Policy Statement

Title/Topic: Cataract Surgery
Date: April 2014
Reference: GM026
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<th>Version</th>
<th>Date</th>
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<td>0.1</td>
<td>07/01/14</td>
<td>Initial draft</td>
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<tr>
<td>0.2</td>
<td>21/01/14</td>
<td>Amendments made by GM EUR Steering Group on 15/01/2014: 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.</td>
<td>7, 9, 10 &amp; 11</td>
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<tr>
<td>0.3</td>
<td>24/03/14</td>
<td>Amendments made by the GM EUR Steering Group on 19/03/2014: First bullet point in mandatory criteria to read ‘worse than 6/9’. Add ‘reading’ to second bullet point in mandatory criteria. Draft policy approved by GM EUR Steering Group subject to the above amendments.</td>
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<tr>
<td>0.4</td>
<td>08/04/14</td>
<td>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’.</td>
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### POLICY STATEMENT

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#### Commissioning Recommendation:

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.

Cataract surgery is justified and appropriate when the patient experiences one, or more of the following:

- The best corrected visual acuity score is worse than 6/9 in the affected eye.
- Difficulty carrying out everyday tasks such as recognising faces, watching TV, reading, cooking, playing sport/cards etc.
- 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.

The referral criteria for second eye are:

- As above for first eye
- Where there are binocular considerations

#### Date of Review:

Insert Date (one year from the date of adoption and annually thereafter)

#### Prepared By:

The Greater Manchester Commissioning Support Unit Effective Use of Resources Policy Team
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<th>Approved By</th>
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CONTENTS

Policy Statement ............................................................................................................. 6
Equality & Equity Statement ........................................................................................... 6
Governance Arrangements ............................................................................................. 6
1. Introduction ................................................................................................................. 6
2. Definition ..................................................................................................................... 7
3. Aims and Objectives ................................................................................................. 7
4. Criteria for Commissioning ....................................................................................... 7
5. Description of Epidemiology and Need .................................................................... 8
6. Evidence Summary ..................................................................................................... 9
7. Absence of Evidence Summary .................................................................................. 10
8. Rationale behind the Policy Statement ..................................................................... 10
9. Mechanism for Funding ............................................................................................ 10
10. Audit Requirements ................................................................................................. 10
11. Documents which have informed this Policy ........................................................... 10
12. Links to other Policies ............................................................................................. 10
13. Date of Review ......................................................................................................... 11
14. Glossary .................................................................................................................... 11
References ...................................................................................................................... 11
Appendix 1 – Evidence Review ...................................................................................... 12
Policy Statement

The Greater Manchester Commissioning Support Unit (GMCSU) has developed this policy on behalf of Clinical Commissioning Groups (CCGs) within Greater Manchester, who will commission cataract surgery in accordance with the criteria outlined in this document.

In creating this policy the GMCSU 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.

Equality & Equity Statement

The GMCSU/CCG has 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. The GMCSU/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, sex (gender) or sexual orientation. In carrying out its functions, the GMCSU/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 GMCSU 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 GMCSU evidencing taking ‘due regard’ for fair access to healthcare information, services and premises.

An Equality Analysis has been carried out on 9th April 2014. 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.

1. Introduction

This commissioning policy has been produced in order to provide and ensure equity, consistency and clarity in the commissioning of cataract surgery services by Clinical Commissioning Groups in Greater Manchester. When this policy is reviewed all available
additional data on outcomes will be included in the review and the policy updated accordingly.

2. Definition

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 intraocular lens is then inserted through the incision.

3. Aims and Objectives

Aim

This policy document aims to specify the conditions under which cataract surgery will be routinely commissioned by Clinical Commissioning Groups in Greater Manchester.

Objectives

- To reduce the variation in access to cataract surgery.
- To ensure that cataract surgery is commissioned where there is acceptable evidence of clinical benefit and cost-effectiveness.
- To reduce unacceptable variation in the commissioning of cataract surgery across Greater Manchester.
- To promote the cost-effective use of healthcare resources.

4. Criteria for Commissioning

Mandatory Criteria

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.

Cataract surgery is justified and appropriate when the patient experiences one, or more of the following:

- The best corrected visual acuity score is worse than 6/9 in the affected eye.
- Difficulty carrying out everyday tasks such as recognising faces, watching TV, reading, cooking, playing sport/cards etc.
- 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.

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.

The referral criteria for second eye are:
• As above for first eye
OR
• Where there are binocular considerations

Policy Exclusions

Exceptions to the above criteria include: 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 concomitent 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.

Clinicians can submit an Individual Funding Request (IFR) 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.

5. Description of 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.

6. Evidence Summary

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.

Full details of the Evidence Review are contained with Appendix 1.

7. Absence of Evidence Summary

See Search Strategy Table in Appendix 1.

8. 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.

9. Mechanism for Funding

Funding will be via the relevant contracting arrangements and referrals may be accepted in line with the criteria.

Where a patient does not meet the above criteria, but their clinical circumstances are deemed to be exceptional, funding will be made available on an individual patient basis. Individual Funding Requests should be made in line with the procedures described in the Greater Manchester EUR Operational Policy.

10. Audit Requirements

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

11. Documents which have informed this Policy

- Health Technology Assessment of Scheduled Surgical Procedures: Cataract Surgery, Health Information and Quality Authority, Ireland (2013)
- BMJ Clinical Evidence, Cataract
- Cochrane Review: Surgical interventions for age-related cataract
- Greater Manchester EUR Operational Policy

12. Links to other Policies

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).
13. Date of Review

Insert Date (one year from the date of adoption and annually thereafter)

14. Glossary

<table>
<thead>
<tr>
<th>Term</th>
<th>Meaning</th>
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<tr>
<td>HTA</td>
<td>Health Technology Assessment</td>
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<td>BMJ</td>
<td>British Medical Journal</td>
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<tr>
<td>Exceptionality</td>
<td>A person to which the general rule is not applicable (see policy exclusions sections above for a detailed definition).</td>
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<tr>
<td>NICE</td>
<td>National Institute for Health and Care Excellence</td>
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<td>Visual acuity</td>
<td>Visual acuity is a measure of your central vision, the ability to distinguish details and shapes of objects.</td>
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<tr>
<td>Glaucoma</td>
<td>Glaucoma is a group of eye conditions in which the optic nerve is damaged due to changes in eye pressure</td>
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References

1. **Cataract Surgery Guidelines**
   The Royal College of Ophthalmologists (2010)

2. **Health Technology Assessment of Scheduled Surgical Procedures: Cataract Surgery**
   Health Information and Quality Authority, Ireland (2013)

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

4. 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?

5. **Surgical interventions for age-related cataract**
   Cochrane Database of Systematic Reviews
## Appendix 1 – Evidence Review

**Title/Topic:** Cataract Surgery  
**Ref:** GM026

### Search Strategy

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| NICE                      | • No Clinical Guideline  
                           • NICE IPG 209, 264                                                                                                                             |
                           • Cataract Surgery Guidelines, The Royal College of Ophthalmologists (2010).  
| SIGN                      | None                                                                                                                                                                                                  |
| Cochrane                  | • Surgical interventions for age-related cataract (Review)  
                           • Surgical interventions for bilateral congenital cataract (Review)  
                           • Surgery for post-vitrectomy cataract (Review)  
                           • Surgery for cataracts in people with age-related macular degeneration (Review)                                                                 |
| York                      | As per Cochrane and HTA                                                                                                                                                                             |
| BMJ Clinical Evidence     | Cataract  
                           Search date May 2010  
                           David Allen                                                                                                                                 |
| BMJ Best Practice         | Cataract condition information  
                           Patient information from the BMJ Group - Cataracts: Should I have surgery?                                                                                  |
| General Search (Google)  | • Evidence-based guidelines for cataract surgery: Guidelines based on data in the European Registry of Quality Outcomes for Cataract and Refractive Surgery database.  
                           • NHS Choices pages on Cataract Surgery.                                                                                                               |
| Medline / Open Athens     | Search restricted to key papers related to the above reviews                                                                                                                                              |
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.

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 evidence

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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 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?

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.
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.

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.