**Cover page**

1. Title of the article:

Cost-minimisation analysis from a non-inferiority trial of Ready-Made versus Custom-Made Spectacles for school children in India

1. Running head:

Cost-savings to programmes using ready-made spectacles

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**Abstract**

Purpose

Uncorrected refractive error is the leading cause of visual impairment in children. Many countries, including India, implement school eye health programmes involving vision screening and provision of free spectacles. This is costly for governments/organisations involved. This analysis estimates potential cost-savings if ready-made spectacles, in addition to traditional custom-made spectacles, are available for dispensing in school eye health programmes.

Methods

An economic evaluation was conducted alongside a randomised controlled trial comparing spectacle wear of ready-made spectacles versus custom-made spectacles for children aged 11-15 years in schools in India. A cost-minimisation approach was used to calculate cost-savings of a ‘ready-made spectacles available’ programme compared with a ‘custom-made spectacles only’ school programme. The analysis was from a service provider perspective. Main outcomes: cost-saving per child needing spectacles and cost-saving per 1000 children screened.

Results

The prevalence of uncorrected refractive error was 2.23%, and 86% of children were eligible for ready-made spectacles. The cost per child needing spectacles in a custom-made spectacles only programme was USD$26.91, and in a ready-made spectacles available programme was $11.15, producing a 58.6% cost-saving per child needing spectacles of $15.76. Considering the total cost of the eye health programme, this equated to a 15.1% cost-saving per 1000 children screened of $361. Results were robust to multivariate sensitivity analyses.

Conclusion

Our study is the first to demonstrate the significant cost-saving potential of ready-made spectacles in school eye health programmes for uncorrected refractive error compared with custom-made spectacles alone. This has substantial economic benefits for national/international programmes.

**INTRODUCTION**

Uncorrected refractive error is the leading cause of visual impairment in children, affecting approximately 1% of children aged 5-15 years worldwide (i.e. 14 million)1. Visual impairment impacts negatively on educational opportunities and overall quality of life, and the global economic productivity loss from uncorrected refractive error for all ages is approximately 269 billion international dollars2. Correcting refractive error with spectacles is straightforward and highly cost-effective3. However, poor access and high prices create a barrier to many in low and middle-income countries. Many countries, including India, have introduced school-based programmes involving screening children and providing spectacles to address high levels of correctable visual impairment4. The provision of free spectacles improves the number of children who have and wear spectacles compared with providing a prescription alone5.

Most school eye health programmes provide free, custom-made spectacles in which each pair is made by a dispensing optician according to the prescription required. Provision of free spectacles is costly for the governments and organisations. Ready-made spectacles (i.e., where the prescription is the same spherical power lens for each eye, without cylinder correction for astigmatism) may reduce the cost, particularly where the prevalence of uncorrected refractive error in children is high. Low-cost, ‘off-the-shelf’, spectacles have been used successfully in some low-resource settings to correct simple refractive errors, i.e. where there is no astigmatism and minimal difference in spherical correction between the two eyes6-10. An inventory of ready-made spectacles in commonly prescribed powers can be stored at the schools for immediate dispensing, reducing manufacturing, labour and delivery costs of custom-made spectacles. Manufacturing costs are reduced because the lenses are pre-cut and they can be fitted into the frames without any additional equipment or time required of the dispensing optician. The time taken for multiple deliveries is also reduced as spectacles can be delivered in several batches and are available for immediate use. Whilst several studies have demonstrated equivalent effectiveness of ready-made versus custom-made spectacles in the school-aged population11-12, there have been no cost-analyses.

To our knowledge, school-based eye health programmes in India currently dispense custom-made spectacles only, regardless of severity or type of refractive error. The objective of this study was to estimate potential cost-savings if ready-made spectacles were also available for dispensing. The economic evaluation ran alongside, and used data from, a randomised controlled trial (RCT) with a non-inferiority design. The primary outcome was spectacle wear amongst children aged 11-15 years given ready-made spectacles compared with children dispensed custom-made spectacles in schools in urban and peri-urban areas surrounding Bangalore in Karnataka State, India.

**METHODS**

**The randomised controlled trial (RCT)**

Full details of the trial are published elsewhere13-14. Briefly, government schools surrounding Bangalore were stratified by location and size and were selected for inclusion by block randomisation. Children aged 11-15 years were offered vision screening by trained field workers. Those who failed screening (visual acuity (VA) <6/9 in each eye) were referred to study optometrists for further assessment. Children underwent objective and subjective refraction with assessment to ascertain whether they would be suitable for ready-made spectacles and eligible for the trial. The following inclusion criteria were used: (1) VA with full correction improved in the better seeing eye by two or more lines of VA, (2) the spherical equivalent (SE) (spherical correction + ½ the cylindrical correction) corrected the VA to not more than one line less than best-corrected VA with a full prescription in the better eye, (3) the difference between SE of the right and left eyes was not more than 1.0 diopter (D), (4) inter-pupillary distance (IPD) matched that of the ready-made spectacle frames available (i.e., 54-62 mm), and (5) spectacle frames were of acceptable size and fit. Exclusion criteria were other causes of visual impairment, custom made spectacles required and no parental consent. Ineligible children were prescribed custom-made spectacles or referred to Sankara Eye Hospital.

After recruitment, children were individually randomly assigned to ready-made spectacles or custom-made spectacles. Optometrists refracted the children on the school premises, and all children were given the same choice of frames. The custom-made spectacles were made at Sankara Eye Hospital by an optical technician, and all (i.e., custom-made and ready-made) spectacles were delivered to the school at the same time, within 2 weeks of refraction, to maintain masking. Children, teachers, and parents were masked to the allocation arm, as were the field workers and optometrist assessing the primary outcome. The primary outcome of the trial was the proportion of children wearing spectacles at unannounced visits 3-4 months after the intervention.

The RCT had a non-inferiority design and was powered to detect a non-inferiority margin of 10%. In the trial, 23,345 children were screened in 112 government schools. The prevalence of uncorrected refractive error was 2.2%. Of the 535 children who were screened, 460 (86%) failed screening and were eligible for ready-made spectacles, and were randomised. Overall, 362 of 460 children (78.7%) were identified at follow-up. 139 of 184 (75.5%) children in the ready-made spectacles arm and 131 of 178 (73.6%) in the custom-made spectacles arm were wearing their spectacles or had them at school at follow-up, with a risk difference between the two arms of 1.8% (95% confidence interval −7.1% to 10.8%). The results demonstrated that, at the 3- to 4-month follow-up, spectacle wear among children with ready-made spectacles was not inferior to those with custom-made.

**Cost analysis**

As non-inferiority was demonstrated, a cost-minimisation approach was used to compare costs of two school-based eye health programmes:

1. A ‘ready-made spectacles (RMS) available’ programme: all children screened with those requiring spectacles given ready-made spectacles if suitable, and custom-made if not.
2. A ‘custom-made spectacles (CMS) only’ programme: all children screened with all those requiring spectacles given custom-made spectacles.

The analysis was conducted from a service provider perspective. Costs were determined in Indian Rupees and converted into US dollars using the 2015 exchange rate (1USD = 65 Indian Rupees). All unit costs for equipment and spectacles, salaries and vehicle/fuel costs were obtained from Sankara Eye Hospital. Many parameters (Table 1) used in the cost analysis came directly from the trial data, and any relating to resource use that were not directly measured were estimated by the trial expert working group (including an optometrist). For personnel costs, it was assumed that there were 225 school days15 and 240 working days in a year16.

Each school-based eye health programme was analysed as comprising two stages.

*Stage 1:*

*Cost of screening*

This comprised field worker and driver, equipment and travel costs. Equipment costs were based on unit costs of a LogMAR chart, retinoscope, trial set and trial frame, plus their estimated workable longevity. Travel costs included vehicle rental and fuel to transport the field screeners from Sankara Eye Hospital to the schools.

*Cost of project management*

This comprised personnel (project manager) costs.

*Stage 2:*

*Cost of refraction*

This comprised personnel (optometrist) and equipment costs. An assumption was made that optometrists would refract fewer children per day in the ready-made spectacles available programme, as more time is required to ascertain eligibility for ready-made spectacles, to retrieve the correct ready-made spectacles from inventory and to fit them to the child.

*Cost of dispensing custom-made spectacles*

Personnel (optical technician) costs were included, alongside the proportion of spectacles that had to be custom-made in each programme.

*Cost of spectacles*

Unit costs of ready-made spectacles, low-prescription custom-made, astigmatic custom-made and high myopic custom-made spectacles were included, alongside proportions of each type of spectacle required per programme.

*Cost of transport/delivery of custom-made spectacles*

Transport costs to deliver the custom-made spectacles (from Sankara Eye Hospital where they were manufactured to the schools) comprised vehicle rental, fuel and driver costs. As the vehicle would have to wait at the school whilst the spectacles were fitted to the children, the more spectacles per school, the fewer schools delivered to per day. Additional transport costs to deliver ready-made spectacles to the schools was considered negligible as the inventory of spectacles would be delivered in batch by the screeners at time of screening.

*Cost of fitting custom-made spectacles*

Personnel (optometrist) costs were included, alongside the proportion of spectacles that had to be custom-made and fitted in each programme.

*Cost of training*

Trainer costs were included. An assumption was made that in the first year of a programme, three full days of training would be required, reducing to two days per year for the following three years. For the fifth year, a further three days of training were assumed to be required to refresh knowledge. This cycle would continue. In the trial, each training session could accommodate 7 optometrists.

**Cost-saving to programmes**

Figure 1 shows the methodology for cost calculations. Stage 1 costs (per child screened) and Stage 2 costs (per child needing spectacles) were calculated by summation of the above components for each programme, and then whole programme cost (per child screened with appropriate children provided with spectacles).

The cost difference between the programmes for Stage 2 gave the cost-savings per child needing spectacles. The cost difference between the two programmes for whole programme cost (Stage 1 and Stage 2) gave the cost-saving per child screened (where appropriate children were provided with spectacles) and henceforth cost-saving per 1000 children screened.

**Sensitivity analysis**

Univariate deterministic sensitivity analyses were conducted, varying personnel salaries, equipment costs, vehicle/fuel costs and spectacles costs by +/- 10%, and the number of school and working days per year by +/-30. Resource use parameters included the number of children optometrists could refract per day and could fit custom-made spectacles to per day, the number of custom-made spectacles optical technicians could manufacture per day, the life expectancy of equipment and days needed for training, duration of training cycle and the number of optometrists trained per training day were varied by +/-25%. The number of schools that the vehicles could visit per day to deliver custom-made spectacles (based on the average number of children requiring custom-made spectacles per school) was varied by +/- 1.

A Tornado diagram (Figure 2) was created to examine which of the parameters results were most sensitive to. These parameters were used to perform multivariate deterministic sensitivity analyses to give ‘best-case’ and ‘worst-case’ results. Of particular importance was determining whether the ready-made spectacles only programme was cost-saving using the ‘worst-case’ parameters.

Sensitivity analyses were conducted to examine results when varying the prevalence of uncorrected refractive error over the range: 1% - 70% and varying the proportion of children eligible for ready-made spectacles over the range 70% - 90%.

**Ethical Approval**

The trial and cost-analysis were approved by the Interventions and Research Ethics Committee of the London School of Hygiene & Tropical Medicine, and the institutional review board of Sankara Eye Hospital.

**RESULTS**

**Parameters used**

Parameters used in the cost-analysis, along with sources of data are shown in Table 1. All costs are in USD (costs originally in Indian Rupees were converted using the exchange rate in 2015).

**Base-case analysis**

A breakdown of the component costs for Stage 1 and Stage 2, as well as whole programme costs for the custom-made only and ready-made spectacles available programmes, and the overall cost-saving results are shown in Table 2.

The Stage 1 cost was $1.78 per child screened. The Stage 2 cost was $26.91 per child needing spectacles in the custom-made spectacles only programme and $11.15 in the ready-made spectacles available programme. This gave a cost-saving (for refraction and provision of spectacles) of 58.6%, or $15.76 per child needing spectacles. Using the RCT prevalence of uncorrected refractive error of 2.23%, the whole programme cost was $2.40 per child screened in the custom-made spectacles only programme and $2.03 in the ready-made spectacles available programme. This gave a cost-saving of 15.1% of the whole programme cost, or $361 per 1000 children screened.

**Sensitivity analysis**

Univariate deterministic sensitivity analysis was conducted (Figure 1). The results were most sensitive to the number of schools the vehicles were able to visit per day, due to the relatively high cost of vehicle rental and fuel. If the vehicles were able to deliver custom-made spectacles to more schools per day, the cost-saving was more conservative. In the base-case it was assumed that to deliver between 4 and 6 pairs of custom-made spectacles to each school, the vehicles were able to visit 2 schools per day. Reducing this to 1 school per day increased the cost-saving per child needing spectacles to $26.09, and increasing it to 3 schools per day reduced the cost-saving to $12.32.

The second most influential parameter was the proportion of children eligible for ready-made spectacles, with greater cost savings at higher levels. In the base-case, 460 of 535 children (86%) who required spectacles were eligible for ready-mades, directly from the RCT. Reducing this by 10% to 414 children (77%) reduced the cost-saving per child needing spectacles to $15.18, and increasing the proportion by 10% to 506 children (95%) increased the cost-saving to $26.67.

The cost of vehicle rental and fuel, of low-prescription custom-made spectacles and of ready-made spectacles changed the overall cost-saving within about +/-$1 per child needing spectacles.

Multivariate sensitivity analysis was conducted, varying the five most influential parameters simultaneously, to give ‘worst-case’ and ‘best-case’ scenarios (Table 3). In the ‘worst-case’, the programme with ready-made spectacles remains cost-saving, at $9.96 per child needing spectacles, or $228 per 1000 children screened. In the ‘best-case’, the cost-saving is $29.94 per child needing spectacles, or $686 per 1000 children screened.

**Scenario 1: Varying the proportion of children eligible for ready-made spectacles**

In the RCT, 86% of children requiring spectacles were eligible for ready-made spectacles. In the sensitivity analyses this was varied by +/-10% (relative), but a more informative range, deemed from expert opinion, would have been to explore 70-90% eligibility. Results are shown in table 4. The cost-saving using this range was from $14.68 to $26.36 per 100 child needing spectacles.

**Scenario 2: Varying the prevalence of uncorrected refractive error**

In the RCT, the prevalence of uncorrected refractive error was 2.23%. Using the range of 1-70% prevalence of uncorrected refractive error, the cost-saving per child needing spectacles does not change, but the cost-saving per 1000 children screened changes substantially. Results are shown in table 4. The cost-saving per 1000 children screened ranges from $158 (7.7% of whole programme cost) to $11,032 (53.5% of whole programme cost).

**DISCUSSION**

School eye health programmes for refractive error in children aged 11-15 years using ready-made spectacles are significantly cost-saving compared to programmes where custom-made spectacles only are available. Using data from our RCT in India, where the prevalence of uncorrected refractive error was 2.23%, the cost-saving was 58.6%, or $15.76 per child needing spectacles. For the total eye health programme, including the cost of screening and project management, the cost-saving was 15.1%, or $361 per 1000 children screened. Even in the “worst-case” scenario, the ready-made programme remains cost-saving.

Using ready-made spectacles in school-based screening programmes offers a strategy for governments and organisations that will likely save substantial resources. Generalising our result across India, where about 10.5% of the 1.339 billion population17 are in the 11-15 year age group18, using ready-made spectacles in universal school eye health programmes for children of this age would save over 50 million $USD. School eye health programmes for uncorrected refractive error will play a role in addressing the increased prevalence of myopia. Some estimates suggest that 34% of the global population will be myopic by 202019. The highest prevalence is in East Asia, where about 70% of children have myopia by age 15 years20. Our sensitivity analyses demonstrated that with higher prevalence of uncorrected refractive error, the cost-saving from using ready-made spectacles increased.

The largest determinants of cost in the custom-made only programmes are the cost of the spectacles compared with ready-made spectacles, and the cost of transporting and delivering them. It would be sound to assume that costs, distances and time constraints would be similar in other semi-urban locations in India and in other middle and low income countries. With more rural locations the transport and delivery cost of custom-made spectacles would likely be even higher. Having an inventory of ready-made spectacles for immediate dispensing at the schools would increase cost-savings.

Our study joins a growing body of evidence supporting the use of ready-made spectacles in resource poor settings, including the only other economic analysis of ready-made spectacles for an adult population in India21. Our study does have some limitations. We did not include many itemised costs related to manufacture and dispensing of the custom-made spectacles, such as the hospital buildings, utilities and overhead costs. Inclusion would have increased costs in a custom-made only programme and would have increased estimated cost-saving. We performed a financial rather than full economic analysis, not including opportunity costs such as the time that optometrists attending training sessions effectively ‘lost’ with respect to refracting and fitting spectacles. Personnel costs were not the main drivers in the difference in overall costs between the two programmes. We also did not include the cost of maintaining an inventory of ready-made spectacles. This may have reduced the overall cost-savings. However, it is important to note that the recent innovation of ‘clip-and-go’ spectacles would reduce the inventory required. Lenses of relevant powers for each eye are clipped into the spectacle frames. This would increase the proportion of children eligible for ready-made spectacles, as anisometropic, non-astigmatic prescriptions could be dispensed.

**CONCLUSIONS**

Our study is the first, to our knowledge, to demonstrate the significant cost-saving potential of using ready-made spectacles in school eye health programmes for uncorrected refractive error compared with custom-made spectacles alone. This can have substantial economic benefits for national and international programmes. Ready-made spectacles are currently not commonly used and anecdotally there has been some resistance amongst clinicians to use them. However, ‘clip-and-go’ spectacles, which can be assembled in schools, are becoming more widely available22. The results of this economic evaluation and the availability of high-quality ready-made spectacles supports wider adoption in school eye health programmes.

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**CONTRIBUTORS**

PM and CG conceived and oversaw the trial. PM and NM collected data. NM designed this cost-analysis with input from PM, KF and CG. NM analysed the data. NM wrote the initial draft of the manuscript. All authors provided input and approved the final manuscript for submission. NM and PM had full access to all the data in the study and take responsibility for the integrity of the data and the accuracy of the data analysis.

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**COMPETING INTERESTS**

None declared.

**PATIENT CONSENT**

Not required.

**ETHICS APPROVAL**

The trial and cost-analysis were approved by the Interventions and Research Ethics Committee of the London School of Hygiene & Tropical Medicine, and the institutional review board of Sankara Eye Hospital.

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| Table 1. Parameters used in cost-analysis with sources of data |
| Parameter | **Baseline value** | **Source** |
| % screened who required spectacles | 535/23345 (2.29%) | RCT |
| % requiring spectacles who were eligible for RM spectacles | 460/535 (85.98%) | RCT |
| % screened who were eligible for RM spectacles | 460/23345 (1.97%) | RCT |
| % screened requiring CM low-prescription spectacles for frame/IPD issues | 4/23345 (0.02%) | RCT |
| % screened requiring CM high-myopia spectacles | 51/23345 (0.22%) | RCT |
| % screened requiring CM astigmatic spectacles | 20/23345 (0.09%) | RCT |
| *Screening: number of children field worker can screen per day* Both CM spectacles only and RM spectacles available programmes | 100 | TEWG |
| *Cost: Personnel salaries (USD)* Field worker (monthly) Optometrist (monthly) Optical technician (monthly) Driver (monthly) Trainer (daily) | $175$350$225$280$169 | SEHSEHSEHSEHSEH |
| *Cost: Transport (USD)*  Vehicle rental and fuel (daily) | $125 | SEH |
| *Cost: Equipment (USD)* LogMAR chart Retinoscope Trial set Trial frame | $1340$505$150$70 | SEH (Keeler)SEH (Keeler)SEH (Keeler)SEH (Keeler) |
| *Cost: Spectacles (USD)* Low prescription CM spectacles High myopia CM spectacles Astigmatism CM spectacles RM spectacles | $10$15$20$5 | SEHSEHSEHSEH (Essilor) |
| *Refraction: number of children optometrist can refract per day* CM spectacles only programme RM spectacles available programme | 2015 | TEWGTEWG |
| *Life expectancy of equipment (years)* LogMAR chart Retinoscope Trial set Trial frame | 3323 | TEWGTEWGTEWGTEWG |
| *Training* No. of days in year 1 of each training cycle No. of days in years 2,3,4 of each training cycle No. of years in each training cycle No. of optometrist trainees in each session | 3247 | TEWGTEWGTEWGRCT |
| *Dispensing CM spectacles* No. of spectacles optical technician can make per day | 10 | TEWG |
| *Delivery CM spectacles: schools driver/vehicle can visit per day (n)* >6 pairs of spectacles per school 4 to ≤6 pairs of spectacles per school 2 to ≤4 pairs of spectacles per school ≤2 pairs of spectacles per school | 1234 | TEWGTEWGTEWGTEWG |
| *Fitting CM spectacles*  No. of children optometrist can fit per day | 30 | TEWG |
| Proportion of schools with children eligible for RM spectacles | 79/112 (70.54%) | RCT |
| Mean number of children eligible for RM spectacles per school | 460/79 (5.82) | RCT |
| Proportion of schools with children not eligible for RM spectacles and requiring CM spectacles only | 33/112 (29.46%) | RCT |
| Mean number of children ineligible for RM spectacles and requiring CM spectacles per school | 75/33 (2.27) | RCT |
| No. of school days per year | 225 | [15] |
| No. of working days per year | 240 | [16] |

**Abbreviations: RM = ready-made; CM=custom-made; RCT = randomized controlled trial; SEH = Sankara Eye Hospital; TEWG = Trial expert working group**

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| Table 2. Base-case analysis results showing cost-saving for the ready-made spectacles available school programme versus custom-made only spectacles school programme (2015 USD) |
|  | **Cost per child (USD)** |
| Cost category | **Custom-made only programme** | **Ready-made available programme**  |  |
| Stage 1: |  |  |  |
| Screening | $1.51 | $1.51 |  |
| Project management | $0.27 | $0.27 |  |
| Total Stage 1 cost per child screened | $1.78 | $1.78 |  |
| Stage 2: |  |  |  |
| Refraction | $1.09 | $1.46 |  |
| Dispensing custom-made spectacles | $1.13 | $0.16 |  |
| Spectacles | $10.85 | $6.55 |  |
| Transport/delivery of custom-made spectacles | $13.21 | $2.88 |  |
| Fitting custom-made spectacles | $0.62 | $0.09 |  |
| Training | $0.01 | $0.02 |  |
| Total Stage 2 cost per child needing spectacles | $26.91 | $11.15 |  |
| Cost-saving per child needing spectacles |  |  | **$15.75** |
|  |  |  |  |
| Whole programme cost: |  |
| Stage 1 (n=23,345 children screened) | $41554.10 | $41554.10 |  |
| Stage 2 (n=535 children needing spectacles) | $14396.85 | $5959.90 |  |
| Total cost (n=23,345 children) | $55950.95 | $47514 |  |
| Total cost per child screened | $2.40 | $2.04 |  |
| Cost-saving per 1000 children screened |  |  | **$361.17** |

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| Table 3. Multivariate deterministic sensitivity analysis |
| Parameter varied | **“Worst-case”** | **“Best-case”** |
| No. of schools driver/vehicle can visit per day to deliver 4 to ≤6 pairs of custom-made spectacles | High | Low |
| Number of children eligible for ready-made spectacles | Low | High |
| Cost of vehicle rental and fuel per day | Low | High |
| Cost of low prescription custom-made spectacles | Low | High |
| Cost of ready-made spectacles | High | Low |
| Cost-saving per child needing spectacles (USD) | **$9.96** | **$29.94** |
| Cost-saving per 1000 children screened (USD) | **$228.25** | **$686.04** |

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| Table 4. Results of scenario analyses when varying the proportion of children eligible for ready-made spectacles, and prevalence of uncorrected refractive error in children aged 11-15 years |
|  | **Cost-saving for ready-made spectacles available programme versus custom-made spectacles only programme** |
|  | **Per child needing spectacles****(USD)** | **Per 1000 children screened** **(USD)** |
| Percentage of children needing spectacles eligible for ready-made spectacles |
| Base-case 86% | $15.76 | $361.17 |
| 70% | $14.68 | $336.46 |
| 90% | $26.36 | $604.15 |
| Prevalence of uncorrected refractive error |
| Base-case 2.23% | $15.76 | $361.17 |
| 1% | $15.76 | $157.60 |
| 20% | $15.76 | $3151.94 |
| 50% | $15.76 | $7879.86 |
| 70%a | $15.76 | $11031.80 |

Cost saving = cost for custom-made spectacles only programme – cost for ready-made spectacles available programme

**Figure 1. Flow diagram outlining cost variables and methods for cost calculations in custom-made spectacles only programme and in ready-made spectacles available programme**

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**Abbreviations: CMS = custom-made spectacles; RMS = ready-made spectacles; URE = uncorrected refractive error**

**Figure 2: Univariate deterministic sensitivity analysis: Cost saving per child needing spectacles**

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