

Greater Manchester EUR Policy Statement on: Cataract Surgery

GM Ref: GM026

Version: 3.1 (15 Nov 2017)



Commissioning Statement

| Cataract Surgery | |
|----------------------------------|---|
| Policy Exclusions | <p>Juvenile cataract, lens-induced disease (such as phacomorphic glaucoma, phacolytic glaucoma, and other lens-induced disease), cataracts in patients with concomitant ocular disease that require clear media (such as diabetic retinopathy) for which cataract surgery is indicated and patient having surgery for any eye condition where concomitant removal of a cataract is clinically indicated. Individuals with any one of these indications, or where these are suspected, should be referred to an ophthalmologist. These conditions are managed as part of the agreed pathway and funded either within contracts or via monitored approval.</p> <p>Treatment/procedures undertaken as part of an externally funded trial or as a part of locally agreed contracts / or pathways of care are excluded from this policy, i.e. locally agreed pathways take precedent over this policy (the EUR Team should be informed of any local pathway for this exclusion to take effect).</p> |
| Policy Inclusion Criteria | <p>The presence of a cataract does not in itself indicate a need for surgery. The decision to refer a patient for surgery should be based on consideration of their visual acuity, visual impairment and their potential for functional benefits.</p> <div style="background-color: #e6f2ff; padding: 10px;"> <p>Funding Mechanism</p> <p>Monitored approval: Referrals may be made in line with the criteria without seeking funding. NOTE: May be the subject of contract challenges and/or audit of cases against commissioned criteria.</p> <p><u>NOTE: If both eyes meet the criteria at the time of the initial referral then both eyes can be treated. If only one eye meets the criteria then ONLY THAT EYE can be treated at the time of first referral. The second eye may be treated if it later meets the referral criteria or funding has been obtained via the IFR route for the second eye.</u></p> <p><u>If the patient does NOT meet the criteria BUT the cataract causes severe functional difficulties:</u> Individual prior approval by Clinical Triage. Requests <u>must</u> be submitted with all relevant supporting evidence.</p> <p>Clinicians can submit an individual funding request outside of this guidance if they feel there is a good case for clinical exceptionality. Requests on the grounds of exceptionality <u>must</u> be submitted with all relevant supporting evidence.</p> </div> <div style="background-color: #e6f2ff; padding: 10px; margin-top: 10px;"> <p>First Eye</p> <p>Cataract surgery is justified and appropriate when the patient fulfils the following criteria:</p> <ul style="list-style-type: none"> • The best corrected visual acuity score is worse than 6/9 (Snellen) or 0.2 (Logmar) in the affected eye. <p>OR</p> <ul style="list-style-type: none"> • The patient's visual acuity is 6/9 or better but they report excessive difficulty in twilight or dark conditions and the difficulty has been confirmed by a clinician to be the result of reduced contrast sensitivity. <p>AND has <u>one</u> of the following (with correction):</p> <ul style="list-style-type: none"> • Difficulty carrying out everyday tasks such as recognising faces, watching TV, reading, cooking, playing sport/cards etc. </div> |

- Reduced mobility, experiencing difficulties in driving, for example, due to glare, or experiencing difficulty with steps or uneven ground.
- Ability to work, give care or live independently is affected.

In cases where the cataract causes severe functional difficulties, application can be made for individual prior approval (see funding mechanism above).

A patient should NOT be referred for cataract surgery if:

- The patient does not desire surgery.
- Glasses or other visual aids provide functional vision satisfactory to the patient.
- The patient's quality of life or ability to function is not compromised.
- The patient has concomitant ocular disease where functional improvement is unlikely.
- Patients who are not referred for surgery should remain under the care of their primary care practitioner (GP, community ophthalmologist, optometrist) and be reassessed at one to two year intervals, as appropriate.

Second Eye

The referral criteria for second eye are:

- As above for first eye

OR any of the following:

- Where there are binocular considerations
- Where there is anisometropia
- Where there is disabling glare

NOTE: Implantation of lenses following or as part of cataract surgery is funded for the use of any monofocal lenses only.

Clinical Exceptionality

Clinicians can submit an Individual Funding Request (IFR) outside of this guidance if they feel there is a good case for exceptionality.

Exceptionality means 'a person to which the general rule is not applicable'. Greater Manchester sets out the following guidance in terms of determining exceptionality; however the over-riding question which the IFR process must answer is whether each patient applying for exceptional funding has demonstrated that his/her circumstances are exceptional. A patient may be able to demonstrate exceptionality by showing that s/he is:

- Significantly different to the general population of patients with the condition in question.

and as a result of that difference

- They are likely to gain significantly more benefit from the intervention than might be expected from the average patient with the condition.

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Policy Statement

Greater Manchester Shared Services (GMSS) Effective Use of Resources (EUR) Policy Team in conjunction with GM EUR Steering Group have developed this policy on behalf of Clinical Commissioning Groups (CCGs) within Greater Manchester, who will commission treatments/procedures in accordance with the criteria outlined in this document.

In creating this policy GMSS has reviewed this clinical condition and the options for its treatment. It has considered the place of this treatment in current clinical practice, whether scientific research has shown the treatment to be of benefit to patients, (including how any benefit is balanced against possible risks) and whether its use represents the best use of NHS resources.

This policy document outlines the arrangements for funding of this treatment for the population of Greater Manchester.

This policy follows the principles set out in the ethical framework that govern the commissioning of NHS healthcare and those policies dealing with the approach to experimental treatments and processes for the management of individual funding requests (IFR).

Equality & Equity Statement

GMSS/CCGs have a duty to have regard to the need to reduce health inequalities in access to health services and health outcomes achieved, as enshrined in the Health and Social Care Act 2012. GMSS/CCG is committed to ensuring equality of access and non-discrimination, irrespective of age, gender, disability (including learning disability), gender reassignment, marriage and civil partnership, pregnancy and maternity, race, religion or belief, gender or sexual orientation. In carrying out its functions, GMSS/CCG will have due regard to the different needs of protected characteristic groups, in line with the Equality Act 2010. This document is compliant with the NHS Constitution and the Human Rights Act 1998. This applies to all activities for which they are responsible, including policy development, review and implementation.

In developing policy the GMSS Policy Team will ensure that equity is considered as well as equality. Equity means providing greater resource for those groups of the population with greater needs without disadvantage to any vulnerable group.

The Equality Act 2010 states that we must treat disabled people as *more equal* than any other protected characteristic group. This is because their 'starting point' is considered to be further back than any other group. This will be reflected in GMSS evidencing taking 'due regard' for fair access to healthcare information, services and premises.

An Equality Analysis has been carried out on the policy. For more information about the Equality Analysis, please contact policyfeedback.gmscu@nhs.net.

Governance Arrangements

Greater Manchester EUR policy statements will be ratified by the Greater Manchester Association Governing Group (AGG) prior to formal ratification through CCG Governing Bodies. Further details of the governance arrangements can be found in the Greater Manchester EUR Operational Policy.

Aims and Objectives

This policy document aims to ensure equity, consistency and clarity in the commissioning of treatments/procedures by CCGs in Greater Manchester by:

- reducing the variation in access to treatments/procedures.

- ensuring that treatments/procedures are commissioned where there is acceptable evidence of clinical benefit and cost-effectiveness.
- reducing unacceptable variation in the commissioning of treatments/procedures across Greater Manchester.
- promoting the cost-effective use of healthcare resources.

Rationale behind the policy statement

Due to a lack of consensus in the international guidelines, there is no one tool that can be recommended for use as a referral threshold for cataract surgery. There is a need for clear surgical referral criteria. These should consist of a measure of visual acuity in conjunction with a measure of the effect of the cataract on a patient's lifestyle. This should be applied in the primary care setting prior to referral to an outpatient clinic, and should be quick and easy to use, and be able to distinguish between those patients who would benefit most from surgery, how urgently they need to be seen and those who would be better served through watchful waiting or non-surgical interventions. Therefore, the above criteria are used.

Treatment / Procedure

Cataract is the opacification of the crystalline lens that results from the normal ageing process, trauma, metabolic disorders (hereditary or acquired), medications, or congenital problems.

Surgical treatment involves removing the patient's cloudy lens and implanting an artificial lens. Phacoemulsification is the preferred technique for cataract surgery. It involves using an ultrasound probe to break the opacified lens into tiny pieces which are then removed through a small incision in the cornea. However, there are a small number of instances where large-incision, manual, extracapsular cataract extraction may be the preferred option. An intra-ocular lens is then inserted through the incision.

Epidemiology and Need

Cataracts are generally progressive and chronic. The main symptoms of cataracts are reduced or blurred vision, increased problems associated with glare or low-contrast conditions and sometimes changes in refractive error. Several factors can promote the formation of cataracts including: age; trauma; hereditary factors; exposure to ultraviolet radiation; prior intraocular surgery; diabetes mellitus; and history of smoking or alcohol consumption. Age is however the most common as cataracts particularly affect people over 50 years and their prevalence has been reported to rise steadily with age. However, a cataract must cause significant reduction in visual acuity (VA) or functional impairment to be considered clinically significant.

The Department of Health's National Eye Care Plan reported that a quarter of the population of the United Kingdom (UK) will develop cataracts by the age of 75 years. The rate of cataract surgery carried out in England and Wales, doubled from 1997/1998 (approximately 153,000) to 2007/2008 (approximately 311,000).

The North London Eye Study provides prevalence data specifically for visually impairing cataract (i.e. Snellen visual acuity less than 6/12 that is attributable to a lens opacity) in one or both eyes in a random sample of 1547 people of 65 years and over in an outer metropolitan district. Overall, 30% of people of 65 years and over in this population were found to have visually impairing cataract in one or both eyes. A further 10% of people in this age group had previous cataract surgery in one or both eyes. The prevalence of visually impairing cataract rose steadily with age: 16% in the 65 to 69 year age group, 24% in people of 70 to 74 years of age, 42% in those 75 to 79 years of age, 59% in those 80 to 84 years, and 71% in people of 85 years or more. The prevalence of cataract (after adjusting for age) was higher in women, the overall prevalence ratio (females:males) was 1.22 (95% confidence limits 1.07 to 1.40). Notably, the majority (88%) of people with treatable visual impairment from cataract were not in touch with eye health services, representing the level of potentially unmet need for eye health care for cataract in the population. It was estimated that 225,000 new cases of visually impairing cataract should

be expected each year, the 5-year cumulative incidence being estimated at 1.1 million new cases among the population aged 65 years and older.

Adherence to NICE Guidance

Although the policy has a visual acuity requirement, it allows patients with normal visual acuity who experience functional issues due to the cataract to have treatment, therefore the policy is NICE NG77 compliant.

Audit Requirements

There is currently no national database. Service providers will be expected to collect and provide audit data on request.

Date of Review

Five years from the date of the last review, unless new evidence or technology is available sooner.

The evidence base for the policy will be reviewed and any recommendations within the policy will be checked against any new evidence. Any operational issues will also be considered at this time. All available additional data on outcomes will be included in the review and the policy updated accordingly. The policy will be continued, amended or withdrawn subject to the outcome of that review.

Glossary

| Term | Meaning |
|---------------|---|
| Anisometropia | A significant difference in refractive error between the two eyes of more than 1.00D in any meridian is often given as a definition of anisometropia. |
| Glaucoma | Glaucoma is a group of eye conditions in which the optic nerve is damaged due to changes in eye pressure |
| HTA | Health Technology Assessment |
| NICE | National Institute for Health and Care Excellence |
| Visual acuity | Visual acuity is a measure of your central vision, the ability to distinguish details and shapes of objects. |

References

1. Greater Manchester Effective Use of Resources Operational Policy
2. Cochrane Review: Surgical interventions for age-related cataract
3. Cataract Surgery Guidelines, The Royal College of Ophthalmologists (2010) – Updated 2015
4. Health Technology Assessment of Scheduled Surgical Procedures: Cataract Surgery, Health Information and Quality Authority, Ireland (2013)
5. BMJ Clinical Evidence: Cataract, Allen, D (2010)
6. Is it clinically and cost effective to perform second-eye cataract surgery in the absence of other ocular co-morbidities in patients who have already had first-eye surgery?, Healthcare Improvement Scotland, Technologies Scoping Report. (2012)
7. Surgical interventions for age-related cataract, Cochrane Database of Systematic Reviews 2006, Issue 4, Riaz Y, Mehta JS, Wormald R, Evans JR, Foster A, Ravilla T, Snelling T.

Governance Approvals

| Name | Date Approved |
|---|---|
| Greater Manchester Effective Use of Resources Steering Group | 09/07/2014 |
| Greater Manchester Chief Finance Officers / Greater Manchester Directors of Commissioning | 12/08/2014 |
| Greater Manchester Association Governing Group | 09/2014 |
| Bury Clinical Commissioning Group | 27/11/2014 |
| Bolton Clinical Commissioning Group | 24/10/2014 |
| Heywood, Middleton & Rochdale Clinical Commissioning Group | 19/09/2014 |
| Manchester Clinical Commissioning Group | Central: 23/10/2014 North: 12/11/2014 South: 21/10/2014 |
| Oldham Clinical Commissioning Group | 02/10/2014 |
| Salford Clinical Commissioning Group | 01/10/2014 |
| Stockport Clinical Commissioning Group | 22/10/2014 |
| Tameside & Glossop Clinical Commissioning Group | 15/10/2014 |
| Trafford Clinical Commissioning Group | 16/09/2014 |
| Wigan Borough Clinical Commissioning Group | 05/11/2014 |

Appendix 1 – Evidence Review

Cataract Surgery GM026

Search Strategy

The following databases are routinely searched: NICE Clinical Guidance and full website search; NHS Evidence and NICE CKS; SIGN; Cochrane; York; and the relevant Royal College and any other relevant bespoke sites. A Medline / Open Athens search is undertaken where indicated and a general google search for key terms may also be undertaken. The results from these and any other sources are included in the table below. If nothing is found on a particular website it will not appear in the table below:

| Database | Result |
|-----------------------|--|
| NICE | <ul style="list-style-type: none"> • NICE IPG 209 (not cited here) • NICE IPG 264 (not cited here) |
| NHS Evidence / CKS | <ul style="list-style-type: none"> • Health Technology Assessment of Scheduled Surgical Procedures: Cataract Surgery, Health Information and Quality Authority, Ireland, 2013 • Cataract Surgery Guidelines: The Royal College of Ophthalmologists (2010) replaced by The Royal College of Ophthalmologists Commissioning guide: Cataract Surgery February 2015 (updated at review October 2015) • Is it clinically and cost effective to perform second-eye cataract surgery in the absence of other ocular co-morbidities in patients who have already had first-eye surgery?, Healthcare Improvement Scotland, Technologies Scoping Report, 2012 • NICE CKS: Cataracts, Last Revised: September 2015 (added at review October 2015) |
| Cochrane | <ul style="list-style-type: none"> • Surgical interventions for age-related cataract, Cochrane Database of Systematic Reviews 2006, Issue 4, Riaz Y, Mehta JS, Wormald R, Evans JR, Foster A, Ravilla T, Snellingen T. • The Cochrane Collaboration 2015: Combined surgery versus cataract surgery alone for eyes with cataract and glaucoma, Mingjuan Lisa Zhang, Phenpan Hirunyachote, Henry Jampel (added at review October 2015) • The Cochrane Collaboration 2014: Accommodative intraocular lens versus standard monofocal intraocular lens implantation in cataract surgery, Hon Shing Ong, Jennifer R Evans, Bruce DS Allan (added at review October 2015) • The Cochrane Collaboration 2012: Multifocal versus monofocal intraocular lenses after cataract extraction, Calladine D, Evans JR, Shah S, Leyland M (added at review October 2015) • Surgical interventions for bilateral congenital cataract (Review not cited here) • Surgery for post-vitrectomy cataract (Review not cited here) • Surgery for cataracts in people with age-related macular degeneration (Review not cited here) |
| BMJ Clinical Evidence | BMJ Clinical Evidence: Cataract, Allen, D. (2010) |
| BMJ Best Practice | <ul style="list-style-type: none"> • Cataract condition information on website (not cited here) • Patient information from the BMJ Group – Cataracts: Should I have surgery? (not cited here) |
| General Search | <ul style="list-style-type: none"> • Evidence-based guidelines for cataract surgery: Guidelines based on data |

| | |
|----------|---|
| (Google) | <p>in the European Registry of Quality Outcomes for Cataract and Refractive Surgery database. (not cited here)</p> <ul style="list-style-type: none"> • NHS Choices pages on Cataract Surgery (not cited here) |
|----------|---|

Summary of the evidence

The key document relating to commissioning cataract surgery was the Health Technology Assessment of Scheduled Surgical Procedures: Cataract Surgery, from the Irish Health Information and Quality Authority. Reference was made to The Royal College of Ophthalmologists: Cataract Surgery Guidelines in the development of the Health Technology Assessment.

The HTA includes a review of clinical and cost effectiveness, as well as existing guidelines and threshold policies and concludes that due to a lack of consensus in the international guidelines, there is no one tool that can be recommended for use as a referral threshold for cataract surgery. The HTA outlines the need for clear surgical referral criteria which should consist of a measure of visual acuity in conjunction with a measure of the effect of the cataract on a patient's lifestyle. It is recommended that this criteria should be applied in the primary care setting prior to referral to an outpatient clinic, and should be quick and easy to use, and be able to distinguish between those patients who would benefit most from surgery, how urgently they need to be seen and those who would be better served through watchful waiting or non-surgical interventions. The criteria recommended from the HTA are used within this policy.

There is randomised controlled trial evidence that second-eye surgery in bilateral cataract patients, compared to surgery in one eye only, can result in improvements in outcomes such as visual acuity, stereopsis, patient-reported visual disability and confidence.

A UK-based cost utility analysis evaluating the cost effectiveness of second-eye cataract surgery, compared to waiting list controls, concluded that second-eye cataract surgery was cost effective for those with mild visual impairment pre-operation (£17,299 per quality-adjusted life year) in the long term (expected lifetime).

Given the lack of objective referral and surgical criteria, individual patient need should always be considered in prioritising access to second-eye cataract surgery.

The Cochrane reviews and the NICE IPGs suggest that alternative lenses to the standard monofocal lens meet the GMEUR definition of an unproven treatment and need further study.

Multifocal lenses are commonly associated with the recurrence of halos and glare (two of the key functional reasons for cataract surgery). The key reason for requesting this type of lens is to remove the need for wearing glasses.

There is insufficient evidence that that accommodating lenses do achieve accommodation.

At the time of the July 2017 review no new evidence was found after the usual search was completed.

The evidence

| Levels of evidence | |
|--------------------|---|
| Level 1 | Meta-analyses, systematic reviews of randomised controlled trials |
| Level 2 | Randomised controlled trials |
| Level 3 | Case-control or cohort studies |
| Level 4 | Non-analytic studies e.g. case reports, case series |

| | |
|---------|----------------|
| Level 5 | Expert opinion |
|---------|----------------|

1. LEVEL 1: SYSTEMATIC REVIEW

Health Technology Assessment of Scheduled Surgical Procedures: Cataract Surgery, Health Information and Quality Authority, Ireland, 2013

During early cataract development, visual improvement may be achieved through a number of non-surgical means including: changes in glasses prescriptions, strong bifocals, tinted lenses, dilation of the pupil for small central cataracts, magnifying lenses and appropriate lighting. However, without cataract surgery, vision in the affected eye will continue to deteriorate and the only effective treatment to restore vision is the surgical replacement of the affected lens.

Cataract surgery is widely perceived to be a safe procedure. Risks include anaesthetic and surgical complications. The majority of cases are done under local anaesthetic which has reduced the potential risks. Serious complications include endophthalmitis (0.02%-1.16%), cystoid macular oedema (1.2%-3.3%), retinal detachment (0.26%-4%), haemorrhage (0.06%-0.5%) as well as toxic anterior segment syndrome, persistent corneal oedema, decreased vision and general complications associated with surgery in the elderly. The most common post-operative complication is posterior capsular opacity which may occur in up to 40% of patients 10 years postoperatively, although it is less common following phacoemulsification.

Cataract surgery is considered an effective and cost-effective procedure, both in developed and developing countries. However, its cost-effectiveness for those patients who gain little or no significant improvement in visual acuity or functional ability is less clear.

For a cataract to be clinically significant, it must cause significant reduction in visual acuity, functional ability or both. Seven clinical guidelines for cataract surgery were found that specifically mention referral criteria for cataract surgery. These guidelines highlight and recommend best practice based on the available evidence base.

2. LEVEL: N/A (BASED ON EXPERT OPINION AND NATIONAL GUIDELINES)

NICE CKS: Cataracts, Last Revised: September 2015

- **Encourage the person to have an eye examination** by an optometrist to:
 - Assess visual acuity for distance vision, near vision (with and without corrective contact lenses and glasses), and the refractive power of the eyes.
 - Exclude other causes of visual impairment.
- **Consider referral for cataract surgery** when the person has:
 - Visual impairment caused by the cataract, *and* the cataract is affecting the person's lifestyle (for example driving, reading), *and* the person wants to undergo cataract surgery.
 - There is no set level of vision for which an operation is essential.
 - A comorbidity that might benefit from surgery (for example an elderly person at risk of a fall).
 - Another ocular condition, where cataract surgery would help facilitate treatment and/or monitoring (for example a diabetic person whose photographic screening is compromised by the presence of a cataract).
- **If referral for surgery is being considered:**
 - Consider whether the patient has the capacity to co-operate with eye examinations, surgery, and postoperative eye drop treatment.
 - Frail patients with mental health problems such as dementia may be unfit for general anaesthesia and unable to lie still for surgery under local anaesthetic.
 - Discuss the risks and benefits of surgery.
 - Give advice on what to expect before, during, and after surgery.
 - This is discussed in a patient information leaflet Understanding cataracts (pdf) produced by the Royal College of Ophthalmologists.

- **If the person does not understand the issues relating to their specific case**, offer referral to an ophthalmologist to discuss the risks and benefits of surgery as well as the risks relating to their particular cataract and any comorbidity they may have.
- **Referral for cataract surgery is not always necessary.**
 - It is not usually necessary to refer people who do not want to undergo surgery, or who do not fit the referral criteria (when it is certain that any visual loss is secondary to cataract alone).
- **If referral is appropriate**, include the person's most recent visual acuity (measured on a Snellen chart) or a copy of the most recent optometrist's eyesight test with the referral.
- **If referral is not appropriate**, advise the person to attend for an annual eye examination to assess for decreasing visual acuity and worsening symptoms.
- **Provide advice on fitness to drive** to all people with a cataract (when appropriate).

This information is based on published expert opinion from the Royal College of Ophthalmologists [Royal College of Ophthalmologists, 2010] and a textbook [Khaw et al, 2004].

3. LEVEL: N/A (NATIONAL GUIDELINES)

The Royal College of Ophthalmologists Commissioning guide: Cataract Surgery, February 2015

Plain language summary

- The presence of cataract causes disability and increases the likelihood that individuals will suffer adverse events such as falls.
- Cataract surgery is the only effective intervention to treat cataracts and is cost effective.
- Visual acuity on its own is not an adequate measure of visual disability from cataract and cataract surgery should be considered in the first or second eye of patients with significant visual symptoms due to cataract.
- Further research is required to validate additional measures of visual disability due to cataract and Patient Reported Outcome Measures of cataract surgery.
- A typical cataract surgery care pathway is described in the document but this must be personalised to the patient and adaptable for patients with specific needs.
- The risk of a poor outcome from cataract surgery is generally low but can be increased substantially by a range of systemic and ocular risk factors, many of which can be mitigated by careful preoperative planning by the cataract surgical team.
- Outcome measures of cataract surgery such as visual acuity, accuracy of refractive correction, occurrence of significant operative and postoperative complications should be recorded routinely. The data should be available to care providers and commissioners
- Commissioning of cataract care should encompass the whole cataract care pathway from initial assessment and treatment planning to final postoperative review.

4. LEVEL 1: SYSTEMATIC REVIEW

Is it clinically and cost effective to perform second-eye cataract surgery in the absence of other ocular co-morbidities in patients who have already had first-eye surgery?, Healthcare Improvement Scotland, Technologies Scoping Report, 2012

The findings from two RCTs suggest that second-eye surgery in people with bilateral cataract without severe ocular co-morbidities, compared with surgery in one eye only, can result in improvements in outcomes such as VA, stereopsis, patient-reported visual disability and confidence. However, one of the trials was unable to demonstrate that second-eye surgery reduces the risk of falling.

Of the three cost-utility studies identified, only one was UK-based. The results suggest that in people who have minor preoperative visual dysfunction, second-eye cataract surgery is not likely to be cost-effective in the short-term. However, the authors also report that in the long-term, cataract surgery appears to be cost-effective in this patient group if carer costs are not included. A Finnish study included a similar patient group (ie people who reported that they had minor seeing problems preoperatively), and reported a reduction (not significant) in HRQoL after second-eye surgery.

An American-based cost-utility analysis concluded that 'second-eye cataract surgery is an extremely cost-effective procedure'. The difference in results, compared with the other studies, may be because

the patient populations were different (it is not clear whether the different data sources in the American study relate to the same population). Further, the American study derived utilities from general ophthalmic patients, rather than people with cataracts themselves.

5. LEVEL 1: SYSTEMATIC REVIEW

BMJ Clinical Evidence: Cataract, Allen, D. (2010)

This review aimed to answer the following clinical questions: What are the effects of surgery for age-related cataract without other ocular comorbidity? What are the effects of treatment for age-related cataract in people with glaucoma? What are the effects of surgical treatments for age-related cataract in people with diabetic retinopathy? What are the effects of surgical treatments for age-related cataract in people with chronic uveitis?

The authors searched: Medline, Embase, The Cochrane Library, and other important databases up to May 2010 (Clinical Evidence reviews are updated periodically; please check our website for the most up-to-date version of this review).

The study found 20 systematic reviews, RCTs, or observational studies that met the inclusion criteria. GRADE evaluations of the quality of evidence for interventions were performed on all included studies. Expedited phaco extracapsular extraction may be more effective at improving visual acuity compared with waiting list control in people with cataract without ocular comorbidities.

6. LEVEL 1: SYSTEMATIC REVIEW

Surgical interventions for age-related cataract, Cochrane Database of Systematic Reviews 2006, Issue 4, Riaz Y, Mehta JS, Wormald R, Evans JR, Foster A, Ravilla T, Snelling T.

This review compared different surgical techniques have been developed to remove the cloudy lens which is replaced either by an intraocular lens (positioned in the posterior chamber or the anterior chamber of the eye), aphakic glasses or contact lens.

There are four main forms of cataract extraction surgery: intracapsular (ICCE), extracapsular (ECCE), phacoemulsification (PHACO) and manual small incision (MSICS). The review authors searched the medical literature and identified 17 randomised controlled trials (9627 participants) investigating the different surgical interventions. Six of these trials suggested that PHACO gives a better outcome than ECCE. They suggest a better uncorrected visual acuity (UCVA) following PHACO than ECCE but the majority of the trials showed no difference in best corrected visual acuity (BCVA) between the two groups. The costs per procedure were not markedly different between the two techniques in a UK based study, however, a Malaysian study showed ECCE to be significantly cheaper.

A study comparing MSICS and ECCE, advocated MSICS as the procedure of choice due to equal costs and better visual results. Two studies compared the results of PHACO and MSICS, phacoemulsification having a significantly higher proportion of patients with UCVA > 6/18 (81.1% versus 71%) but there was no difference in BSCVA.

Manual small incision surgery offers an alternative technique in developing countries as it provides acceptable visual outcomes when compared to PHACO yet is likely to be more economical as it avoids the initial outlay of costs of PHACO.

Authors' conclusions

This review provides evidence from seven RCTs that phacoemulsification gives a better outcome than ECCE with sutures. We also found evidence that ECCE with a posterior chamber lens implant provides better visual outcome than ICCE with aphakic glasses. The long term effect of posterior capsular opacification (PCO) needs to be assessed in larger populations. The data also suggests that ICCE with an anterior chamber lens implant is an effective alternative to ICCE with aphakic glasses, with similar safety. Phacoemulsification provides the best visual outcomes but will only be accessible to the poorer countries if the cost of phacoemulsification and foldable IOLs decrease. Manual small incision cataract surgery provides early visual rehabilitation and comparable visual outcome to PHACO. It has better visual outcomes than ECCE and can be used in any clinic that is currently carrying out ECCE with IOL. Further research from developing regions are needed to compare the cost and longer term outcomes of these procedures e.g. PCO and corneal endothelial cell damage.

7. LEVEL 1: SYSTEMATIC REVIEW

The Cochrane Collaboration 2015: Combined surgery versus cataract surgery alone for eyes with cataract and glaucoma, Mingjuan Lisa Zhang, Phenpan Hirunyachote, Henry Jampel

Key results: We concluded from the available evidence that combined glaucoma and cataract surgery may lead to slightly greater decreases in IOP one year after surgery compared with cataract surgery alone. However, due to differences in the effects among the individual studies and potential for bias in the study results, this conclusion is not definitive. The effect between combined surgery and cataract surgery alone on the rate of complications was uncertain. No information was available for long-term outcomes (five or more years after surgery).

Quality of the evidence: Overall, the quality of the evidence was very low to low due to differences in study characteristics (e.g., type of glaucoma surgery) and poor reporting of outcomes from included studies. These factors may influence the treatment effects when comparing combined glaucoma and cataract surgery versus cataract surgery alone.

8. LEVEL 1: SYSTEMATIC REVIEW

The Cochrane Collaboration 2014: Accommodative intraocular lens versus standard monofocal intraocular lens implantation in cataract surgery, Hon Shing Ong, Jennifer R Evans, Bruce DS Allan

Key findings: The results of the review showed that participants who received accommodative IOLs had improvements in near vision at six months and at 12 months after surgery compared to those who received monofocal IOLs. However, such improvements were small and reduced with time. Low-quality evidence also showed that more than 12 months after surgery, there was a compromise in distance vision for people with accommodative IOLs. This may be related to the finding that those who received accommodative IOLs also appeared to have a higher rate of posterior capsular opacification (thickening and clouding of the tissue behind the IOL). However, these findings were uncertain. Further research on accommodative IOLs is required before we can draw conclusions on their effectiveness and safety compared to monofocal IOLs

Quality of the evidence: Overall the quality of the evidence was low or very low with the exception for the findings on near vision at six months.

9. LEVEL 1: SYSTEMATIC REVIEW

The Cochrane Collaboration 2012: Multifocal versus monofocal intraocular lenses after cataract extraction, Calladine D, Evans JR, Shah S, Leyland M

Main results: Sixteen completed trials (1608 participants) and two ongoing trials were identified. All included trials compared multifocal and monofocal lenses but there was considerable variety in the make and model of lenses implanted. Overall we considered the trials at risk of performance and detection bias because it was difficult to mask patients and outcome assessors. It was also difficult to assess the role of reporting bias. There was moderate quality evidence that similar distance acuity is achieved with both types of lenses (pooled risk ratio (RR) for unaided visual acuity worse than 6/6: 0.98, 95% confidence interval (CI) 0.91 to 1.05). There was also evidence that people with multifocal lenses had better near vision but methodological and statistical heterogeneity meant that we did not calculate a pooled estimate for effect on near vision. Total freedom from use of glasses was achieved more frequently with multifocal than monofocal IOLs. Adverse subjective visual phenomena, particularly haloes, or rings around lights, were more prevalent and more troublesome in participants with the multifocal IOL and there was evidence of reduced contrast sensitivity with the multifocal lenses.

Authors' conclusions: Multifocal IOLs are effective at improving near vision relative to monofocal IOLs. Whether that improvement outweighs the adverse effects of multifocal IOLs will vary between patients. Motivation to achieve spectacle independence is likely to be the deciding factor.

Appendix 2 – Diagnostic and Procedure Codes

Cataract Surgery GM026

(All codes have been verified by Mersey Internal Audit's Clinical Coding Academy)

| GM026 - Cataract Surgery Policy | |
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| Simple linear extraction of the lens | C71.1 |
| Phacoemulsification of lens | C71.2 |
| Aspiration of lens | C71.3 |
| Other specified extracapsular extraction of the lens | C71.8 |
| Unspecified extracapsular extraction of the lens | C71.9 |
| Forceps extraction of lens | C72.1 |
| Suction extraction of lens | C72.2 |
| Cryoextraction of lens | C72.3 |
| Other specified intracapsular extraction of lens | C72.8 |
| Unspecified intracapsular extraction of the lens | C72.9 |
| Currettage of lens | C74.1 |
| Discission of cataract | C74.2 |
| Mechanical lensectomy | C74.3 |
| Other specified other extraction of the lens | C74.8 |
| Unspecified other extraction of the lens | C74.9 |
| Insertion of prosthetic replacement for lens NEC | C75.1 |
| Revision of prosthetic replacement for lens | C75.2 |
| Removal of prosthetic replacement for lens | C75.3 |
| Insertion of prosthetic replacement for lens using suture fixation | C75.4 |
| Other specified prosthesis of lens | C75.8 |
| Unspecified prosthesis of lens | C75.9 |
| With the following ICD-10 diagnosis code(s): | |
| Senile incipient cataract | H25.0 |
| Senile nuclear cataract | H25.1 |
| Senile cataract, morgagnian type | H25.2 |
| Other senile cataract | H25.8 |
| Senile cataract, unspecified | H25.9 |
| Traumatic cataract | H26.1 |

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| Complicated cataract | H26.2 |
| Drug-induced cataract | H26.3 |
| After-cataract | H26.4 |
| Other specified cataract | H26.8 |
| Cataract, unspecified | H26.9 |
| Diabetic cataract (E10-E14 with common fourth character .3+) | H28.0* |
| Cataract, unspecified | H26.9 |
| Exceptions (ICD-10); the following in a primary or secondary diagnostic position: | |
| Infantile, juvenile and presenile cataract | H26.0 |
| Diabetic retinopathy (E10-E14 with common fourth character .3+) | H36.0* |
| Glaucoma secondary to other eye disorders | H40.5 |

Appendix 3 – Version History

Cataract Surgery GM026

The latest version of this policy can be found here: [GM Cataract Surgery policy](#)

| Version | Date | Summary of Changes |
|---------|--|---|
| 0.1 | 07/01/2014 | Initial draft |
| 0.2 | 21/01/2014 | Amendments made by GM EUR Steering Group on 15/01/2014: <ul style="list-style-type: none"> • Mandatory criteria - Inclusion of criteria relating to glare and inclusion of criteria related to second eye. • Reference made to The Royal College of Ophthalmologists: Cataract Surgery Guidelines in the development of the Health Technology Assessment. |
| 0.3 | 24/03/2014 19/03/2014 | Amendments made by the GM EUR Steering Group on 19/03/2014: <ul style="list-style-type: none"> • First bullet point in mandatory criteria to read '<i>worse than 6/9</i>'. • Added '<i>reading</i>' to second bullet point in mandatory criteria. Draft policy approved by GM EUR Steering Group subject to the above amendments. |
| 0.4 | 08/04/2014 17/04/2014 09/07/2014 | <ul style="list-style-type: none"> • Statement regarding treating disabled people as more equal than other protected characteristic groups added to Equality and Equity section. • Ratification through CCG Governing Bodies added to 'Governance Arrangements'. Policy published for consultation. Policy reviewed by GM EUR Steering Group following consultation. |
| 1.0 | 09/07/2014 | Policy approved by the GM EUR Steering Group |
| 2.0 | Sept 2015 | <p>Following annual review of the policy in September 2015 the following changes have been made to the policy:-</p> <ul style="list-style-type: none"> • Date of review added and commissioning criteria updated. • Section 4 - Criteria for Commissioning under Mandatory Criteria wording amended to read:- • Cataract surgery is justified and appropriate when the patient fulfils the following criteria: <i>'The best corrected visual acuity score is worse than 6/9 (Snellen) or 0.2 (Logmar) in the affected eye, AND has one of the following (with correction):</i> <ul style="list-style-type: none"> • <i>Difficulty carrying out everyday tasks such as recognising faces, watching TV, reading, cooking, playing sport/cards etc.</i> • <i>Reduced mobility, experiencing difficulties in driving, for example, due to glare, or experiencing difficulty with steps or uneven ground.</i> • <i>Ability to work, give care or live independently is affected.</i> <i>The referral criteria for second eye are:</i> <ul style="list-style-type: none"> • <i>As above for first eye</i> OR <ul style="list-style-type: none"> • <i>Where there are binocular considerations</i> • <i>Where there is anisometropia</i> • <i>Where there is disabling glare</i> <p>NOTE: Implantation of lenses following or as part of cataract surgery is</p> |

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| | 18/11/2015 | <p><i>funded for the use of monofocal lenses only'</i></p> <ul style="list-style-type: none"> The following sentences have been added to Section 4 Criteria for Commissioning under Policy Exclusions:- <ul style="list-style-type: none"> At the end of the first paragraph: <i>'These conditions are managed as part of the agreed pathway and funded either within contracts or via monitored approval.'</i> A separate paragraph added: <i>'Externally funded trials and locally agreed pathways supported by the appropriate commissioning arrangements are excluded from this policy.'</i> Sentence added to Section 10 - Mechanism for Funding: <i>'Policy exclusions are funded either within contracts or via monitored approval'</i> The following had been added to Section 14 - Glossary: <i>'Anisometropia - A significant difference in refractive error between the two eyes of more than 1.00D in any meridian is often given as a definition of anisometropia.'</i> The Evidence Review section of the policy has been updated following annual review of the policy. <p>The GM EUR Steering Group reviewed and agreed the above minor changes to the policy. It was also agreed that no material changes had been made to the policy.</p> |
| 2.1 | 20/01/2016 | Following GM EUR Steering Group Meeting on 20/1/2016, policy amended to clarify that <u>any</u> monofocal lenses are included. |
| 2.2 | 05/04/2016 | <ul style="list-style-type: none"> List of diagnostic and procedure codes in relation to this policy added as Appendix 2. Policy changed to Greater Manchester Shared Services template and references to North West Commissioning Support Unit changed to Greater Manchester Shared Services. Wording for date of review amended to read: <i>'One year from the date of approval by Greater Manchester Association Governing Group thereafter at a date agreed by the Greater Manchester EUR Steering Group (unless stated this will be every 2 years)'</i> on the Policy Statement and section 13: Date of Review. |
| 2.3 | 21/09/2016 | <p>Policy reviewed by GM EUR Steering Group following feedback from local hospital clinicians and the following change was agreed:</p> <ul style="list-style-type: none"> The following wording added under the mandatory criteria for when surgery is justified and appropriate: <p><u>OR</u></p> <ul style="list-style-type: none"> <i>The individual has the type of cataract that cause considerable loss of low contrast vision so that, although their best corrected visual acuity score is 6/9 or 6/6, at high contrast they have an effective acuity of 6/24 or worse in twilight or dark conditions, <u>AND</u> has one of the following:</i> <ul style="list-style-type: none"> <i>Difficulty carrying out everyday tasks such as recognising faces, watching TV, reading, cooking, playing sport/cards etc.</i> <i>Reduced mobility, experiencing difficulties in driving, for example, due to glare, or experiencing difficulty with steps or uneven ground.</i> <i>Ability to work, give care or live independently is affected.'</i> |
| 2.4 | 16/11/2016 | <p>Amendments made by the GM EUR Steering Group on 16/11/2016 following review of draft v2.3 by ophthalmologic clinicians:</p> <p><u>Section 4, Criteria for Commissioning</u></p> <ul style="list-style-type: none"> The amended criteria added under "Cataract surgery is justified and appropriate when the patient fulfils the following criteria": <i>'The best corrected visual acuity score is worse than 6/9 (Snellen) or 0.2 (Logmar) in the affected eye.</i> |

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| | | <p>OR <i>The patient's visual acuity is 6/9 or better but they report excessive difficulty in twilight or dark conditions and the difficulty has been confirmed by a clinician to be the result of reduced contrast sensitivity.</i></p> <p>AND has one of the following (with correction):</p> <ul style="list-style-type: none"> • <i>Difficulty carrying out everyday tasks such as recognising faces, watching TV, reading, cooking, playing sport/cards etc.</i> • <i>Reduced mobility, experiencing difficulties in driving, for example, due to glare, or experiencing difficulty with steps or uneven ground.</i> <p><i>Ability to work, give care or live independently is affected.'</i></p> |
| 3.0 | 19/07/2017 | <p>Following scheduled review at GM EUR Steering Group on 19 July 2017 the following amendments were agreed (review date brought forward):</p> <ul style="list-style-type: none"> • Policy moved to new policy format • <u>Policy Inclusion Criteria</u>: The following paragraph added under the final bullet point for the first eye '<i>In cases where the cataract causes severe functional difficulties, application can be made for individual prior approval (see funding mechanism above)</i>'. • <u>Funding Mechanism</u> Note added regarding treatment of the second eye. • <u>Date of Review</u>: Section amended to read: '<i>Updated NICE guidance 'Cataracts in adults: management' [GID-CGWAVE0741] is expected to be published on 24th October 2017. Once this has been published the policy will reviewed again against this guidance.</i>' • <u>Summary of Evidence</u>: Paragraph added to end of section to read: '<i>At the time of the July 2017 review no new evidence was found after the usual search was completed.</i>' |
| 3.1 | 15/11/2017 | <p>Reviewed at GM EUR Steering Group on 15/11/2017 due to new NICE NG77 guidance being issued on 26/10/2017:</p> <ul style="list-style-type: none"> • <u>Adherence to NICE Guidance</u>: Statement added: '<i>Although the policy has a visual acuity requirement, it allows patients with normal visual acuity who experience functional issues due to the cataract to have treatment, therefore the policy is NICE NG77 compliant.</i>' • <u>Date of Review</u>: Standard wording on next review added to state '<i>5 years</i>' <p>The above changes were not considered to be material and therefore it was not necessary for the revised policy to go back through the governance process again.</p> |