# Assessment of cataract surgical outcomes in settings where follow-up is poor: PRECOG, a multicentre observational study

*Nathan Congdon, Xixi Yan, Van Lansingh, Alemayehu Sisay, Andreas Müller, Ving Chan, Ling Jin, Mirjam E Meltzer, Sasipriya M Karumanchi, Chunhong Guan, Quy Vuong, Nelson Rivera, Joan McCleod-Omawale, Mingguang He*

## Summary

**Background** Poor follow-up after cataract surgery in developing countries makes assessment of operative quality uncertain. We aimed to assess two strategies to measure visual outcome: recording the visual acuity of all patients 3 or fewer days postoperatively (early postoperative assessment), and recording that of only those patients who returned for the final follow-up examination after 40 or more days without additional prompting.

**Methods** Each of 40 centres in ten countries in Asia, Africa, and Latin America recruited 40–120 consecutive surgical cataract patients. Operative-eye best-corrected visual acuity and uncorrected visual acuity were recorded before surgery, 3 or fewer days postoperatively, and 40 or more days postoperatively. Clinics logged whether each patient had returned for the final follow-up examination without additional prompting, had to be actively encouraged to return, or had to be examined at home. Visual outcome for each centre was defined as the proportion of patients with uncorrected visual acuity of 6/18 or better minus the proportion with uncorrected visual acuity of 6/60 or worse, and was calculated for each participating hospital with results from the early assessment of all patients and the late assessment of only those returning unprompted, with results from the final follow-up assessment for all patients used as the standard.

**Findings** Of 3708 participants, 3441 (93%) had final follow-up vision data recorded 40 or more days after surgery, 1831 of whom (51% of the 3581 total participants for whom mode of follow-up was recorded) had returned to the clinic without additional prompting. Visual outcome by hospital from early postoperative and final follow-up assessment for all patients were highly correlated (Spearman's $r_s$=0·74, p<0·0001). Visual outcome from final follow-up assessment for all patients and for only those who returned without additional prompting were also highly correlated ($r_s$=0·86, p<0·0001), even for the 17 hospitals with unprompted return rates of less than 50% ($r_s$=0·71, p=0·002). When we divided hospitals into top 25%, middle 50%, and bottom 25% by visual outcome, classification based on final follow-up assessment for all patients was the same as that based on early postoperative assessment for 27 (68%) of 40 centres, and the same as that based on data from patients who returned without additional prompting in 31 (84%) of 37 centres. Use of glasses to optimise vision at the time of the early and late examinations did not further improve the correlations.

**Interpretation** Early vision assessment for all patients and follow-up assessment only for patients who return to the clinic without prompting are valid measures of operative quality in settings where follow-up is poor.

**Funding** ORBIS International, Fred Hollows Foundation, Helen Keller International, International Association for the Prevention of Blindness Latin American Office, Aravind Eye Care System.

## Introduction

Unoperated cataract remains the most common cause of blindness worldwide,[1] even though the disorder can be effectively and inexpensively treated with a standard procedure. When treated by skilled surgeons, 90% of patients can achieve good vision (best-corrected visual acuity of 6/12 or better),[2–4] and an equal proportion are satisfied with their surgical result.[5]

Poor surgical outcomes and inadequate access to surgery are major impediments to the reduction of blindness from cataract, particularly in low-resource settings.[6–13] Improving surgical capacity by training additional surgeons and providing equipment could help to address both issues,[14,15] but success also depends on monitoring surgical quality. Visual acuity after cataract surgery has traditionally been measured weeks to months after the operation, since wound healing can change refractive power, and gradual resolution of common complications such as corneal oedema can substantially improve vision. Less often, visual decline from surgical complications can also occur.

In many developing countries, postoperative follow-up rates are as low as 20–30%,[16] because of poor transportation infrastructure, costs to patients, and failure to communicate the benefits of returning,[17] which can include distribution of corrective glasses. Low rates of postoperative follow-up and uncertainty about whether returning patients are representative of the operated cohort make assessment of performance against objective standards difficult. WHO[18] recommends that 80% of patients should have uncorrected (without refraction) visual acuity of 6/18 or better in the operated eye, but does not stipulate a specific time after surgery for assessment.

*Lancet Glob Health* 2013; 1: e37–45

See **Comment** page e9

Copyright © Congdon et al. Open Access article distributed under the terms of CC BY

**Preventive Ophthalmology and State Key Laboratory, Zhongshan Ophthalmic Centre, Sun Yat-sen University, Guangzhou, China** (Prof N Congdon MD, X Yan MD, L Jin MS, M E Meltzer PhD, Prof M He MD); **ORBIS International, New York, NY, USA** (N Congdon, A Sisay MD, Q Vuong MD, J McCleod-Omawale PhD); **International Agency for the Prevention of Blindness/VISION 2020 Latin America Regional Office, Miami, FL, USA** (V Lansingh MD, N Rivera OD); **Fred Hollows Foundation, Sydney, NSW, Australia** (A Müller PhD, C Guan MSc); **Brien Holden Vision Institute, Sydney, NSW, Australia** (V Chan OD); **WHO Western Pacific Region Office, Manila, Philippines** (A Müller); **Lions Aravind Institute of Community Ophthalmology, Aravind Eye Care System, Madurai, India** (S M Karumanchi MHM); **and Helen Keller International, New York, NY, USA** (M He)

Correspondence to:
Prof Nathan Congdon, Division of Preventive Ophthalmology and State Key Laboratory, Zhongshan Ophthalmic Centre, Sun Yat-sen University, Guangzhou 510060, China
**ncongdon1@gmail.com**

In the past 20 years, phacoemulsification and small-incision cataract surgery, both of which use small, rapidly healing cataract surgical wounds, have been widely adopted. Although studies have shown that vision changes during healing are reduced with these techniques,[19–21] only a few studies have examined whether early visual assessment is predictive of final vision.[16,22]

An international group of organisations with a focus on eye health undertook the Prospective Review of Early Cataract Outcomes and Grading (PRECOG) study to test new approaches for the measurement of cataract surgical quality in settings with poor rates of follow-up. Our hypothesis was that, even in these settings, data that accurately represent visual outcomes for an operated cohort can be obtained. Our aims were to measure the correlation for individual patients and for hospitals between visual acuity at 3 or fewer days postoperatively and at 40 or more days postoperatively, when acuity should have stabilised; to assess the extent to which the visual acuity of patients who return without additional prompting to the clinic after 40 or more days for follow-up examination is representative of the entire operative cohort; and to establish evidence-based targets for good visual acuity results for hospitals.

## Methods

### Study design and participants

A geographically diverse range of large and small, urban and rural, and public and private hospitals in developing countries were invited to take part in the PRECOG study through ORBIS International (New York, NY, USA), the Fred Hollows Foundation (Sydney, NSW, Australia), Helen Keller International (New York, NY, USA), the International Association for the Prevention of Blindness Latin American Office (Miami, FL, USA), and the Aravind Eye Care System (Madurai, India). The only requirement for hospitals was that surgical output be sufficient to complete recruitment within 6 months. The principal investigator (NC) did a single, 1-day training session in each country, during which the study investigators at participating centres reviewed the study protocol and forms. Investigators at the coordinating centre (Zhongshan Ophthalmic Centre, Guangzhou, China) regularly reviewed submitted forms and provided feedback to regional coordinators, who discussed any protocol or data entry issues with participating centres.

Each hospital enrolled 40–120 consecutive patients aged 30 years or older scheduled to undergo surgery for adult-onset cataract. We chose this range of number of patients per hospital to provide a representative sample of surgical procedures at each centre, while minimising the burden of postoperative follow-up. Patients had been diagnosed with visually significant cataract, and could have any visual acuity in the operative eye, but could not have ocular comorbidities apparent during preoperative examination. If comorbidities initially masked by lens opacity were discovered postoperatively, patients were not censored, since this situation is common in developing-country settings. Patients underwent surgery by any widely used method, including phaco-emulsification, small-incision cataract surgery, or extra-capsular cataract extraction.

The study protocol was approved by the institutional review boards at the coordinating centre and at other participating organisations. Some hospitals did not have their own institutional review boards, in which case review was done by the sponsoring organisation. All participants provided written informed consent, and the principles of the Declaration of Helsinki were followed throughout.

| | Number of hospitals | Mean annual surgical volume | Median annual surgical volume (range) | Public* | Rural† |
|---|---|---|---|---|---|
| Asia | | | | | |
| China | 18 | 521 | 350 (42–2000) | 17 | 14 |
| Vietnam | 4 | 1573 | 1160 (772–3200) | 4 | 0 |
| India | 5 | 43748 | 31794 (10117–91759) | 0 | 0 |
| Indonesia | 2 | 244 | 244 (200–288) | 2 | 2 |
| Latin America | | | | | |
| Peru | 2 | 1381 | 1381 (534–2229) | 1 | 0 |
| Ecuador | 1 | 1951 | .. | 0 | 1 |
| Paraguay | 1 | 3758 | .. | 1 | 0 |
| Guatemala | 1 | 1897 | .. | 0 | 0 |
| Mexico | 2 | 2387 | 2387 (1136–3639) | 0 | 0 |
| Africa | | | | | |
| Ethiopia | 2 | 307 | 307 (267–346) | 2 | 0 |
| Eritrea | 2 | 1860 | 1860 (1820–1900) | 2 | 0 |
| Total | 40 | 6360 | 766 (42–91759) | 29 | 17 |

Data are n, unless otherwise indicated. *Other participating hospitals are private. †Other participating hospitals are urban.

*Table 1:* **Characteristics of participating hospitals, by geographical location**

### Preoperative examination

All patients underwent preoperative ocular examinations by an ophthalmologist with slit lamp and dilation of the pupil. Patients' demographic information and cataract surgical histories were recorded, as were uncorrected visual acuity and best-corrected visual acuity (with glasses) in both eyes, presence of ocular comorbidities, and biometric measurements to identify the power of the intraocular lens needed for surgery.

Visual acuity was assessed at each hospital with that hospital's usual charts and at the recommended distance (usually 4 m). Tumbling E charts were used in all locations. Measurements were made separately for each eye, beginning with the right, in a well-lit area of the clinic. After correctly identifying the direction of more than half of the optotypes on the uppermost line (usually equivalent to a visual acuity of 3/60), patients moved to the next and then to successively lower lines. The lowest line on which more than half of the

optotypes were correctly read was recorded as the patient's visual acuity. Patients unable to read the top line at the standard distance attempted to read it from 1 m, and visual acuity was divided by the standard distance. Throughout testing, the examiner ensured that the non-tested eye was fully occluded, and that the patient maintained the proper distance from the chart and did not squint (which creates an optical pinhole effect that improves vision).

### Early postoperative examination

The early postoperative examination was done within 72 h after surgery, at hospital discharge in most centres. Data recorded included dates of surgery and of

| | China (n=1580) | India (n=504) | Vietnam (n=394) | Indonesia (n=221) | Latin America (n=707) | Africa (n=302) | Total (n=3708) |
|---|---|---|---|---|---|---|---|
| **Sex** | | | | | | | |
| Male | 693 (44%) | 199 (39%) | 127 (36%) | 109 (49%) | 317 (45%) | 140 (46%) | 1585 (43%) |
| Female | 887 (56%) | 305 (61%) | 221 (64%) | 112 (51%) | 389 (55%) | 162 (54%) | 2076 (57%) |
| Missing data | 0 | 0 | 46 | 0 | 1 | 0 | 47 |
| **Age group (years)** | | | | | | | |
| ≤50 | 66 (4%) | 94 (19%) | 11 (3%) | 22 (10%) | 57 (8%) | 85 (28%) | 335 (9%) |
| 51–60 | 152 (10%) | 211 (42%) | 29 (8%) | 44 (20%) | 107 (15%) | 75 (25%) | 618 (17%) |
| 61–70 | 384 (24%) | 169 (34%) | 85 (24%) | 86 (39%) | 166 (23%) | 88 (29%) | 978 (27%) |
| ≥71 | 977 (62%) | 30 (6%) | 233 (65%) | 69 (31%) | 377 (53%) | 54 (18%) | 1740 (47%) |
| Missing data | 1 | 0 | 36 | 0 | 0 | 0 | 37 |
| **Preoperative uncorrected visual acuity** | | | | | | | |
| 6/60 or worse | 1377 (88%) | 340 (67%) | 339 (90%) | 219 (99%) | 557 (79%) | 292 (97%) | 3124 (85%) |
| 6/60 to 6/18 | 173 (11%) | 105 (21%) | 19 (5%) | 1 (<1%) | 120 (17%) | 4 (1%) | 422 (11%) |
| 6/18 or better | 14 (1%) | 59 (12%) | 18 (5%) | 1 (<1%) | 28 (4%) | 5 (2%) | 125 (3%) |
| Missing data | 16 | 0 | 18 | 0 | 2 | 1 | 37 |
| **Type of surgery** | | | | | | | |
| SICS | 1258 (80%) | 448 (89%) | 7 (2%) | 1 (<1%) | 346 (49%) | 237 (78%) | 2297 (63%) |
| ECCE (or ICCE*) | 28 (2%)* | 23 (5%) | 110 (29%) | 220 (100%) | 147 (21%)* | 65 (22%) | 593 (16%)* |
| Phacoemulsification | 276 (18%) | 32 (6%) | 262 (69%) | 0 | 212 (30%) | 0 | 782 (21%) |
| Missing data | 18 | 1 | 15 | 0 | 2 | 0 | 36 |
| **Follow-up vision results available** | | | | | | | |
| Yes | 1426 (90%) | 473 (94%) | 362 (92%) | 189 (86%) | 690 (98%) | 301 (100%) | 3441 (93%) |
| No | 154 (10%) | 31 (6%) | 32 (8%) | 32 (14%) | 17 (2%) | 1 (<1%) | 267 (7%) |
| Missing data | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| **Returned unprompted for final follow-up assessment** | | | | | | | |
| Yes | 416 (27%) | 206 (41%) | 284 (83%) | 91 (41%) | 650 (93%) | 184 (61%) | 1831 (51%) |
| No | 1099 (73%) | 298 (59%) | 57 (17%) | 130 (59%) | 50 (7%) | 116 (39%) | 1750 (49%) |
| Missing data | 65 | 0 | 53 | 0 | 7 | 2 | 127 |
| **Early postoperative uncorrected visual acuity** | | | | | | | |
| 6/60 or worse | 150 (10%) | 31 (6%) | 150 (39%) | 149 (67%) | 207(29%) | 122 (40%) | 809 (22%) |
| 6/60 to 6/18 | 679 (43%) | 106 (21%) | 55 (14%) | 23 (10%) | 220 (31%) | 101 (33%) | 1184 (32%) |
| 6/18 or better | 740 (47%) | 367 (73%) | 181 (47%) | 49 (22%) | 278 (39%) | 79 (26%) | 1694 (46%) |
| Missing data | 11 | 0 | 8 | 0 | 2 | 0 | 21 |
| **Late postoperative (final follow-up) uncorrected visual acuity** | | | | | | | |
| 6/60 or worse | 74 (5%) | 24 (5%) | 78 (22%) | 55 (29%) | 59 (9%) | 45 (15%) | 335 (10%) |
| 6/60 to 6/18 | 446 (31%) | 115 (24%) | 55 (16%) | 39 (21%) | 160 (23%) | 82 (27%) | 897 (26%) |
| 6/18 or better | 906 (64%) | 334 (71%) | 218 (62%) | 95 (50%) | 471 (68%) | 174 (58%) | 2198 (64%) |
| Missing data | 154 | 31 | 43 | 32 | 17 | 1 | 278 |
| **Late postoperative (final follow-up) glasses-corrected visual acuity** | | | | | | | |
| 6/60 or worse | 46 (3%) | 5 (1%) | 41 (12%) | 41 (22%) | 16 (2%) | 22 (8%) | 171 (5%) |
| 6/60 to 6/18 | 177 (12%) | 28 (6%) | 28 (8%) | 29 (15%) | 20 (3%) | 39 (14%) | 321 (10%) |
| 6/18 or better | 1196 (84%) | 440 (93%) | 272 (80%) | 119 (63%) | 606 (94%) | 214 (78%) | 2847 (85%) |
| Missing data | 161 | 31 | 53 | 32 | 65 | 27 | 369 |

(Continues on next page)

| | China (n=1580) | India (n=504) | Vietnam (n=394) | Indonesia (n=221) | Latin America (n=707) | Africa (n=302) | Total (n=3708) |
|---|---|---|---|---|---|---|---|
| (Continued from previous page) | | | | | | | |
| **Patient-level correlation between early postoperative and late postoperative uncorrected visual acuity** | | | | | | | |
| Spearman's $r_s$† | 0·62 | 0·63 | 0·78 | 0·38 | 0·49 | 0·53 | 0·59 |
| **Intraoperative complication present** | | | | | | | |
| Yes | 146 (9%) | 10 (2%) | 46 (12%) | ..‡ | 63 (9%) | 86 (29%) | 351 (10%) |
| No | 1411 (91%) | 494 (98%) | 331 (88%) | ..‡ | 642 (91%) | 214 (71%) | 3092 (90%) |
| Missing data | 23 | 0 | 17 | ..‡ | 2 | 2 | 265 |
| **Postoperative complication present** | | | | | | | |
| Yes | 29 (2%) | 3 (1%) | 11 (4%) | ..‡ | 21 (3%) | 30 (11%) | 94 (3%) |
| No | 1356 (98%) | 470 (99%) | 256 (96%) | ..‡ | 656 (97%) | 250 (89%) | 2988 (97%) |
| Missing data | 195 | 31 | 127 | ..‡ | 30 | 22 | 626 |

Data are n (%), unless otherwise indicated (missing data are excluded from all percentage calculations). Early postoperative assessment was done within 3 days after surgery; late postoperative assessment was done 40 or more days after surgery All visual acuity results are for the operative eye. SICS=small-incision cataract surgery. ECCE=extracapsular cataract extraction. ICCE=intracapsular cataract extraction. *One patient in China and three in Latin America underwent ICCE. †p<0·0001 for all correlations. ‡No data were available for complications in the Indonesian population.

*Table 2:* **Patient demographic characteristics and clinical outcomes**

examination, examiner's identity (the operating surgeon was not allowed to do the examination), uncorrected and best-corrected visual acuity in the operated eye, type of surgery done (phacoemulsification, small-incision cataract surgery, or extra-capsular cataract extraction), identity of the operative eye, presence of intraoperative or perioperative complications, and reason for postoperative uncorrected visual acuity of 6/60 or worse in the operative eye, if relevant. All patients were instructed to return for a final examination 40 days after surgery, with additional visits in the intervening period at the discretion of the centre.

### Final follow-up examination

Final follow-up examinations were completed on all patients who returned without further prompting to the clinic 40 or more days after surgery. 40 days after enrolment of the final patient, clinic staff could use methods such as telephone calls and transport subsidies to encourage unexamined patients to return. 3 months after enrolment of the final patient, clinic staff began home visits for unexamined patients, with a target of examining at least 90% of enrolees. Clinics maintained a log to record whether each patient had returned without further prompting, had returned after a study intervention to promote follow-up, or was examined at home.

The final examination included pupil dilation by an ophthalmologist. Data recorded included date and location of examination, examiner's identity (the operating surgeon was not allowed to do the examination), identity of operative eye, uncorrected and best-corrected visual acuity (assessed with the same chart as was used in previous examinations, irrespective of location), presence of postoperative complications, and reason for uncorrected visual acuity of 6/60 or worse in the operative eye, if relevant.

### Statistical analysis

All visual acuity data were log-transformed. We used Spearman's rank correlation coefficient ($r_s$) to assess the correlation between patients' early and late postoperative (final follow-up) uncorrected visual acuity measurements. Visual outcome for each hospital was defined as the proportion of patients with uncorrected visual acuity of 6/18 or better (ie, good surgical outcome by WHO standards[18]) minus the proportion with uncorrected visual acuity of 6/60 of worse (blindness, as defined in the USA and some other countries).[23] The visual outcome based on assessment of uncorrected visual acuity at final follow-up for all patients at a hospital was treated as the standard, to which the visual outcomes based on early assessment of all patients and final follow-up assessment of only the patients who returned without additional prompting were compared by use of Spearman's rank correlation coefficient. We classified hospitals on the basis of visual outcome into high (top 25%), middle (middle 50%), and low (bottom 25%) performance, and compared the proportion of hospitals that ranked in the same category when the standard data (final follow-up for all patients) were used and when data from either of the two strategies under investigation (early assessment and late assessment of only those who returned unprompted) were used. All statistical analyses were done with Stata 11.0 (StataCorp, College Station, TX, USA).

### Role of the funding source

None of the funders had any role in study design, data collection, data analysis, data interpretation, or writing of the report. The corresponding author had full access to all the data in the study and had final responsibility for the decision to submit for publication.

## Results

40 hospitals in China (n=18), Vietnam (n=4), India (n=5), Indonesia (n=2), Mexico (n=2), Guatemala (n=1), Peru (n=2), Ecuador (n=1), Paraguay (n=1), Ethiopia (n=2), and Eritrea (n=2) participated in the study, each of which enrolled at least 40 patients (table 1). Annual cataract surgical output ranged from 42 to 91759 cases, with a median of 766 overall, 350 for China, 1160 for Vietnam, 244 for Indonesia, 31794 for India, 1951 for Latin America, and 1083 for Africa.

Study centres recruited 3708 patients with a mean age of 68 years (SD 12; table 2). The early postoperative examination was done on the first postoperative day for 3062 (85%) of 3601 patients for whom the date was recorded. 3441 (93%) patients completed the final follow-up examination at 40 or more days postoperatively. Patients who did not complete the final follow-up examination were older by a mean of 1·7 years (95% CI 0·3–3·2, p=0·02) than those who did and were more likely to have uncorrected visual acuity of 6/60 or worse at early postoperative examination (27% [72/266] *vs* 21% [737/3421], p=0·005). The groups did not differ by sex (44% [1480/3402] male in those with final follow-up results *vs* 41% [105/259] in those without, p=0·35). Completion of final follow-up examination was greater than 90% for all three world regions and for all countries apart from Indonesia (86% [189/221]). Overall, 1831 (51%) of 3581 patients whose mode of follow-up was recorded returned to the clinic for the final examination without additional study-related prompting or inducement (table 2). Median time between hospital discharge and final examination was 98 days (IQR 71–171).

Most patients underwent small-incision cataract surgery, with the rest undergoing either phaco-emulsification surgery or extra-capsular cataract extraction (table 2). Most patients were blind (uncorrected visual acuity of 6/60 or worse) in the operative eye before surgery, and most had substantial improvements in visual acuity at the early postoperative examination and at the final follow-up examination (table 2).

The correlation for uncorrected visual acuity between early and late (final follow-up) examination results for all patients ($r_s$=0·59, p<0·0001; table 2) was similar to that for best-corrected visual acuity ($r_s$=0·60, p<0·0001). Correlation between early and late postoperative uncorrected visual acuity in the 550 people who underwent extra-capsular cataract extraction ($r_s$=0·49, p<0·0001) was lower than that for best-corrected visual acuity ($r_s$=0·61, p<0·0001).

We calculated the proportion of patients with uncorrected visual acuity of 6/18 or better minus the proportion with uncorrected visual acuity of 6/60 or worse (visual outcome) for each hospital, with results from the final follow-up assessment for all patients taken as the standard. Visual outcome from late (final follow-up) postoperative examination for all patients was highly correlated with that from early postoperative examination for all patients ($r_s$=0·74, p<0·0001; figure 1) and that from late postoperative examination of those who returned unprompted only ($r_s$=0·86, p<0·0001; figure 2). The correlation between visual outcome from late postoperative assessment of all patients and of those who returned unprompted only persisted when only hospitals with unprompted follow-up rates of less than 50% (n=17; $r_s$=0·71, p= 0·002) or less than 30% (n=10; $r_s$=0·63, p=0·05) were included in the analysis.

Table 3 shows the 25th, 50th, 75th, and 90th centiles for visual outcome, and the proportion of patients with good uncorrected visual acuity and poor uncorrected visual acuity (blindness), for the different assessment strategies. Among low-ranking hospitals at the early examination, the proportion with poor visual acuity was similar to that with good visual acuity, which means that the visual outcome (difference) was small or even negative

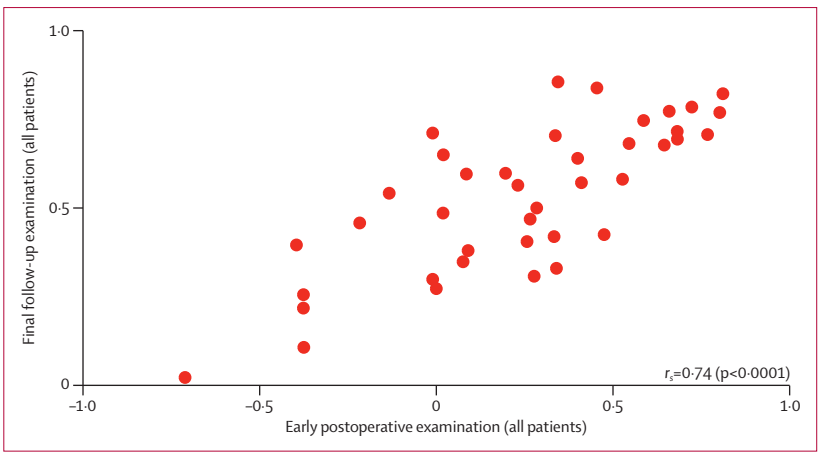


***Figure 1:*** **Hospital-level correlation between visual outcome from early postoperative examination for all patients and from final follow-up examination for all patients**
Early postoperative examinations took place 3 or fewer days after surgery. Final follow-up examinations took place 40 or more days after surgery. Visual outcome for each hospital was measured as the proportion of patients with uncorrected visual acuity of 6/18 or better minus the proportion with uncorrected visual acuity of 6/60 or worse.

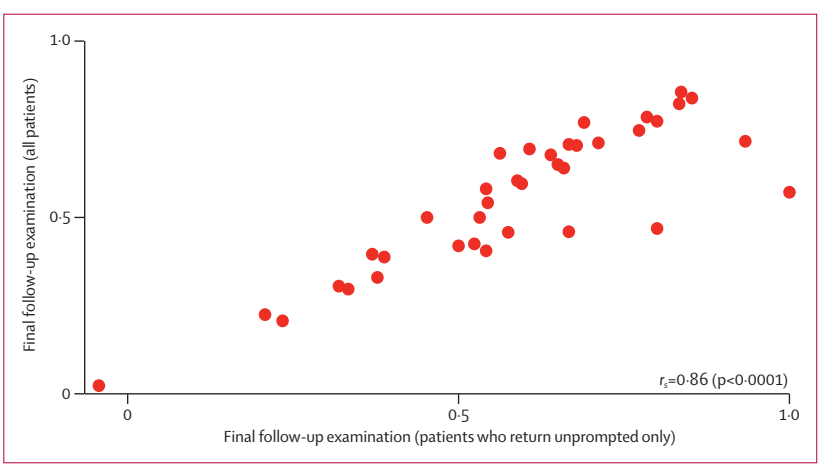


***Figure 2:*** **Hospital-level correlation between visual outcome from final follow-up examination for those who returned unprompted only and for all patients**
All examinations took place 40 or more days after surgery. Visual outcome for each hospital was measured as proportion of patients with uncorrected visual acuity of 6/18 or better minus the proportion with uncorrected visual acuity of 6/60 or worse.

| | 25th centile | 50th centile | 75th centile | 90th centile |
|---|---|---|---|---|
| **Early postoperative assessment of all patients** | | | | |
| Proportion with visual acuity of 6/18 or better | 31% | 43% | 60% | 75% |
| Proportion with visual acuity of 6/60 or worse | 36% | 15% | 5% | 3% |
| Visual outcome | 1% | 28% | 54% | 70% |
| **Late postoperative assessment of those who returned unprompted only*** | | | | |
| Proportion with visual acuity of 6/18 or better | 58% | 67% | 80% | 87% |
| Proportion with visual acuity of 6/60 or worse | 13% | 6% | 1% | 0% |
| Visual outcome | 50% | 60% | 71% | 84% |
| **Late postoperative assessment of all patients** | | | | |
| Proportion with visual acuity of 6/18 or better | 51% | 64% | 75% | 83% |
| Proportion with visual acuity of 6/60 or worse | 13% | 6% | 4% | 1% |
| Visual outcome | 39% | 57% | 71% | 78% |

Early postoperative assessment was done within 3 days after surgery; late postoperative assessment was done 40 or more days after surgery. The visual outcome was defined as the proportion of patients with visual acuity of 6/18 or better minus the proportion with visual acuity of 6/60 or worse at each hospital. *Those who returned unprompted are patients who returned for follow-up assessment after 40 or more days as instructed, without additional study-related prompting or inducement.

***Table 3:*** **Uncorrected visual acuity and visual outcome results by centile rank of hospital for three assessment strategies**

| | Classified by late follow-up assessment of all patients | | | Total |
|---|---|---|---|---|
| | High performance | Middle performance | Low performance | |
| **Classification by early assessment of all patients** | | | | |
| High performance | 7 | 3 | 0 | 10 |
| Middle performance | 2 | 14 | 4 | 20 |
| Low performance | 1 | 3 | 6 | 10 |
| Total | 10 | 20 | 10 | 40 |
| **Classification by late assessment of those who returned unprompted only** | | | | |
| High performance | 7 | 2 | 0 | 9 |
| Middle performance | 2 | 16 | 1 | 19 |
| Low performance | 0 | 1 | 8 | 9 |
| Total | 9 | 19 | 9 | 37* |

Hospitals are classified as high (top 25%), middle (middle 50%), and low (bottom 25%) on the basis of visual outcome (proportion of patients with uncorrected visual acuity ≥6/18 [good vision] minus the proportion with uncorrected visual acuity ≤6/60 [blind]) by use of two different assessment strategies: early (≤3 days postoperatively) uncorrected visual acuity for all patients and late (≥40 days postoperatively) for only those patients who returned to the clinic without additional study-related prompting or inducement. Both strategies are compared with the gold standard of visual outcome based on late (≥40 days postoperatively) uncorrected visual acuity for all patients. *Complete information on return to clinic (whether unprompted, only after a study intervention, or home examination required) was missing from two hospitals in Indonesia, and one hospital in China reported that no patients returned to the clinic unprompted; thus only 37 hospitals could be included in this analysis.

***Table 4:*** **Agreement in classification of hospitals by visual outcome for different assessment strategies**

(figure 1). Although early and late visual acuity are strongly correlated at both patient and hospital levels, substantial improvement in vision still occurred between the time of the early and late postoperative assessments.

We classified hospitals by visual outcome as high (top 25%), middle (middle 50%), and low (bottom 25%) performance, with classification by visual outcome based on late (≥40 days postoperatively) uncorrected visual acuity for all patients as the standard. Hospital classification based on this standard was the same as that based on early postoperative assessment in 27 of 40 hospitals (68%), and was the same as that based on late assessment of only those who returned unprompted in 31 of 37 hospitals (84%) (table 4). When only hospitals with unprompted follow-up rates of less than 50% were included in this comparison, 11 of 17 were in the same classification as the standard; the figure for hospitals with less than 30% follow-up was seven of ten.

Adjustment of visual outcome at early postoperative assessment for patient factors (age, sex, surgery type, and presence of surgical complications) and hospital characteristics (annual surgical volume, private *vs* public, and urban *vs* rural) did not further improve the hospital-level correlation between visual outcome at early assessment and late assessment for all patients (data not shown).

## Discussion

Training programmes are urgently needed to reduce the burden of unoperated cataract, and such programmes depend on the ability to assess quality of surgical outcomes. This ability in turn depends on easy-to-use and reliable metrics. Existing standards[18] are neither evidence-based nor validated in settings with low postoperative follow-up. Common practice has been to assess patients' visual acuity at their final follow-up visit, whenever this visit takes place. Since the time between surgery and the final visit can vary greatly between patients, acuity is recorded at different times in the ocular healing process, which increases variability in the outcome.

We have shown that two alternative strategies, early postoperative assessment of all patients and later assessment of only those who return unprompted to the clinic, provide a sufficiently valid measure of hospital performance to be useful to programme planners (panel). Although some hospitals might find it simpler in practice to measure visual acuity at the time of discharge on all patients, other centres where follow-up rates are not very low might prefer to assess later visual acuity on those who return without prompting, in view of the slightly greater accuracy of this method.

Classification with these measures might distinguish between hospitals capable of serving as training centres (high performance) and those in acute need of further training (low performance), and in most cases will be representative of a hospital's actual performance record based on final visual acuity for all patients (definitive data for which are not obtainable without the substantial, resource-intensive effort made in this research context). We chose to use an unconventional outcome measure to include the proportion of patients with both good and poor visual acuity after surgery, because of the equal importance of achieving good outcomes and avoiding bad ones. When only the proportion of patients with visual acuity of 6/18 or better was used as the outcome measure, our results were substantially the same (data not shown). In view of our results, we suggest that WHO

targets for cataract surgery be modified to include evidence-based measures, including specific targets for early assessment of visual acuity, potentially based on the data presented here.

Extra-capsular cataract extraction surgery, which uses a larger wound than newer surgical techniques and requires sutures, is generally expected to require more time for healing and visual recovery than more modern surgical methods. As our cohort shows, this technique is still widely practised in some regions. That early best-corrected visual acuity correlates equally well with later best-corrected vision in these cases as in those with more modern surgery in which smaller wounds are used (small-incision cataract surgery and phacoemulsification) is therefore encouraging. Refraction (measurement of the strength of corrective lenses needed for optimum visual acuity) improved the correlation between early and late visual acuity for extra-capsular cataract extraction. However, refraction did not improve the correlation between early and late visual acuity for our study cohort as a whole, the large majority of whom underwent other types of surgery. The automated devices needed for refraction are expensive, and the training needed to refract accurately without complex machinery is substantial.

Strengths of our study include the geographical breadth and range of participating centres with respect to various characteristics. High follow-up rates were achieved in all of the regions studied with the use of home visits, meaning that our estimates of final follow-up results for all patients are unlikely to be biased. Although a few hospitals had high rates of unprompted return for follow-up, the fact that overall only half of patients returned unprompted is consistent with previous work,[16] and emphasises the need for strategies to measure cataract visual outcomes in settings with poor follow-up.

Our study also has several limitations. Large studies typically standardise eye charts and testing distances between centres, often with charts designed for research.[27] We believed that allowing hospitals to use equipment similar to that used in their usual practice was important, although the vision measurement protocol was carefully standardised. Differences in charts might have increased variability in our measurements. Systematic audits of visual acuity and other data reported by hospitals were not practical to undertake. Thus, we cannot exclude the possibility of inaccurate or even deliberately falsified data, although we attempted to prevent such occurrences. Inaccuracies were minimised by onsite training and careful feedback to hospitals about issues encountered early in the study. The risk of data falsification was reduced by prohibiting surgeons from assessing the visual acuity of their own patients. Although we cannot rule out the possibility of exaggerated good results, only five of the 40 hospitals in the study achieved the WHO target of 80% late uncorrected visual acuity of 6/18 or better.

### *Panel:* Research in context

#### Systematic review

We searched PubMed on April 11, 2013, using the terms "cataract surgery" and "early", cross-indexed with "vision", "visual acuity", "outcome", and "result" for articles published in any language since Jan 1, 1970. Few previous studies have sought to examine the correlation between early and later postoperative visual acuity after cataract surgery. Investigators of a small study of four centres in Indonesia[22] (two of which were also participants in our study) reported that even with large-incision surgery, early assessment of postoperative visual acuity was representative of final vision. Osher and colleagues[24] noted uncorrected visual acuity of 6/12 or better at both 1 day and 5 weeks postoperatively in more than 95% (n=98 at 1 day, n=97 at 5 weeks) of 100 consecutive best-case scenario eyes that underwent phacoemulsification. Other reports[19,25,26] have suggested that refractive power measured as early as 30 min after modern cataract surgery is well correlated with later refractive power. However, only the study by Briesen and colleagues[26] was concerned with assessment of surgical quality in settings with poor follow-up, and the investigators did not assess the usefulness of early visual acuity measurement. Limburg and colleagues[16] reported a low correlation between early and late postoperative visual acuity after cataract surgery, perhaps because of differences in follow-up timing between centres, and possible data entry problems. Patients who return without additional prompting or encouragement to the clinic after cataract surgery might be expected to represent a biased sample (eg, they might be more likely to have symptomatic surgical complications that affect visual acuity than are patients who do not return). Although few studies have addressed this question, the investigators of the study in Indonesia[22] noted that the visual acuity of returning patients could be representative of the entire operated cohort.

#### Interpretation

Our results validate the use of early assessment of all patients and of later assessment of only those patients who return for follow-up to measure the quality of cataract surgery in settings where follow-up is poor. Which of these approaches hospitals will prefer will probably depend on specific circumstance: measuring visual acuity at hospital discharge might be logistically easier in some settings, although later assessment, as long as patient return rates are reasonable, might be somewhat more accurate.

Although outcomes from both early assessment of all patients and late assessment of only those who returned unprompted are well correlated with those from late assessment of all patients, these correlations are not perfect—a fact that must be understood and accepted by users of these data. We attempted to improve the hospital-level association between visual outcomes based on early assessment and on late assessment for all patients by adjusting for hospital and patient factors, but were unable to do so.

Finally, although the range of participating hospitals was wide, it does not represent a random sample of the institutions that do cataract surgery in developing countries. Many hospitals had ties with international development-focused non-governmental organisations, and doctors might have received additional training with support from these organisations. However, since only a small proportion of hospitals reached the WHO outcome standard, there is no clear evidence to suggest that ours was an unusually strong cohort of centres.

Despite its limitations, our study validates practical new strategies to assess the quality of cataract surgery, usable in settings where follow-up rates are low, extra-capsular

cataract extraction is still practised, and refraction is impractical. This ability to measure quality is an essential requirement for programmes designed to reduce the burden of the world's most common cause of blindness.

#### Contributors

NC contributed to the study design, search of the scientific literature, data analysis and interpretation, and writing of the report. XY contributed to the search of the scientific literature, study design, data analysis, and review and revision of the report. VL contributed to data collection and management, review of the scientific literature, data interpretation, and review and revision of report. AM contributed to the study design, data interpretation, and review and revision of the report. LJ and MEM contributed to data analysis and interpretation, and to review and revision of the report. AS, VC, SMK, CG, QV, NR, and MH contributed to data collection and management, and to review and revision of the report. JM-O contributed to the study design, and to review and revision of report.

#### PRECOG investigators (China)

Gao'an City People's Hospital: D Junping, H Hong. Xiushui County People's Hospital: D Yonglei, A Qiong. Xingguo County People's Hospital: D Yong, L Gang. Ningdu County People's Hospital: C Guohua, Z Ying. Wuning County People's Hospital: F Yuhua, L Xingxing. Wan'an County People's Hospital: L Xiaofei, W Wenbin. Yujiang County People's Hospital: Z Xuping. Poyang County People's Hospital: Z Ming, X Wei. Hengfeng County People's Hospital: Z Zhiqiang, H Ting. Yushan County People's Hospital: Z Jianxiang, Z Bin. Dianbai County People's Hospital: H Jialin, C Jiangbing. Dabu County People's Hospital: Z Yitian. Dongyuan County Traditional Chinese Medicine Hospital: Q Zhihua. Gaoyao City People's Hospital: X Honghui, F Wei. Jieyang City People's Hospital: X Zhongyu, L Liyong. Xinyi County Traditional Chinese Medicine Hospital: C Jian, L Lijun. Yangjiang Bright Eye Hospital: C Shaona, Y Tianman. Yangxi County People's Hospital: C Chunhui, Z Baoqiang.

#### PRECOG investigators (Eritrea)

Ministry of Health: G Mebrahtu, A Tesfa, M Zerom. Godaif Hospital: N Gebremicheal. Barentu Hospital: S Khanthamaly, H Gebregergis. Keren Hospital: S Mustafa.

#### PRECOG investigators (Ethiopia)

Duramie, Areka, and Wolkitie Hospitals: D Hailu (cataract surgeon), C Abity (cataract surgeon), A Gabre (cataract surgeon), D Almaz (integrated eye-care worker), P Shegitu (integrated eye-care worker), A Abera (integrated eye-care worker).

#### PRECOG investigators (Vietnam)

Eye Hospital of Ninh Binh Province: T N Quynh. Eye Centre of Ha Tinh Province: D K Dung. Eye Hospital of Nghe An Province: N H Le. Eye Hospital of Ho Chi Minh City: T T P Thu. *Centre of Social Disease Control* of Yen Bai Province: N X Phuong.

#### PRECOG investigators (Latin America)

Instituto de la Visión Montemorelos (Mexico): D Garcia, H Silva. Tabasco Instituto de la Visión (Mexico): C G Salazar, B Lopez. Instituto Regional de Oftalmología (Peru): J Huaman. Divino Niño (Peru): C Tasayco, A Lazo. Fundación Visión (Paraguay): M Zegarra, H Burga, J C Gines. Visualiza (Guatemala): G Pivaral, M Yee. Fundación Oftalmológica Del Valle (Ecuador): F Chiriboga.

#### PRECOG investigators (India)

Aravind Eye Hospital, Madurai: A Haripriya (consultant), N Srinivasan (coordinator), S Preetha (coordinator). Aravind Eye Hospital, Tirunelveli: C Shivkumar (consultant), D Subha (coordinator). Aravind Eye Hospital, Pondicherry: T Badrinath (consultant), P Thilagavathy (coordinator), P Jayanthi (coordinator). Aravind Eye Hospital, Coimbatore: V Prabhu (consultant), D Vivek (coordinator). Aravind Eye Hospital, Theni: D Datta (consultant), P Balasiva (coordinator).

#### PRECOG investigators (Indonesia)

Puskesmas Kopang, Puskesmas Tanjung: A Bani.

#### Conflicts of interest

We declare that we have no conflicts of interest.

#### Acknowledgments

Support was provided by the Fred Hollows Foundation (Sydney, NSW, Australia), ORBIS International (North and South Asia, Latin America/Caribbean, and Africa Offices; New York, NY, USA), Helen Keller International (New York, NY, USA), the International Agency for the Prevention of Blindness/VISION 2020 Latin American Regional Office (Miami, FL, USA), and Aravind Eye Care System (Madurai, India). NC is supported by a Thousand Man Plan programme grant from the Chinese Government. No payment was received by any external funder or outside source for the writing of this report.

#### References

1 Resnikoff S, Pascolini D, Etya'ale D, et al. Global data on visual impairment in the year 2002. *Bull World Health Organ* 2004; **82:** 844–51.

2 Powe NR, Schein OD, Gieser SC, et al. Synthesis of the literature on visual acuity and complications following cataract extraction with intraocular lens implantation. *Arch Ophthalmol* 1994; **112:** 239–52.

3 Prajna NV, Chandrakanth KS, Kim R, et al. The Madurai intraocular lens study—II: clinical outcomes. *Am J Ophthalmol* 1998; **125:** 14–25.

4 Zaidi FH, Corbett MC, Burton BJ, Bloom PA. Raising the benchmark for the 21st century—the 1000 cataract operations audit and survey: outcomes. *Br J Ophthalmol* 2007; **91:** 731–36.

5 Lundstrom M, Stenevi U, Thorburn W, Roos P. Catquest questionnaire for use in cataract surgery care: assessment of surgical outcomes. *J Cataract Refract Surg* 1998; **24:** 968–74.

6 He M, Xu J, Li S, Wu K, Munoz SR, Ellwein LB. Visual acuity and quality of life in patients with cataract in Doumen County, China. *Ophthalmology* 1999; **106:** 1609–15.

7 Zhao J, Sui R, Jia L, Fletcher AE, Ellwein LB. Visual acuity and quality of life outcomes in patients with cataract in Shun-yi County, China. *Am J Ophthalmol* 1998; **126:** 515–23.

8 Murthy GV, Ellwein LB, Gupta S, Tanikachalam K, Ray M, Dada VK. A population-based eye survey of older adults in a rural district of Rajasthan: II. Outcomes of cataract surgery. *Ophthalmology* 2001; **108:** 686–89.

9 Thulasiraj RD, Reddy A, Selvaraj S, Munoz SR, Ellwein LB. The Sivaganga eye survey: II. Outcomes of cataract surgery. *Ophthalmic Epidemiol* 2002; **9:** 313–24.

10 Nirmalan PK, Thulasiraj RD, Maneksha V et al. A population-based eye survey of older adults in Tirunelveli district of south India: blindness, cataract surgery and visual outcomes. *Br J Ophthalmol* 2002; **86:** 505–12.

11 Pokharel GP, Lelvaraj S, Ellwein LB. Visual functioning and quality of life outcomes among cataract operated and unoperated blind populations in Nepal. *Br J Ophthalmol* 1998; **82:** 606–10.

12 Zhao J, Ellwein LB, Cui H et al. Prevalence and outcomes of cataract surgery in rural China: the China nine-province survey. *Ophthalmology* 2010; **117:** 2120–28.

13 Bourne RR, Dineen BP, Ali SM, Huq DM, Johnson GJ. Outcomes of cataract surgery in Bangladesh: results from a population-based nationwide survey. *Br J Ophthlmol* 2003; **87:** 813–19.

14 Lam DS, Congdon NG, Rao SK, et al. Visual outcomes and astigmatism after sutureless, manual cataract extraction in rural China: study of cataract outcomes and up-take of services (SCOUTS) in the caring is hip project, report 1. *Arch Ophthalmol* 2007; **125:** 1539–44.

15 Huang W, Ye R, Liu B et al. Visual outcomes of cataract surgery performed by supervised novice surgeons during training in rural China. *Clin Experiment Ophthalmol* 2012; published online Oct 19. DOI:10.1111/ceo.12021.

16 Limburg H, Foster A, Gilbert C, Johnson GJ, Kyndt M, Myatt M. Routine monitoring of visual outcomes of cataract surgery. Part 2: results from 8 study centres. *Br J Ophthalmol* 2005; **89:** 50–52.

17 Huang G, Crooms R, Chen Q, Congdon N, He M. Compliance with follow-up after cataract surgery in rural China. *Ophthalmic Epidemiol* 2012; **19:** 67–73.

18 WHO. Informal consultation on analysis of blindness prevention outcomes. Geneva: World Health Organization, 1998.

19 Lyle WA, Jin GJ. Prospective evaluation of early visual and refractive effects with small clear corneal incision for cataract surgery. *J Cataract Refract Surg* 1996; **22:** 1456–60.

20 Briesen S, Ng EYJ, Roberts H. Validity of first post-operative day automated refraction following dense cataract extraction. *Clin Exp Optom* 2011; **94:** 187–192.

21 El-Maghraby A, Anwar M, el-Sayyad F, et al. Effect of incision size on early post-operative visual rehabilitation after cataract surgery and intraocular lens implantation. *J Cataract Refract Surg* 1993; **19:** 494–98.

22 Bani A, Wang D, Congdon N. Early assessment of visual acuity after cataract surgery in rural Indonesia. *Clin Experiment Ophthalmol* 2012; **40:** 155–61.

23 United States Social Security Administration. Titles II and XVI: basic disability evaluation guidelines. http://www.socialsecurity.gov/OP_Home/rulings/di/01/SSR82-53-di-01.html (accessed May 22, 2013).

24 Osher RH, Barros MG, Marques DM, Marques FF, Osher JM. Early uncorrected visual acuity as a measurement of the visual outcomes of contemporary cataract surgery. *J Cataract Refract Surg* 2004; **30:** 1917–20.

25 Olsen T. Predicting the refractive result after cataract surgery. *J Cataract Refract Surg* 1996; **22:** 575–78.

26 Briesen S, Ng EY, Roberts H. Validity of first post-operative day automated refraction following dense cataract surgery extraction. *Clin Exp Optom* 2011; **94:** 187–92.

27 Ferris FL 3rd, Kassoff A, Bresnick GH, Bailey I. New visual acuity charts for clinical research. *Am J Ophthalmol* 1982; **94:** 91–96.