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► BACKGROUND

In bilateral cataract the eye with greatest vision impairment from cataract is operated on first. First-eye surgery can improve vision and quality of life. However, it is unclear whether cataract surgery on the second eye provides enough incremental benefit to be considered clinically effective and cost-effective.

► OBJECTIVE

To conduct systematic reviews of clinical effectiveness, cost-effectiveness and health-related quality of life (HRQoL) after 2nd-eye cataract surgery in England and Wales, and develop an economic model informed by these systematic reviews.

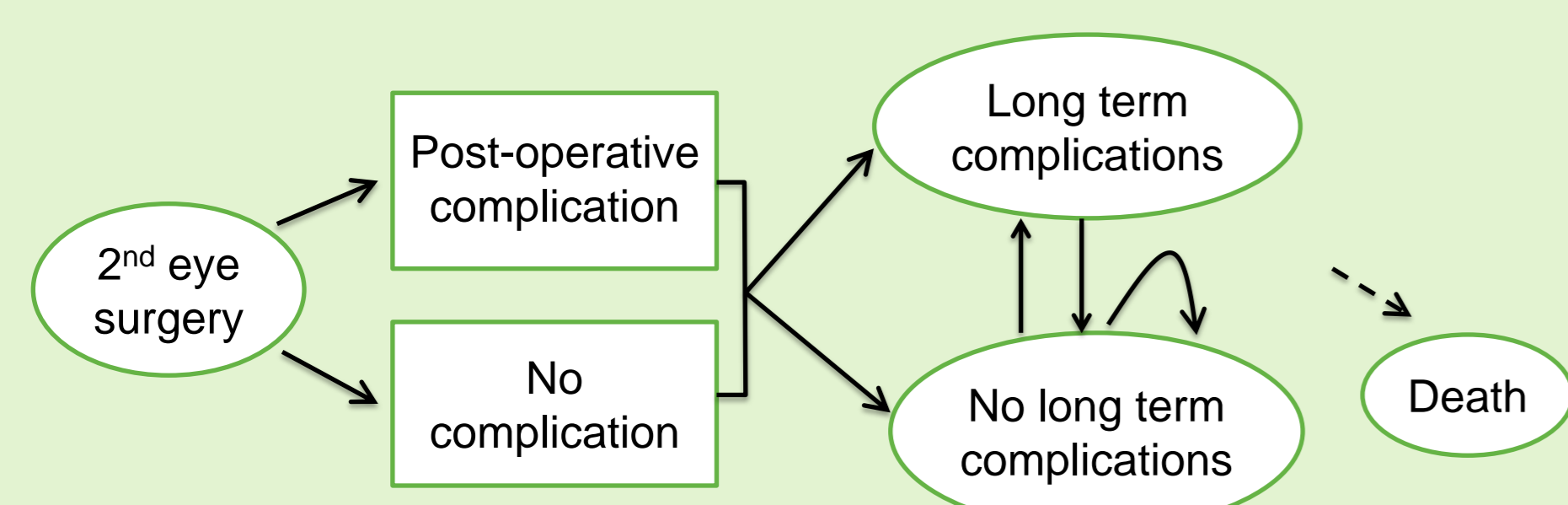
► METHODS

Data sources 12 electronic bibliographic databases, including MEDLINE, EMBASE, Web of Science, the Cochrane Library and the Centre for Reviews and Dissemination databases were searched in April 2013, with searches updated in July 2013. Reference lists of relevant publications were also checked and experts consulted.

Review methods 2 reviewers independently screened references against pre-specified inclusion criteria, extracted and checked data from the included studies and appraised their risk of bias. Inclusion criteria for the clinical effectiveness review are shown in Box 1.

Economic model Based on the review of cost-effectiveness, a de novo economic model (Figure 1) was developed to estimate cost-effectiveness of 2nd-eye surgery in patients with bilateral cataract, compared to cataract surgery in one eye only. In the model, 2nd-eye surgery is associated with a change in visual acuity and a corresponding change in HRQoL, assumed to last the patient's lifetime. Patients undergoing surgery either experience post-surgical complications or no complications. Post-surgical complications and consequences are associated with a health disutility and require additional treatment. Outcomes in the model are expressed as Quality Adjusted Life Years (QALYs), and cost-effectiveness is expressed in terms of Incremental Cost-Effectiveness Ratios (ICERs).

Figure 1: Model structure



Post-operative complications: endophthalmitis, cystoid macular oedema, retained lens fragments

Long-term complications: posterior capsular opacification, retinal detachment



Elective cataract surgery is the most commonly performed surgical procedure in the NHS

Box 1: Inclusion criteria

Population – Adults aged 18 years and above who have had one cataract operation already and still have or develop significant cataract-related visual impairment in the other eye.

Intervention – Cataract surgery for the second eye (any surgical technique).

Comparator – Cataract surgery in one eye only (with additional supportive care if this is usual practice, such as prescription glasses).

Outcomes – Any measures of clinical vision (including measures of visual acuity, contrast sensitivity and stereopsis); any patient-reported measures of visual disability and symptoms; patient satisfaction with surgery and vision; health related quality of life (e.g. EuroQol EQ-5D); adverse events (different outcomes were permissible for the cost-effectiveness and HRQoL reviews).

Study designs – Randomised controlled trials (RCTs) (different designs were permissible for the cost-effectiveness and HRQoL reviews).

CLINICAL EFFECTIVENESS RESULTS

- 3 RCTs met the inclusion criteria: 2 in England (1994-95, 2000-04), 1 in Spain (1999-00). They randomised 208 to 296 patients. Mean ages were 71.1 to 79.9 years.
- The RCTs compared patients expedited to receive 2nd-eye surgery within a target period (intervention) and those scheduled for 2nd-eye surgery at end of study according to routine practice (waiting-list comparator). Target time for 2nd-eye surgery was 4 to 6 weeks after randomisation (2 RCTs) or 2 to 4 months after first-eye surgery (1 RCT).
- Outcomes were measured 4 to 12 months after 2nd-eye surgery. Heterogeneity of the study characteristics precluded meta-analyses.
- Improvements in binocular visual acuity and contrast sensitivity in the second-eye surgery groups were small, unlikely of clinical significance.
- Stereopsis was improved to a clinically meaningful extent in all 3 RCTs following 2nd-eye surgery.
- Patient-reported outcomes were assessed but had several limitations (see right).

COST-EFFECTIVENESS AND HRQoL REVIEW RESULTS

- 3 studies of cost-effectiveness were included. They differed in modelling approaches, patient characteristics, and results, though 2nd-eye surgery would be considered cost-effective under currently employed willingness-to-pay thresholds if a lifetime horizon is used. However, the economic evaluations had various limitations, indicating a need to develop a de novo economic model for relevance to the NHS.
- 10 studies of HRQoL were included. They were diverse in terms of aims, comparisons made, study designs, patient characteristics and locations. A range of HRQoL instruments was used, most commonly EQ-5D. In 4 studies comparison between 1st and 2nd-eye surgery was possible. Utility changes varied from negative to positive but the more robust studies indicated net utility gains after 2nd-eye surgery.

RESULTS OF THE ECONOMIC MODEL

- 2nd-eye surgery yielded 0.68 incremental QALY with an ICER of £1,964 per QALY gained. Worst-case ICER was £6,432 per QALY gained. The probability that 2nd-eye surgery would be cost-effective at willingness-to-pay thresholds of £10,000 and £20,000 was 100%.
- Results were robust to a range of scenarios and assumptions but are sensitive to utility values chosen from published studies, meaning that 2nd-eye surgery was not cost-effective in at least one scenario analysis.

CONCLUSIONS & DISCUSSION

- 2nd-eye cataract surgery would be cost-effective based on the best available data. However, no relevant RCTs have been conducted recently so results might not reflect the current case mix, efficacy and safety profile of current techniques. The key aspect of clinical vision which improved after second-eye surgery was stereopsis; however, other visual outcomes affected by cataracts, such as glare disability, which are important to patients were not assessed in the RCTs.
- A further limitation of RCTs that informed this analysis is that patients generally had good visual acuity before 2nd-eye surgery and good baseline scores on some of the patient-reported outcomes employed (notably the Visual Function index, VF-14) which may have limited the room for improvement in these outcomes. To fully capture effects of bilateral cataracts and 2nd-eye cataract surgery on patients' clinical vision, HRQoL and visual disability, development of a 'core' set of outcome measures may be appropriate. This could include tests of vision which may be more sensitive than binocular visual acuity (e.g. including stereopsis and glare disability) as well a validated and responsive patient reported functional disability outcome.
- To improve estimates of clinical and cost-effectiveness of 2nd-eye surgery, a well-designed RCT reflecting the current population case mix would be appropriate. This would need to capture (e.g. in a stratified design) the current geographical variation within the NHS in the assessment criteria used in referring patients for 2nd-eye surgery.

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The full report for this project will be published in the NIHR Journals Library: <http://www.journalslibrary.nihr.ac.uk/> (project number 12/72/01)