Appendix B: Guideline scope

B.1 Guideline title

Cataracts in adults: management

B.1.1 Short title

Cataracts in adults: management

B.1.2 Topic

The Department of Health in England has asked NICE 'to develop a clinical guideline on Cataracts: diagnosis and management of cataracts' and to consider issues surrounding 'indications for cataract extraction' and 'wrong lens implant errors'.

B.1.3 Who the guideline is for

- people using services, families and carers and the public
- healthcare professionals in primary care
- healthcare professionals in secondary care
- social care practitioners
- local authorities
- commissioners of ophthalmic and optometric services
- providers of ophthalmic and optometric services
- practitioners in ophthalmic and optometric services.

It may also be relevant for:

- private sector and voluntary organisations
- people working in related services.

NICE guidelines cover health and care in England. Decisions on how they apply in other UK countries are made by ministers in the Welsh Government, Scottish Government, and Northern Ireland Executive.

B.2 Equality considerations

NICE has carried out an equality impact assessment [link in final version] during scoping. The assessment:

- lists equality issues identified, and how they have been addressed
- explains why any groups are excluded from the scope, if this was done.

B.3 What the guideline is about

B.3.1 Who is the focus?

Groups that will be covered

- Adults (18 years and older) diagnosed with cataracts.
- The following subgroups have been identified as needing specific consideration:

  - people with other conditions that may affect management, including people who are frail, older people, people with impaired cognitive function, people with impaired mobility, people in residential care and people with learning disabilities.
- The following subgroups will be considered where appropriate:
  - people with an ocular or systemic condition that affects perioperative management, including people with diabetes, uveitis, glaucoma, retinal disease, macular degeneration, Fuch's corneal endothelial dystrophy, high myopia, hypermetropia and iris defects
  - people who are using medicines that affect perioperative management, including aspirin, oral anticoagulants, low-molecular-weight heparins, alpha antagonists and prostaglandin analogues.

Groups that will not be covered

- Children and young people under 18 years with congenital and/or juvenile cataracts, because the management pathway and issues associated with cataracts are very different in this group compared with adults.
- People with trauma-induced cataracts, who have other pathologies related to the injury.

B.4 Settings

Settings that will be covered

- All settings in which NHS-funded health and social care is received.

Settings that will not be covered

- Elective privately funded surgery.

B.5 Activities, services or aspects of care

Key areas that will be covered

1. Information and support for people with cataracts and their carers.
2. Management
   - Indications and clinical thresholds for referral for surgical treatment.
   - Optimal preoperative assessment strategies in cataract extraction. Specific aspects that will be considered are biometry and risk stratification techniques.
   - Optimal treatment strategies in cataract surgery. Specific aspects that will be considered are: surgical procedures; type and administration of anaesthesia; selection and types of intraocular lens (it is proposed that this would include evaluating the effectiveness of multifocal [non-accommodative] intraocular lenses [subject to approval by NICE's Guidance Executive]). Note that guideline recommendations will normally fall within licensed indications; exceptionally, and only if clearly supported by evidence, use outside a licensed indication may be recommended. The guideline will assume that prescribers will use a medicine’s summary of product characteristics to inform decisions made with individual patients.
   - Cataract surgery for people with astigmatism, specifically the use of toric intraocular lenses and limbal relaxing incisions.
   - Cataract surgery for people with high myopia, specifically interventions to prevent retinal detachment.
   - Second eye surgery. Specific aspects that will be considered are timing and visual acuity level.

- Optimal treatment strategies to prevent complications and errors in cataract surgery. Specific aspects that will be considered are: interventions to prevent intraoperative complications; use of postoperative eye shields; use, administration and timing of antibiotics to minimise the risk of infection; use, administration and timing of topical corticosteroids and/or NSAIDs (non-steroidal anti-inflammatory drugs) to control postoperative inflammation and cystoid macular oedema; strategies to reduce the risk of wrong lens implant errors. Note that guideline recommendations will normally fall within licensed indications; exceptionally, and only if clearly supported by evidence, use outside a licensed indication may be recommended. The guideline will assume that prescribers will use a medicine's summary of product characteristics to inform decisions made with individual patients.
- Management of operative complications, specifically interventions to manage perioperative posterior capsule rupture and postoperative cystoid macular oedema.

3. Ongoing care
   - Optimal postoperative follow-up strategies, including: timing and setting of postoperative assessment and care; healthcare professionals undertaking postoperative assessment and care; and strategies to effectively communicate outcomes between surgical units and providers of postoperative assessment and care.

Areas that will not be covered

1. Training and competency in specialist cataract surgery.
2. Access to general optometric care.
3. Processes for assessing and implementing new technology.
4. Diagnosis of cataracts. Following stakeholder consultation, no specific issues in terms of diagnosing the presence of cataracts were identified because the procedures and assessments were considered straightforward.
5. Interventions to prevent the development and progression of cataracts, including supplements such as vitamins, omega fatty acids, lutein and zeaxanthin, and lifestyle changes such as advice to stop smoking and minimise sun exposure.
6. Surgical interventions that are not used in England, including small incision extracapsular cataract extraction.
7. Additional surgical interventions for conditions other than cataracts, including concurrent procedures such as vitreoretinal surgery and glaucoma surgery.

B.6 Economic aspects

We will take economic aspects into account when making recommendations. We will develop an economic plan that states for each review question (or key area in the scope) whether economic considerations are relevant, and if so whether this is an area that should be prioritised for economic modelling and analysis. We will review the economic evidence and carry out economic analyses. The reference case used will be that for interventions with health outcomes in NHS settings; therefore the preferred unit of effectiveness will be the quality-adjusted life year (QALY), and costs will be considered from an NHS and personal social services (PSS) perspective.

B.7 Key issues and questions

While writing this scope, we have identified the following key issues, and review questions related to them:

1. Information and support for people with cataracts and their carers
   - What information do people with cataracts and their carers find useful, and what format (for example written or verbal) do they prefer it to be provided in?

- What information on cataract surgery (before, during and after the operation) do people and their carers find useful, and what format (for example written or verbal) do they prefer it to be provided in?

2. Indications and clinical thresholds for referral for surgical treatment after initial presentation to the optometrist or GP
   - What are the indicators for referral for cataract surgery?
   - What are the optimal clinical thresholds in terms of severity and impairment for referral for cataract surgery?
3. Optimal preoperative assessment strategies in cataract extraction
   - What is the effectiveness of different techniques for undertaking biometry?
   - What are the most appropriate formulae to optimise intraocular lens biometry calculation?
   - How can biometry and postoperative refractive errors be reduced?
   - What is the effectiveness of risk stratification techniques to reduce surgical complications and errors?
4. Optimal treatment strategies in cataract surgery
   - What is the effectiveness of laser phacoemulsification compared with ultrasound phacoemulsification?
   - What is the optimal type and administration of anaesthesia for cataract surgery?
   - What is the optimal strategy when selecting intraocular lenses (for example, different vision in both eyes or same vision in both eyes)?
   - What is the effectiveness of aspheric monofocal lenses compared with spheric monofocal lenses in cataract surgery?
   - What is the effectiveness of square-edged monofocal lenses compared with standard monofocal lenses in cataract surgery?
   - What is the comparable effectiveness of foldable monofocal lenses that are hydrophilic acrylic, hydrophobic acrylic, collagen or hydroxyethyl methacrylate-based compared with silicone-based foldable monofocal lenses?
   - What is the effectiveness of multifocal intraocular lenses compared with standard monofocal lenses?
5. Cataract surgery for people with astigmatism
   - What is the effectiveness of toric intraocular lenses compared with standard monofocal lenses for people with cataracts and astigmatism?
   - What is the effectiveness of limbal relaxing incisions compared with toric intraocular lenses for people with cataracts and astigmatism?
6. Cataract surgery for people with high myopia
   - What is the effectiveness of interventions (for example, prophylactic laser surgery) to prevent retinal detachment in people with cataracts and high myopia?
7. Second eye surgery
   - What is the effectiveness of bilateral simultaneous (rapid sequential) cataract surgery compared with unilateral eye surgery?
   - What is the optimal timing of second eye surgery, taking into account issues of refractive power after first eye surgery?
8. Optimal treatment strategies to prevent complications and errors in cataract surgery
   - In what circumstances are capsular tension rings effective?
   - In what circumstances are interventions to increase pupil size effective?
   - What is the effectiveness of postoperative eye shields to prevent complications after cataract extraction?

- What is the effectiveness of different prophylactic antibiotics to prevent infection after cataract surgery?
- What is the optimal timing to administer prophylactic antibiotics to prevent infection after cataract surgery?
- What is the effectiveness of antibiotics combined with topical corticosteroids and/or NSAIDs compared with antibiotics alone to prevent infection after cataract surgery?
- What is the effectiveness of prophylactic topical corticosteroids and/or NSAIDs to prevent inflammation and cystoid macular oedema after cataract surgery?
- What are the procedural causes of wrong lens implant errors?
- What strategies should be adopted to reduce the risk of wrong lens implant errors?

9. Management of operative complications
   - What is the effectiveness of interventions to reduce the impact of perioperative posterior capsule rupture?
   - What is the effectiveness of interventions used to manage cystoid macular oedema after cataract surgery?
10. Optimal postoperative follow-up strategies
    - What is the optimal time to assess outcomes in the postoperative period?
    - Who and in what setting should carry out postoperative assessment and care?
    - If postoperative assessment and care are undertaken outside of the hospital, how should outcomes between surgical units and these providers be effectively communicated?

B.8 Main outcomes

The main outcomes that will be considered when searching for and assessing the evidence are:

1. Unaided and best-corrected visual acuity (distance and near).
2. Contrast sensitivity.
3. Postoperative refractive outcomes.
4. Patient global improvement.
5. Patient independence (for example, activities of daily living, ability to drive).
6. Patient satisfaction.
7. Adverse effects of treatment, including complications of surgical interventions (for example, surgically induced astigmatism).
8. Accidents, including falls and traffic accidents.
9. Need for further treatment such as laser capsulotomy.
10. Health-related quality of life, including that of carers.
11. Resource use and costs.

B.9 Links with other NICE guidance and NICE Pathways

B.9.1 NICE guidance

NICE guidance about the experience of people using NHS services

NICE has produced the following guidance on the experience of people using the NHS. This guideline will not include additional recommendations on these topics unless there are specific issues related to cataracts:

- Medicines optimisation (2015) NICE guideline NG5

- Patient experience in adult NHS services (2012) NICE guideline CG138
- Service user experience in adult mental health (2011) NICE guideline CG136
- Medicines adherence (2009) NICE guideline CG76

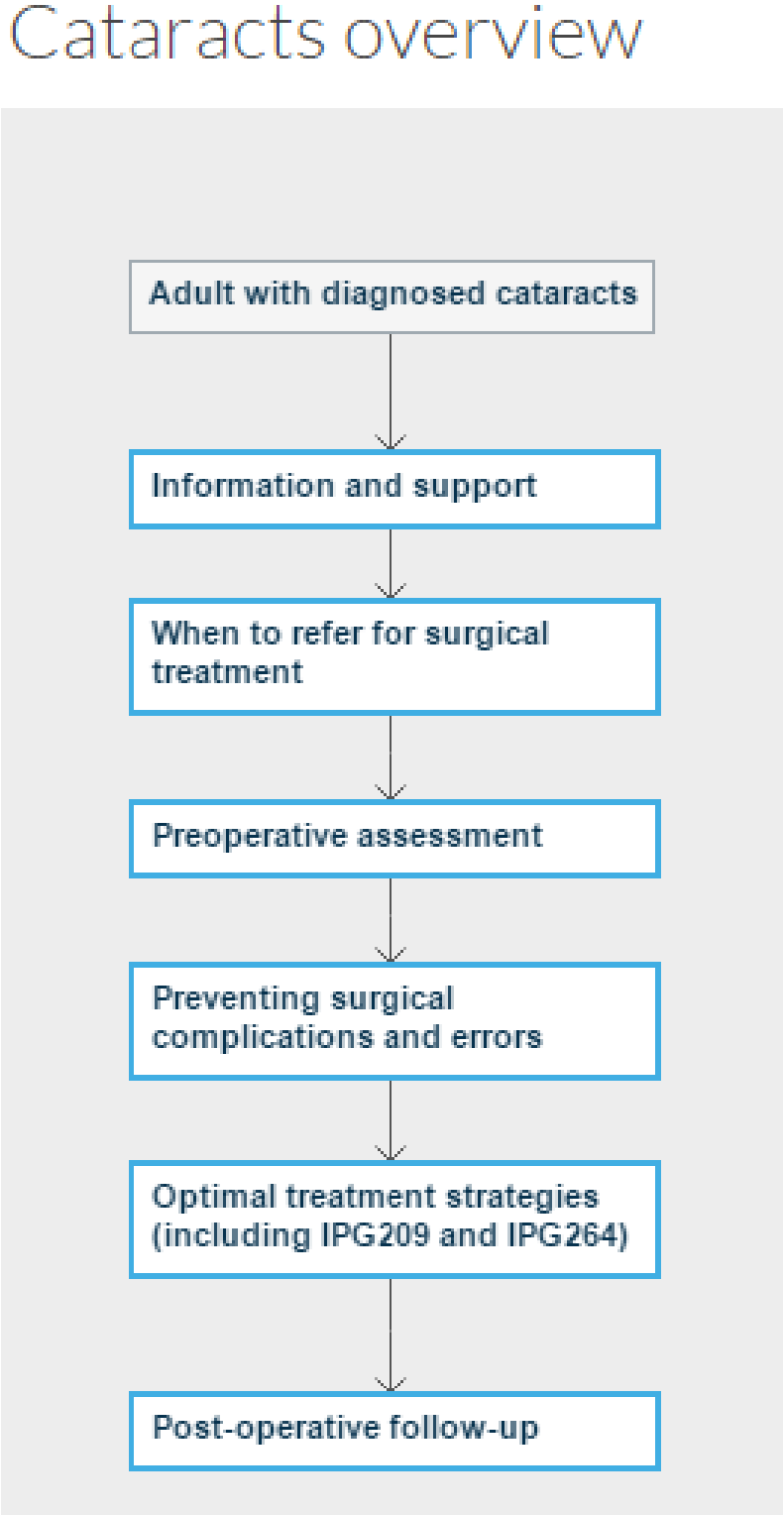
B.10 NICE Pathways

When this guideline is published, the recommendations will be added to NICE Pathways. NICE Pathways bring together all related NICE guidance and associated products on a topic in an interactive topic-based flow chart.

A draft pathway outline on cataracts, based on the draft scope, is included below. It will be adapted and more detail added as the recommendations are written during guideline development. The cataracts pathway will be accessible from the eye conditions pathway.

Other relevant NICE guidance will also be added to the NICE Pathway, including:

- Implantation of multifocal (non-accommodative) intraocular lenses during cataract surgery (2008) NICE interventional procedure guidance IPG264
- Implantation of accommodating intraocular lenses for cataract (2007) NICE interventional procedure guidance IPG209



B.11 Context

B.11.1 Key facts and figures

A cataract is defined as any opacity in the crystalline lens of the eye that can affect one or both eyes. The changes to the transparency and refractive index of the lens result in various levels of visual impairment. This impairment is associated with decreased quality of life,

because it may restrict the person's ability to carry out daily activities and function independently, while increasing the risk of accidents and falls.

Cataracts most commonly affect adults as a result of biological ageing (age-related cataracts) and may be classified according to the area of the lens that is affected (nuclear sclerotic, cortical or posterior subcapsular cataracts). Cataracts can also occur in children, and may be classified according to the age of onset (congenital or infantile/juvenile cataracts). Cataracts may occur secondary to hereditary factors, trauma, inflammation, metabolic or nutritional disorders and radiation. In addition, in adults, lifestyle factors such as tobacco smoking and high alcohol intake are associated with an increased risk of developing age-related cataracts.

Most of the studies on the prevalence and incidence of cataracts in adults and children in England and Wales were conducted more than 15 years ago. Proxy data on the frequency of cataract surgery indicate that, in 2012/13, a total of 340,809 operations were performed in England. This figure does not differentiate between first and second eye surgeries, but it is likely that most of these operations were performed on adults with age-related cataracts.

In adults, a greater prevalence of age-related cataracts is associated with being female, specific minority ethnic groups, including people of Asian, African and African–Caribbean family origin, people from low socioeconomic status groups, people with learning disabilities and people with comorbid conditions, including diabetes and uveitis.

Most cataracts are largely progressive, although the decline in visual function may be variable and unpredictable. The natural history of cataracts depends on the type and severity of cataract and the presence of ocular comorbid conditions. In severe untreated cases, cataracts can lead to blindness, which may be reversible with cataract surgery, although some level of visual impairment may persist.

Cataract surgery has a high success rate in improving visual function, with low morbidity and mortality. It is the commonest operation performed in the NHS, with an ever-growing need as the population ages. Guidance on clinical thresholds to access cataract surgery is needed to address patient need and to optimise the allocation of NHS resources. In addition, an understanding of the most clinically and cost-effective methods for undertaking cataract surgery, and to minimise complications and surgical errors such as wrong intraocular lens implants, is needed to further improve patient care.

B.11.2 Current practice

Cataract management usually involves a multidisciplinary team that includes ophthalmologists, optometrists, nurses and technicians.

Diagnosis is usually based on self-reported symptoms and a series of tests performed by an optometrist, normally based in the community. Symptoms may include blurred vision, difficulty seeing at night, sensitivity to light or glare, seeing 'halos' around lights and double vision in a single eye. Tests include a visual acuity test, and slit-lamp and retinal examinations.

In adults with early age-related cataracts, non-surgical management may include prescription of spectacles, bifocals or magnifying lenses, advice on the lighting of the reading environment and monitoring the progression of the condition. Alternatively, adults with age-related cataracts may be referred for surgery, by an optometrist or a GP. The clinical threshold used to access cataract surgery varies across NHS Trusts in England. This has resulted in differences in access to cataract surgery, since policies vary in scope and content and are not necessarily congruent with research evidence or guidance provided by the Department of Health in its document Action on cataracts and the Royal College of Ophthalmologists' Cataract surgery guideline.

Because age-related cataracts have a higher prevalence with increasing age, consideration of people with other comorbidities that may affect management is needed, including frail people, older people, people with impaired cognitive function and people with impaired mobility.

B.11.3 Policy, legislation, regulation and commissioning

Policy

This guideline will address areas highlighted in the UK Vision Strategy 2013-2018, including improving awareness and understanding of eye health, access to eye care services to detect and prevent sight loss, the coordination, integration and effectiveness of eye health and care services, and consideration of equality issues.

Legislation, regulation and guidance

The Department of Health's report Action on cataracts published in 2000, and the Royal College of Ophthalmologists' Cataract surgery guidelines published in 2010, provide guidance on various aspects of cataract management. This guideline will consider further controversial areas, including indicators for cataract surgery and second eye surgery, and examine in detail optimal treatment strategies for cataract operations. The guideline will also consider relevant guidance from the DVLA's At a glance guide.

B.12 Further information

This is the final scope, incorporating comments from registered stakeholders during consultation.

The guideline is expected to be published in June 2017.

You can follow progress of the guideline.