant to other healthcare professionals, patients, carers, service users and providers and the public.

1.3 Key Terms

Sponsoring Organisation: The sponsoring organisation is the RCOphth which defines the need for guidance, sponsor its development and maintain responsibility for its content and dissemination.

Guideline Development Group (GDG): the multi-professional group established by the RCOphth to develop the clinical guidelines. This group is responsible for the development of the guideline in accordance with the requirements of this Process Manual. This may be facilitated by either face-to-face or virtual meetings.

2 Objectives

2.1 Clinical Guideline

This is topic-specific and is designed to facilitate the delivery of high quality ophthalmic care that is evidence-based and deliverable within the NHS. The RCOphth will produce guidelines that:

- Promote patient safety and quality patient care.
- Inform the clinician and evaluates research findings.
- Improve the quality of healthcare and healthcare related outcomes.
- Recognise knowledge-to-practice gaps and identifies priority areas for research.
- Underpin quality control and promote audit.

2.2 Commissioning guidance

Commissioning Guidance is designed to support the commissioning of high quality services and support local service design to provide evidence-based, cost effective, patient centred ophthalmic health care that meets the needs of the local population. The guidance is topics specific and encourages commissioning within the context of national drivers for change such as the Five Year Forward View.

The guidance:

- supports CCG's to commission high value care for patients with ophthalmic disorders, through the description of evidence based care pathways
- highlights inequalities in the provision of clinical services
- describes process and outcome measures that allow commissioners to make

- intelligent risk based commissioning decisions which optimise clinical effectiveness and patient safety
- provides levers for change within the local healthcare community
- links to patient and clinician facing information, and provides practical examples of high value care pathways that have been implemented in other healthcare communities
- identifies gaps in knowledge and priority areas for research

The guidance does not replace existing clinical guidelines or systematic reviews of the literature but rather provides practical evidence based information to support commissioning, for example, information on the current provision of services, patient outcome indicators in the population for which the CCG is responsible and levers for change such as audit, peer review measures and quality specifications.

The guidance cannot describe every possible care pathway or treatment option and the decision to commission a pathway will depend on the needs of the local population for which the CCG is responsible. However, they do outline the important principles and performance measures for safe high quality care in an population.

Commissioning Guidance for CCGs does not cover commissioning of specialised services (<https://www.england.nhs.uk/commissioning/spec-services/>)

3 Method

Development of RCOphth guidelines will include:

- Proposal by interested party, including consideration of funding
- Decision to commission a topic, considered in a formal and systematic way
- Pre-determined method of searching for evidence
- Standardised appraisal of evidence
- Grading of recommendations
- Independent peer-review
- Consultation
- Dissemination to the RCOphth members

Implementation of the Clinical Guideline is not mandatory. In addition, guidelines are intended to be helpful in specific clinical conditions or circumstances for the majority of the time.

4 Topic Selection

Proposals for new guidance will be considered by the RCOphth, and any partner organisations involved in the guidance and signed off by their executive.

4.1 Clinical Guidelines

Clinical Guidelines should cover eye disorders, ophthalmic surgical procedures, and others defined by specific ICD10 and OPCS4 codes.

Any group or individual may propose a topic to the RCOphth (see Appendix 1: Clinical Guideline Proposal Form). All those involved with a proposal and subsequent development must declare any conflict of interests. The Guideline Topic selection process will follow four stages:

1. Annual call and acceptance of guideline proposals (see Appendix 1)
2. Scientific Committee review proposals to determine Shortlist (add as an annex the Scientific Committee Terms of Reference)
3. Accepted proposals are expounded to provide further details including scoping searches
4. Scientific Committee review shortlist and accept a predetermined number of guidelines for development

The RCOphth will prioritise the development of guidelines using the following selection criteria:

Major Criteria

- The burden of disease
- Potential to improve outcome
- Evidence of variation in practice

Additional Criteria

- Conditions where an effective treatment is proven that could reduce morbidity or mortality
- A clinical priority for the NHS.
- Clinical uncertainty as evidenced by wide variation in practice or outcomes
- Potential resource impact on the NHS
- Evidence of inequalities such as equity of access,
- The perceived need for a guideline, as indicated by a network of relevant stakeholders.
- Where the NHS, Public Health and Adult Social Care Outcomes Frameworks (and future Child Health Outcomes Strategy) come together to deliver integrated services.

4.2 Commissioning Guidance

Commissioning Guidance will cover care pathways and services for patients with eye disorders and undergoing ophthalmic surgical and invasive procedures. They should reflect broad areas of care and be based around interactions between primary and community care and secondary care, access and service specifications.

In scoping the guidance, the Professional Standards Committee will advise the College on the subject matter and key questions to be answered by the guidance and may alert its fellows, members, and registered stakeholders, encouraging comments on the scoping exercise. The GDG will agree the scope of the guidance for each topic.

The College will prioritise the development of the guidance against the following criteria:

- burden of disease: population need, morbidity, mortality
- clinical priority: is there an effective treatment that may reduce morbidity or mortality if widely adopted?
- clinical uncertainty: is there wide variation in practice or outcomes?
- patient safety: is there significant risk for harm?

- resource: what is the resource impact on the NHS?
- equity of access: are some patients being denied appropriate treatment?
- NHS England priority area

4.3 Updating Published Guidelines

As practice continues to develop and new options for treatment become available, guidelines will require revision to reflect current best practice. All RCOphth Guidelines are published with a review date (typically three years after publication) and will come under periodic review when necessary.

An unscheduled review may be triggered by changes in commissioning practices, NHS legislation, NICE clinical guidelines or other new evidence suggesting that a review is in the interest of service users. The Scientific/Professional Standards Committee is responsible for agreeing any unscheduled review.

4.4 Selecting guidelines for updating

1. An update search looking for evidence based guidelines, Health Technology Appraisals (HTA)s, and systematic reviews produced since publication of the last version of a guideline based on the key questions and search strategies used in the original guideline (but also include an element of horizon scanning for new treatments or technologies).
2. The search results are incorporated into a report that summarises the new evidence and looks at how it will affect the recommendations made in the existing guideline.
3. This report will be sent to the guideline development group and other relevant bodies
4. Responses to this consultation are gathered and presented to the Scientific Committee who will then makes recommendations using four possible outcomes:
 - the guideline remains current and a new review date is set
 - the guideline will undergo a complete review
 - the guideline will undergo a partial or selective review
 - the guideline will be withdrawn

5 The Guideline Development Group (GDG)

Responsibility for the composition of the GDG lies with the RCOphth. At the outset of a new guideline development project, the RCOphth will aim to bring together a group that will fulfil the following parameters:

- Multidisciplinary, with all relevant clinical specialties represented alongside lay input
- Relevant to current care practice, with a balance between members actively involved in day-to-day delivery of health care with topic experts and academics where appropriate.
- Membership should represent the range of care or treatment settings related to the clinical condition (e.g. primary, secondary and tertiary care centres), and encompass the range of skills and expertise required for the specific project.

- Specialists other than clinicians may be recruited when necessary, for example health economists or social services
- Geographically representative for the UK, including participants from urban centres and rural locations.

This is an iterative process seeking nominations and issuing invitations followed by refining membership depending on acceptance of individuals whose participation is sought. GDGs may vary in size depending on the scope of the topic under consideration, but generally comprise between 10 and 20 members. The RCOphth will need to identify an appropriate balance between the number of organisations or specialties that should be represented on the guideline development group, and achieving a manageable group size for effective decision-making.

5.1 Guideline Development Group Chair

The role of the Chair is crucial to ensure that the group functions effectively and achieves its aims. The position of chair is advertised via RCOphth communication channels.

Applications are by CV, a completed conflicts of interest declaration (<https://www.rcophth.ac.uk/about/governance/policies/>), equality monitoring form and a personal statement. Selection is by the Scientific Committee Chair (Clinical Guidelines) or the Professional Standards Committee (Commissioning Guidance) or nominated subgroup. In certain circumstances, the selection panel may request applicants to attend for interviews.

The Chair may be a specialist in the guideline topic, but this is not essential because other members provide specialist knowledge. Chairs must be sensitive to challenges in inter-professional relationships and ensure that all members of the group feel able to contribute fully to the guideline development process. The Chair must be prepared to overcome potentially difficult variations in opinions by careful negotiation.

The RCOphth will assist the Chair to identify potential barriers to successful group work, to plan and progress the guidance development project, and acts as facilitator at GDG meetings.

The Chair must ensure that clinical knowledge and expertise is appropriately applied to the interpretation of the evidence base and that all group members can actively contribute when the drafting of guideline recommendations.

The RCOphth guideline adviser will assist the Chair to identify potential barriers to successful group work, to plan and progress the guideline development project, and acts as facilitator at group meetings.

5.2 Guideline Development Group members

Members must be committed to the group and the tasks involved. GDG members represent either a geographical region, a specialty or professional group and must be prepared to consult with colleagues to ensure that the widest possible range of views are considered. The approximate life span of each guideline development group varies e.g. a new project (around 24 months), an update (around 12 months) or a minor revision (3–6 months). For a full guideline project, groups will meet on once every two to three months, although groups may form subgroups that meet more frequently.

Representatives from across the whole treatment pathway relevant to the Guideline are needed and may include (but not be limited to) representatives of:

- patients, carers and the public
- commissioners
- public health
- primary care
- community and social care
- secondary care including multi-professional representatives as appropriate

Patients, carers and the public have a unique perspective on the delivery of eye care services and it is vital that their experience, beliefs and values are reflected in the guidance product. Patient representatives have equal standing to their clinical counterparts.

Patient involvement is secured through links with RCOphth lay group members, or through a relevant charity or patient organisation linked to the topic under consideration. There should be at least two patient representatives in a GDG.

Patient representatives are supported in their duties by their Sponsoring Organisation, usually the RCOphth.

Appropriate representation will support:

- a patient-centred approach
- relevance to the whole health and social care network
- credibility and usefulness of the resulting guidance
- dissemination and implementation
- effective quality assurance and planning processes
- effective utilisation of resources

Responsibility for the composition of the development group lies with the RCOphth. The Chair and members of the GDG will be required to sign a Conflict of Interest declaration (<https://www.rcophth.ac.uk/about/governance/policies/>) and their names and affiliations published in the final guideline document.

The GDG reports quarterly to the RCOphth's Professional Standards Committee (commissioning guidance) or the Scientific Committee (Clinical Guidelines). Day to day oversight is provided by the Head of Professional Support (Commissioning Guidance) and delegated to the Guidelines Scientific Manager for clinical guidelines. The Professional Standards Committee or Scientific Committee approves any published guidance, as relevant, with confirmation that the correct development process has been followed.

A Terms of Reference template for Guideline Development Groups on their key roles and responsibilities is provided at Appendix 3.

6 Developing the Guideline

Products should use clear, unambiguous language, clearly defining terms used to ensure shared understanding by all users. The following describes the methodological steps. These

are consistent with recognised best practice as described in the *NICE Guidelines Manual*ⁱ, Scottish Intercollegiate Guidelines Network (SIGN 50): a guideline developer's handbookⁱⁱ and the *Cochrane Handbook for Systematic Reviews of Interventions*ⁱⁱⁱ.

GDG members will be required to form an opinion that assists the development of realistic, achievable guideline that is relevant to current practice in the context in which it is delivered in the UK. Inevitably, there will be both objective and subjective elements to this grading. The GDG will endeavour to arrive at all decisions by unanimous agreement. When this is not possible the view of the majority plus two will prevail and will be adhered to by all members. However, the GDG will always try to resolve any conflicts in an amicable way.

6.1 Defining Key Review Questions

GDGs are encouraged to break down the guideline remit into a series of key review questions. These should be formulated using a structured framework such as the PICO (Population, Intervention, Comparison, Outcome) or SPICE (Setting, Perspective, Intervention, Comparison, Evaluation) formats.

Patient or population to which the question applies

Intervention (or diagnostic test, exposure, risk factor etc.) being considered in relation to those patients

Comparison(s) to be made between those receiving the intervention and another group who do not receive the information

Outcome(s) to be used to establish the size of the effect caused by the intervention

All clinically important questions are addressed even if it is thought there will not be any good evidence. If there is no good evidence, then highlighting it as an area for research is a useful outcome in itself.

Outcomes must be specified, ideally at the stage of setting the key questions but certainly before making judgments about the quality of evidence.

Outcomes should be discussed by the guideline development group and categorised in terms of their importance:

- Critical outcomes: Those on which the overall quality of evidence for a key question are based.
- Important outcomes: Those that a healthcare professional is likely to take into account when making treatment decisions, but which are not the ultimate aim of the intervention under consideration.
- Patient important outcomes should be considered alongside clinical outcomes.

As part of the question setting process, a set of inclusion and exclusion criteria is drawn up and saved as part of the record of the review. This will provide guidance at a later stage when evidence are selected for review. Inclusion criteria will include

ⁱ NICE Guidelines Manual

ⁱⁱ Scottish Intercollegiate Guidelines Network (SIGN 50): a guideline developer's handbook

ⁱⁱⁱ Cochrane Handbook for Systematic Reviews of Interventions

- Definition of the topic
- Duration of therapy,
- Drug dosage,
- Frequency of treatment.
- Socio Demographic factors

Exclusion criteria are likely to be more variable. They are, however, essential in that they help sift out irrelevant studies from the (often very large) initial search result.

Once the questions are agreed, they form the basis of the literature searches to be undertaken.

6.2 Search Strategy

An explicit search strategy for the topic under consideration is developed using the support of search experts and information scientists. The literature search must focus on the best available evidence to address the key review questions. Searches will aim to identify the following types of evidence:

- systematic reviews
- randomised controlled trials
- observational studies
- diagnostic studies
- economic studies
- Accredited guidelines
- NHS Digital information including Hospital Episode Statistics information or equivalent in other UK nations

The GDG may enlist support from professional information specialists to conduct the search for evidence (subject to available budget). The group will define keywords and terms in terminology in terms of the Medical Subject Headings (MeSH)

6.3 Electronic search for identifying the literature

In order to minimise bias and to ensure adequate coverage the search is performed across the following databases:

- MEDLINE
- EMBASE
- NHS Evidence > Filter > Guidelines
- Cochrane Database of Systematic Reviews – CDSR (Cochrane reviews)
- Cochrane Central Register of Controlled Trials – CENTRAL (clinical trials)
- Database of Abstracts of Reviews of Effects – DARE
- metaRegister of Controlled Trials (mRCT) (<http://www.controlled-trials.com/mrct/>)
- International Clinical Trials Registry Platform (ICTRP) (<http://www.who.int/ictip/>)
- ClinicalTrials.gov (<http://www.ClinicalTrials.gov>)
- National Guidelines Clearing House (<http://www.guideline.gov/>)

Further database searches can be added at the suggestion of the GDG should areas of specific interest dictate. The period of time the search should cover will depend on the topic

of the guideline and is agreed by the GDG. If the initial search retrieves only a small number of results, the GDG will decide whether to widen the search to include other study types or a longer search period. In case of a poor evidence base, the GDG may also consider the need to identify additional evidence through the bibliography of retrieved articles for additional references. Should alterations occur, they are stated in the methods of the guideline.

6.4 Search Results

Initial sifting regarding relevance of the retrieved evidence is based on the abstracts and the inclusion and exclusion criteria outlined in the original literature review request from the GDG. The final sift details will be forwarded to the GDG for critical appraisal (see 6. GRADING THE LEVEL OF EVIDENCE and the critical appraisal check lists below). Further critical appraisal will require review of the full text articles by the GDG and is listed with full citations and abstracts (where available).

If there are pre-existing guidelines in the topic area, the GDG should assess them in terms of their quality using the AGREE II tool^{iv}. They should consider if they are relevant and current to key objectives that the group has set. If they determine that they can be used instead to avoid needless duplication of work, the Chair would alert and discuss this with the relevant RCOphth Committee and the existing guidelines are communicated to Members.

6.5 Evaluating the Evidence

Once studies are selected as potential sources of evidence, the methodology used in each study is assessed to ensure its validity. The methodological assessment is based on criteria that focus on those aspects of the study design. These criteria differ between study types, and a range of Tools or checklists are made available to the GDG to bring a degree of consistency to the assessment process. These include the AMSTAR tool for systematic reviews; a SIGN checklist for RCTs; MERGE for observational studies and QUADAS for diagnostic accuracy studies. Copies of these checklists and accompanying notes on their use are available on the SIGN website (www.sign.ac.uk).

6.6 Considering the Quality of the Evidence

The guideline development group will look at a body of evidence for each question; this raises a number of issues beyond the methodological quality of the individual studies and the evaluation of this body of evidence should be completed before deciding what to recommend in the guideline. The focus here is on the quality of the available evidence, not what conclusions may be drawn from it and there are a number of critical questions that need to be considered.

How **RELIABLE** are the studies in the body of evidence? – Is there a risk of **BIAS**?

Are the studies **CONSISTENT** in their findings? – Is there significant statistical heterogeneity?

Are the studies relevant to the **TARGET POPULATION**? – Are there variations on baseline risks including demographic, socio-economic and disease severity?

Is the **SIZE OF EFFECT** reliable? – How precise are the findings?

Do you have **ALL** the relevant **EVIDENCE**? – Is there a risk of publication bias?

^{iv} Brouwers M, Kho ME, Browman GP, Burgers JS, Cluzeau F, Feder G, Fevers B, Graham ID, Grimshaw J, Hanna S, Littlejohns P, Makarski J, Zitzelsberger L for the AGREE Next Steps Consortium. AGREE ii: Advancing guideline development, reporting and evaluation in healthcare. Can Med Assoc J. 2010. Dec 2010; 182:E839-842; doi: 10. 1503/090449 last accessed 03/11/13

6.7 Recording the Search

The systematic literature search including search strategy, databases and dates searched are recorded and saved for use in future updates. A listing of the search strategies used should be included as an appendix within the published guideline.

6.8 Search reruns

Search reruns should be undertaken if major changes in the evidence bank are identified by GDG members. A request for suggestions will be sent to GDG members 6-8 weeks prior to the submission of the draft guidance to NICE if more than a year has passed since the original search.

6.9 Uncertainties

It is likely that in the process of guideline development a number of questions arise that cannot be answered reliably through the available evidence. If that is the case, it is in the interest of the wider scientific community to share knowledge about these uncertainties in order to prioritise new research. Any identified uncertainties are added by the information specialist(s) involved in the guideline development to the NHS Evidence – UK Database of Uncertainties about the Effects of Treatments (DUETs)^v. In addition, the GDG should report uncertainties to RCOphth. In these circumstances, the GDG may put out a call for evidence from stakeholders.

7 Grading the level of evidence

Evidence is graded according to its strength as detailed by the Scottish Intercollegiate Guidelines Network (SIGN 50)^{vi}:

Type of Evidence	Description
1++	High-quality meta-analyses, systematic reviews of RCTs, or RCTs with a very low risk of bias
1+	Well-conducted meta-analyses, systematic reviews of RCTs, or RCTs with a low risk of bias
1-	Meta-analyses, systematic reviews of RCTs, or RCTs with a low risk of bias
2++	High-quality systematic reviews of case-control or cohort studies High-quality case-control or cohort studies with a very low risk of confounding, bias or chance and a high probability that the relationship is causal
2+	Well-conducted case-control or cohort studies with a low risk of confounding, bias or chance and a moderate probability that the relationship is causal

^v NHS Evidence – UK Database of Uncertainties about the Effects of Treatment (DUETs). www.library.nhs.uk/duets/ last accessed 03/11/2013.

^{vi} Scottish Intercollegiate Guidelines Network (SIGN 50) last accessed 03/11/2013

2-	Case-control or cohort studies with a high risk of confounding, bias or chance and a significant risk that the relationship is not causal
3	Non-analytic studies (for example, case reports, case series)
4	Expert opinion, formal consensus

Note: Studies with a negative level of evidence (‘-’) should not normally be used as a basis for making a recommendation.

Critical appraisal checklists can support GDG in defining the strength of evidence to support guideline recommendations as well as defining inclusions and or exclusions. Checklists can be found at www.casp-uk.net^{vii} or www.sign.ac.uk^{viii}

8 Making Recommendations

Using the evidence the GDG should decide upon its recommendations. The strength of each recommendation should take into account the quality of the evidence.

Some recommendations are 'strong' in that the GDG believes that the vast majority of practitioners or commissioners and people using services would choose a particular intervention if they considered the evidence in the same way as the GDG. However, there is often a closer balance between benefits and harms, and some people would not choose an intervention whereas others would. This may happen, for example, if some people are particularly likely to benefit and others are not. In these circumstances, the recommendation may be considered to be conditional.

A **strong** recommendation is made where:

- the evidence is of high quality (see section 6)
- estimates of the effect of an intervention are precise (i.e. there is a high degree of certainty that effects will be achieved in practice)
- there are few downsides of therapy
- there is a high degree of acceptance among patients

A **conditional** recommendation is made where:

- there are weaknesses in the evidence base
- there is a degree of doubt about the size of the effect that can be expected in practice
- there is a need to balance the upsides and downsides of therapy
- there are likely to be varying degrees of acceptance among patients

The strength of the recommendation can be graded by the GDG as detailed by the Scottish Intercollegiate Guidelines Network (SIGN 50)⁹. The grade of recommendation relates to

^{vii} <http://www.casp-uk.net/#!/appraising-the-evidence/c23r5> (Critical Appraisal Skills Programme) last accessed 03/11/13

^{viii} <http://www.sign.ac.uk/methodology/checklists.html> (Scottish Intercollegiate Guidelines Network) last accessed 03/11/13

the strength of the evidence on which the recommendation is based. It does not reflect the clinical importance of the recommendation.

Grade	Explanation
A	<p>At least one meta-analysis, systematic review, or RCT rated as 1++, and directly applicable to the target populations; or</p> <p>A body of evidence consisting principally of studies rated as 1+, directly applicable to the target population, and demonstrating overall consistency of results</p> <p>A body of evidence including studies rated as 2++, directly applicable to the target population, and demonstrating overall consistency of results; or Extrapolated evidence from studies rated as 1++ or 1+</p>
B	A body of evidence including studies rated as 2+, directly applicable to the target population and demonstrating overall consistency of results; or Extrapolated evidence from studies rated as 2++
C	Evidence level 3 or 4; or Extrapolated evidence from studies rated as 2+

In addition the GDG may choose to present the strength of a recommendation in the wording such as 'should' 'measure', 'advise', 'commission' or 'refer' to reflect a strong recommendation and words like 'consider' to reflect a recommendation for which the evidence of benefit is less certain.

In deciding upon the strength of recommendation based upon the evidence the GDG should consider the following aspects:

- Is this question a priority? – How and how many patients could benefit?
- How sure are we that any given option will work?
- Balancing benefits and harms – Do benefits to the patient outweigh (preferably sustainably) any risks or harms?
- How do patients value the different outcomes?
- Equity – Will the recommendation discriminate against any group of patients?
- Costs and benefits – consider both cost effectiveness and affordability
- Are the key questions to be answered
- The volume, quality, consistency and applicability of the evidence available
- The likely impact of the recommendation from a clinical and patient perspective,
- The population affected, and resource implications
- Potential organisational, economic, cultural and political barriers to
- Implementation

Key Recommendations

The GDG will identify a small number of key recommendations in a separate section of the guideline. These are identified as the recommendations that, in order to improve patient outcomes, should be prioritised for implementation. They should take account of both strength of evidence and size of effect. It should detail the major recommendations with the strength of the recommendation.

9 Guideline Document

The full guideline should be set out according to a uniform template (see Appendix 5). The guideline should use clear, unambiguous language, clearly defining terms used to ensure shared understanding by all users. There should be an abbreviations key used. There should be a directory with links to:

- patient information and shared decision making tools e.g. NHS Choices, NHS Direct
- clinician facing information e.g. NHS Choices, NHS Evidence, Map of Medicine
- examples of good practice (if available) in other healthcare communities e.g. NHS Evidence, Quality, Innovation, Productivity and Prevention (QIPP) Case Studies
- other guidelines that are relevant to the one being developed

Other additional information may be added to the guideline where relevant. This may include:

- patient and carer information leaflets
- clinical audit tool
- proforma for clinical records
- treatment or management protocol

10 External Peer Review

All outputs will be subject to formal peer review by at least three independent referees who have had no prior involvement in the guideline development process. Reviewers are appointed by the College and should include at least one specialist in the subject matter and one ophthalmologist, who does not specialise in the subject matter and, for commissioning guidance, one commissioning organisation representative. They will be required to sign a Conflict of Interest declaration <https://www.rcophth.ac.uk/about/governance/policies/>. Peer reviewers comment specifically on the:

- comprehensiveness and applicability of the document
- content and clarity and its suitability to different environments
- interpretation of the evidence available to support its recommendations
- likely impact on patient groups affected by the guideline
- likely impact / ability of the health service to implement the recommendations.

Draft guidelines will be available on the website of the College and any partner organisations for at least 4 weeks, inviting comments from key stakeholders. Comments received from peer reviewers and via the website are considered by the GDG. Each point raised is considered and any changes made to the guideline noted.

Prior to publication, or during development, in certain circumstances, the College may wish to discuss the guidance document with a relevant focus group or professionals or patients.

Prior to publication, in certain circumstances, the College may wish to subject the guidance document to a small-scale pilot phase with typical users to ensure consistency, applicability and cohesiveness. Feedback from the pilot is incorporated into the final draft of the guidance document, prior to the peer review process.

Once the draft is finalised, each member of the GDG is asked to formally approve the guidance for submission to the RCOphth. The RCOphth has final sign off and takes responsibility for publication, dissemination and communication.

11 Dissemination of Clinical Guidelines

Guidelines will be available free of charge and will be published on the websites of the College, partner organisations and NHS Evidence. RCOphth may engage in various activities to encourage the use of clinical guidelines, such as:

- submission to Eye, the official journal of the RCOphth
- speaking at relevant conferences, seminars or events
- writing articles for journals and newsletters
- supporting workshops and regional events
- encouraging people to submit case studies to NHS Evidence

The RCOphth will provide support to disseminate guidelines at the local level and provide advice.

12. Evaluation and Impact Assessment

This can be assessed by the uptake of guideline recommendations, usually utilising data from audits or routine service indicators (either national or local).

Evaluation of performance against the following tools could facilitate baseline assessment as well as evaluating the impact of implementation of Commissioning Guidance and could be included in service specification for monitoring commissioned services:

- The Portfolio of Indicators for Eye Health and Care¹ – this provides a range of process and outcome indicators incorporating the domains of safety, effectiveness and experience; which are suitable for locality-based review, audit and action. The indicators are informed by College and NICE guidance, the NHS, Public Health and Social Care Outcomes Frameworks; and are reviewed regularly to remain responsive to current practice;
- Quality Indicators specified in Commissioning Guidance;
- The Commissioning Frameworks from the Clinical Council for Eye Health Commissioning – these provide recommendations for the delivery and organisation of pathways within services: Primary Eye Care², Community Ophthalmology³, Low Vision Habilitation and Rehabilitation⁴; so that patients

are managed in the most appropriate pathway based on clinical risk stratification of their condition and the skills of the practitioner.

1. Portfolio of Indicators for Eye Health and Care – 2015.

<http://www.vision2020uk.org.uk/vision-2020-uk-ophthalmic-public-health-committee-portfolio-of-indicators-for-eye-health-and-care/>

2. Primary Eye Care Framework (CCEHC 2016) <https://www.college-optometrists.org/the-college/ccehc/delivery-models.html>

3. Community Ophthalmology Framework (CCEHC 2015) <https://www.college-optometrists.org/the-college/ccehc/delivery-models.html>

4. LVHRS framework (CCEHC 2017) <https://www.college-optometrists.org/the-college/ccehc/delivery-models.html>

13 Editorial Independence

The RCOphth will ensure that commercial interests do not influence the development of guidelines. All stakeholders in the guideline development and peer processes are required to declare competing interests. If any sources of funding are received towards the development of Clinical Guidelines this is reported within the published guideline.

14 Funding of Clinical Guidelines

The cost of the production of a guideline considers:

- the number of members in the Guideline development group (meeting expenses)
- information specialists used in the search process
- length of time in which the guideline is developed
- cost of dissemination of the clinical guideline is minimised by use of electronic methods
- if the guideline is developed with another organisation, the costs could be shared where there is no compromise to the independence of the GDG.

Each guideline must contain a list of all funding sources and ensure all potential bias is kept to a minimum.

Guideline Proposal Form

1	Title	
2	Please provide a brief background to this guideline suggestion [Please insert word count, max 250 words]	
3	Please define the intent of the guideline (e.g. prevention, screening, diagnosis, treatment etc.) [Please insert word count, max 50 words]	
4	Please detail who is the target audience and who would benefit from the proposed guideline. [Please insert word count, max 50 words]	
5	Please describe what the potential clinical impact of a guideline in this topic would be (see notes on selection criteria for guideline) [Please insert word count, max 50 words]	

6	<p>Please detain the evidence base which is currently available to support recommendations on effective practice in this area</p> <p>[Please insert word count, max 250 words]</p>	
7	<p>Are there any existing guidelines relevant to this proposal? Please give source and data of publication. Please comment on their quality and whether they are still valid.</p> <p>[Please insert word count, max 250 words]</p>	
8	<p>Proposed cost, and proposed source of funding.</p> <p>[Please insert word count, max 250 words]</p>	
9	<p>Provide any further information which you would like to be considered (e.g. benefits of implementation, priorities for patients and carers, economic considerations etc.)</p> <p>[Please insert word count, max 250 words]</p>	
10	<p>References</p> <p>[max 5 references]</p>	<p>If applicable please attach any reference(s) that are key to the proposal.</p>

11	Suggested peer reviewers	1. [enter name] [enter title] [enter organisation] [enter email and contact details] 2. [enter name] [enter title] [enter organisation] [enter email and contact details] 3. [enter name] [enter title] [enter organisation] [enter email and contact details]
12	Proposer	[enter name] [enter title] [enter organisation] [enter email and contact details] Signature: Date:
13	Supporter	[enter name] [enter title] [enter organisation] [enter email and contact details] Signature: Date:
14	For Office Use Only Date received	

A Conflict of Interest Declaration Form available on request from the College, MUST be completed and enclosed for both the proposer and the supporter.

Appendix 2 Terms of Reference Template for Guideline Development Groups

Title	Guideline Development Group for Clinical Guideline [enter title]
Description	A Guideline Development Group appointed by the Royal College of Ophthalmologists (RCOphth) to develop Guidelines on [enter topic] following the RCOphth Guidelines Process Manual
Functions/ Responsibilities	<ol style="list-style-type: none"> 1. Receive instruction from the RCOphth as to the topic required and timescale 2. Follow the RCOphth Guidelines Process Manual for the development of Guidelines 3. Identify key questions and work, where appropriate, with library and information specialists in determining search terms of the evidence review. 4. Identify existing evidence and grade the evidence. Reach recommendations. 5. Use the Guideline template to create document 6. Prepare final draft of the Guideline and liaise with the RCOphth regarding independent peer review. 7. Consider comments from the peer review process and incorporate relevant amendments. 8. Submit final draft to the RCOphth. 9. Report any uncertainties/research questions arising from the Guideline development process to the RCOphth. 10. Keep accurate records of key decisions, evidence reviews, etc. 11. Keep RCOphth informed throughout the process to ensure adherence to timescale and finance.
Meetings per year	Up to four during the Guidelines development process. Work should be encouraged via email and teleconference.
Quorum	50% of total membership
Chair	Appointed by RCOphth
Membership	Appointed by the Chair in collaboration with the RCOphth Ex officio: Chairman of the Scientific/Professional Standards Committee

Committee secretaryThe Royal College of Ophthalmologists
Reporting to	Scientific/Professional Standards Committee of The Royal College of Ophthalmologists
Date of approval	TBC

Appendix 3 Template for a Clinical Guideline

1. Title Page
 - 1.1. Title of Clinical Guideline
 - 1.2. RCOphth logo
 - 1.3. Sponsored by the Royal College of Ophthalmologists
 - 1.4. Date of Evidence Search
 - 1.5. Date of Publication
 - 1.6. Date of Review
2. Introduction
 - 2.1. Brief description of the condition
 - 2.2. Population to whom the guideline applies e.g. the age range, gender, clinical description (ICD10) and co-morbidity (ICD10) and any exclusions
 - 2.3. Current practice, and why there is scope for change
3. Objectives
 - 3.1. The overall aim is stated
 - 3.2. The clinical questions covered by the guideline
 - 3.3. Description of the key stakeholders and end users
4. Methods
 - 4.1. Inclusion and exclusion criteria are stated
 - 4.2. Search strategy
 - 4.3. Levels of evidence
 - 4.4. Grades of recommendations
5. Results
 - 5.1. Summary of the results
 - 5.2. Evidence with grade
 - 5.3. Good practice points
6. Summary of review
 - 6.1. Benefits and risks
 - 6.2. Limitations of the evidence
 - 6.3. Limitations of the guidelines
 - 6.4. Identify any organisational barriers that may exist
 - 6.5. Recommendations for implementation
 - 6.6. Consideration of clinical audit
7. Recommendations
8. References
9. Quick Guideline Reference
10. Appendices
 - 10.1. Acknowledgements

- 10.2. Details of the sources of any funding
- 10.3. Details of the external peer-reviewers
- 10.4. Membership of the Guideline Development Group
- 10.5. Contribution of authors
- 10.6. Details of the electronic searches performed
- 10.7. Directory

Appendix 4 Template for the Quick Reference Guide for [Guideline Title]

The following should be included:

Introduction

- Brief description of the condition and patient population
- Why this guideline/topic was selected

Recommendation(s) for practice

Key Question	Recommendation	Strength of Evidence

Appendix 5 Template for Commissioning Guidance

Introduction:

Commissioning Guidance aims to support the commissioning of high quality services and local service design to provide evidence-based, cost effective, patient centred ophthalmic health care that meets the needs of the local population. The guidance is topic-specific and encourages commissioning within the context of national drivers for change such as the Five Year Forward View. They are a resource to assist commissioners and providers deliver high quality and evidence based healthcare across England.

High value care pathways provide patients and the public, health and social care professionals, commissioners and service providers with a clear description of what constitutes a high quality service. Organisations can use the guidance to assess their current performance against evidence-based measures of best practice, and identify priorities for improvement. Quality indicators support the implementation of the recommendations through commissioning and the contracting process and can be used to incentivise provider performance by using the indicators in association with incentive payments such as Commissioning for Quality and Innovation (CQUIN).

Implementation of the guidance is the responsibility of local commissioners and/or providers, in their local context, in light of their duties to avoid unlawful discrimination and to have regard to promoting equality of access. Nothing in the guidance should be interpreted in a way that is inconsistent with compliance with those duties.

We are keen to improve Commissioning Guidance to meet the needs of commissioners. Please send us your comments and ideas for future topics.

email: contact.

*[sponsoring organisation]*The Royal College of Ophthalmologists www.rcophth.ac.uk

The condition:

- Brief description of the condition and how it affects patients and the eye
- headline epidemiology and why this makes it a commissioning priority
- current practice, and why there is scope for change
- headline cost-benefits of commissioning the service

General commissioning guidance for *the condition*:

Recommendation 1: Commissioners of X care should work in partnership with a range of stakeholders, including service users and carers, community optometry services, general practitioners, health and wellbeing boards, the HES, community pharmacy services, established local networks, social care, rehabilitation officers for the visually impaired, voluntary organisations, and adjacent clinical commissioning groups.

Recommendation 2: Commissioners should be mindful of ensuring access for hard to reach groups, including those with special needs. Vulnerable individuals, such as people in long term care and people with learning difficulties, are at increased risk of sight loss and should undergo regular sight tests, including reasonable adjustments as necessary

(<http://www.nib.org.uk/knowledge-and-research-hub/research-reports/prevention-sight-loss/prevalence-VI-learning-disabilities>).

Recommendation 3: Organisations should use the guidance to assess their current performance against evidence-based measures of best practice, and identify priorities for improvement.

High Value Care Pathway:

The following should be considered when describing high value care pathways:

1. Population to whom the guidance applies e.g. the age range, gender, clinical description and co-morbidity and any exclusions
2. Clear and precise description of what is appropriate, in which situation, and in which patient group, as permitted by the body of evidence
3. Criteria for referral to specialist, community and/or secondary care
4. Criteria for investigation and intervention and the procedures involved, particularly where this involves new medical technologies or interventional procedures covered by NICE Guidance
5. The configuration of eye care clinical service
6. Access to treatment/ response times: based on need and expected outcome
7. Discharge from services: including aftercare and communication with other teams
8. Interface/ Integration: with local services, use of third sector
9. Service Location: home, community and secondary care
10. Staff: staffing levels, minimum band or levels of experience and competency and expected skill mix
11. Impact: on admissions to A&E, inpatient hospital care and length of stay in hospital, other services
12. Cost: likely cost of new or additional services, potential cost savings

Quality indicators:

Quality indicators are tools and measures for commissioners and providers to aid implementation of high value care pathways.

Standard	Description	Data Specification (if required)

Other quality assessment: Peer review is a quality assurance programme for health services. The programme may involve both self-assessment by provider teams and external reviews of teams conducted by professional peers, against nationally agreed “quality measures”. Peer review aims to improve care for people and their families by:

- ensuring services are as safe as possible;
- improving the quality and effectiveness of care;
- improving the patient and carer experience;
- undertaking independent, fair reviews of services;
- providing development and learning for all involved;

- encouraging the dissemination of good practice.

The College recommends peer review for a more qualitative assessment.

Directory:

Patient Information for [guide title]

Links to patient information and shared decision making tools

Name	Publisher	Link

Clinician Information for [guide title]

Links to clinical guidelines, decision support tools

Name	Publisher	Link

Case Studies for [guide title]

Links to examples of good practice e.g. NICE, NHS evidence, The Way Forward

Name	Publisher	Link

Benefits and Risks

Consideration	Benefit	Risk
Patient outcome		
Patient safety		
Patient experience		
Equity of Access		
Resource impact		

Research Recommendations

Other recommendations

Evidence Base

Guideline Development Group for [guide title]

A commissioning guidance development group was established to review and advise on the content of the commissioning guide. This group met [*frequency*], with additional interaction taking place via email.

Name	Job Title	Affiliation

Sponsored by The Royal College of Ophthalmologists Date of Evidence Search:
Date of publication: Date of Review: