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Valuing condition specific health states using simulation contact lenses

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Key Words: Health state valuation, Quality of Life, General Population, Age-related macular degeneration

Abstract:

OBJECTIVE: This paper reports on a study that used contact lenses to simulate the effects of a visual impairment caused by Age Related Macular Degeneration (ARMD). The aim was to examine the feasibility of using this method of simulation and to compare the results from this experiment with those obtained from ARMD patients (n=209) using generic preference-based measures (HUI3 and EQ-5D) and patient time trade-off TTO.

METHODS: Utility values were elicited from healthy participants (n=108) by TTO for three ARMD states simulated using contact lenses.

RESULTS: A significant relationship was found between visual acuity and TTO values elicited from members of the general population (n=108). It was stronger than that found for HUI3, EQ-5D and own TTO values from patients (n=209). General population values informed by the experience of simulation were found to be significantly different to values from patient TTO and generic preference-based measures for the same level of visual impairment. Socio-demographic characteristics did not significantly affect results, although baseline TTO utility values were positively associated with TTO values for simulated states.

CONCLUSIONS: ARMD has a major impact on general population TTO health state values. Differences across four visual health states appear larger than those found for a generic preference-based measures and patient TTO values. For conditions that are difficult to describe and imagine, simulation methods may offer an important method for obtaining better informed general population preferences.

Abbreviations:

UK	United Kingdom
ARMD	Age-related macular degeneration
TTO	Time trade off
HRQoL	Health related quality of life
VA	Visual acuity
CS	Contrast sensitivity
LogMAR	Logarithm of minimum angle of resolution

Introduction:

Agencies around the world responsible for informing policy surrounding the reimbursement of new technologies have recommended the use of general population samples for valuing health states for use in economic evaluation. An important concern in the valuation of hypothetical health states by members of the general public is the extent to which participants are able to imagine the state with any degree of accuracy [1,2] and this has been given as one explanation for the divergence between general population values and those from patients[3]. Some advocates of general population values have emphasized the need to elicit *informed* public values[4]. This paper is concerned with the use of simulation to inform participants about the health states to be valued.

Valuation surveys typically involve presenting participants with verbal descriptions of a set of health states. In many cases these are generic health state descriptions, such as those defined by the EQ-5D, HUI3 or SF-6D [5,6,7]. These descriptions tend to be quite abstract and could fail to provide details about the condition that the participant would have regarded as important in making their valuations. For this reason, researchers have developed more sophisticated approaches to describing the states, such as the use of audiotapes for impaired speech[8]; or videos of people with disabilities[9]. Whilst these methods may be helpful, they do not actually allow the participant to experience the state for themselves.

This paper presents a study that helps participants experience health states for the condition of Age Related Macular Degeneration (ARMD) using contact lenses to simulate visual impairment. The values from this experiment are then compared to those obtained from patients' TTO and generic preference-based measures.

Background:

ARMD is the leading cause of incurable blindness and visual impairment in industrialised countries[10]. The main effect of ARMD is to reduce the ability to engage in everyday activities that require clear central vision (such as reading, writing, recognising people, driving, watching TV, etc.). Peripheral vision remains unaffected so the disease does not lead to total blindness. ARMD is a common condition that has been shown to impact significantly on a person's Health Related Quality of Life (HRQoL)[11, 12].

ARMD is monitored by changes in visual acuity (VA). In a previous study, health state values were obtained for VA states from 209 patients with unilateral or bilateral ARMD[12]. Patients underwent visual tests (near and distant VA, contrast sensitivity (CS)) and completed health status questionnaires including the VF-14 (Visual Function questionnaire) and three generic preference-based measures (HUI3, EQ-5D, SF-6D) and time trade-off for their own current state. The VF-14, HUI3 and TTO were found to be significantly related to VA group ($P<0.05$). This study concluded that the HUI3 was the generic instrument of choice for use in economic evaluation where general population values are required. Neither the EQ-5D nor the SF-6D captured the impact of visual impairment in the patient population. The HUI3 results from this work were subsequently used to populate an economic model[13].

While the HUI3 was the best of the preference-based measures for reflecting the impact of visual impairment on health state values, it is a *generic* health state descriptive system. There is a concern that its generic descriptive system may miss important features of visual impairment caused by ARMD and its consequences. The main effect of ARMD is to reduce the ability of the individual to engage in everyday activities that require clear central vision. The HUI3 has one dimension for visual impairment but not the specific effects of ARMD. The general population with a greater awareness of the vision impairment caused by ARMD may give the state a different value to that implied by the HUI3.

Alternatively we could use patient's own TTO, since these should better reflect the impact of the condition. These TTO values had a significant relationship to VA in the patient sample[11,12]. However, most reimbursement agencies around the world prefer general population values. TTO values obtained directly from patients have been found to be very different to values generated by generic preference-based measures valued by members of the general population, such as the HUI3. Of course the difference between TTO and HUI3 values does not simply reflect the source of values, but also the fact that they are obtained using different techniques of valuation (i.e. TTO and Standard Gamble (SG) respectively). The divergence may also arise from the fact that the HUI3 does not reflect the impact of ARMD on health related quality of life. This study aims to examine the extent to which general population TTO values for specific ARMD states differ from the EQ-5D, HUI3 and TTO values obtained from patients.

In a study of retinopathy states Aballéa and Tsuchiya[14] used large plastic spectacles to simulate visual impairment. However, ARMD affects central vision and in order to simulate this condition, spectacles would need to have an obstruction in the middle of the glass (rather than a general blurring of the lens used to reproduce retinopathy). Participants wearing such spectacles would be able to largely overcome the effectiveness of the obstruction by moving their eyes or head. Contact lenses provide a far better method for reproducing ARMD as it is not possible to look around the central opacity on the contact lenses. The innovative use of custom-made contact lenses provides an opportunity for non-patient subjects to gain a personal experience of having ARMD.

Methods:

Sample size and recruitment

One of the primary objectives of this study was to obtain estimates for the mean utility values of three visual states representing different severities of ARMD. The relevant sample size for such a task is determined by the required degree of precision. For this calculation it was assumed that a two sided 95% confidence interval of 0.05 to 0.1 either side of the mean estimate would be sufficient. Given a standard deviation in the TTO valuation of EQ-5D score of approximately 0.25[5], then a sample size of 75 would be sufficient to achieve a confidence interval either side of the estimate of 0.057. To allow for an attrition rate of 25%, we aimed to recruit 100 subjects to the study.

Ethical approval for this study was obtained through the School of Health and Related Research Ethics Committee. To recruit a representative sample of the general population of 100, a random sample of 2000 addresses was selected across six postcode areas around Sheffield. Recruits were sent a letter detailing the study, information sheet and pre-qualification questionnaire. Recruits were excluded if they had known ocular pathology, high myopia (>5.00 dioptres spherical equivalent), recent increase in floaters, or any of a number of high risk medical complaints. A further sample of subjects was recruited via “word-of-mouth” from participants who had completed the study. Subjects recruited by this method were household members, friends or work colleagues of study subjects.

ARMD health states

The ARMD states were produced by a unique method of simulating the visual impairment associated with ARMD through the use of custom made contact lenses. The contact lenses incorporated a central opacity, the size of which determines the degree of visual impairment and the size of central scotoma perceived by the wearer. Custom-made plano contact lenses (CIBA Vision, Southampton, UK) with three different sizes of central opaque black dots were used to approximately reproduce three vision states: VA Log-MAR scores of 0.6 (20/80) (reading limit), 1.0 (20/200) (legal blindness) and 1.4 (20/500) (state to which patients with untreated ARMD deteriorate). The lenses were sterile, single use, soft lens types, with a diameter of 14.5 mm and base curve radius of 8.1 mm. A pilot trial of the contact lenses demonstrated the reproducibility (both between subjects and when repeated by the same subject) of the simulated visual states and tolerability of the lenses. The lenses were labelled 1 to 3, where lens one simulated the mildest VA impairment and 3 the most severe. The three sets of lenses were used in random order for the simulations to minimise any order effects.

Prior to inserting the lenses in both eyes of each recruit, an optometrist instilled pilocarpine eye drops into each eye. The purpose was to ensure standardisation of the effect of the contact lenses by constricting the pupil. Participants were able to familiarise themselves with the effect of each set of lenses on their vision by undertaking five activities of daily living: walking around the room, reading a newspaper, reading a large print book, reading a label on a food tin and watching television. They were questioned about their ability to perform these activities and complete a health status questionnaire prior to being asked to value the state.

Valuation technique

TTO was used to assess participant's valuation of their own state (prior to the lens instillation) and the three ARMD states simulated by the contact lenses. The variant of TTO used in this study was developed by the MVH group at University of York to value the EQ-5D[15].

Measurements

Baseline assessments (i.e. prior to having contact lenses inserted) included measurements of visual acuity (VA) and contrast sensitivity (CS). LogMAR best corrected distance VA in right and left eyes was measured using the ETDRS chart using the letter-by-letter scoring method. VA results are presented using the LogMAR scale. Contrast sensitivity was measured binocularly with a Pelli-Robson chart (in log units) by the triplet scoring method at 1-metre distance. Recruits who were unable to score at all on CS were assigned the minimum value on the test (0 log units). If any participant normally wore glasses to correct their vision, they continued to do so for baseline assessment and the simulations with the contact lenses in place.

Participants completed the interviewer administered HUI3 questionnaire at baseline. In addition participants completed selected items from the VF-14 and a TTO of their current health state. Five questions were selected from the VF-14 to be used in this study[16]. These related specifically to the activities of daily living which the subjects were asked to perform for each set of lenses. These items were chosen as it was possible to reproduce the activities in a standard controlled environment in the simulation.

Following the insertion of each lens, participants undertook the 5 activities of daily living and completed the five VF-14 items, HUI3 and TTO of the new simulated health state.

Analysis:

The data used in the analysis have been adjusted for two potential confounders. First the effect of the lenses was removed by excluding all baseline observations (i.e. those values obtained prior to inserting a lens). Each visual state will be affected in a similar manner by the lens (and in some cases the pilocarpine); therefore any differences between states should be due to the impact on visual acuity. The second was a possible ordering effect, such as valuing the mild lens first may give it and subsequent states a lower value than valuing one of the more severe states first. Though the order of the three sets of lenses was randomised, the proportion of patients experiencing the lenses in each order was not exactly equal so it was also necessary to remove the ordering effect in the analysis by defining dummy variables that represent each possible ordering for the lenses. These adjusted TTO values were used in the main results presented in this paper.

The coefficients from the regression model indicate the average differences in utilities between participants receiving lenses in order 1, 2, 3 and other possible combinations of ordering. For example, prior to adjusting for ordering, on average participants receiving lenses in order 1, 3, 2 were 0.0236 utilities lower than those who received it in order 1, 2, 3, so their TTO scores were adjusted upwards by a value of 0.0236 (Table 1).

Mean TTO values were estimated for four health states defined using distant VA (better seeing eye) on the LogMAR scale. The four states were: > 1.31 (>20/400), 0.61 to 1.30 (20/80 to 20/400), 0.31 to 0.60 (20/40 to 20/80) and ≤ 0.30 (≤20/40). Univariate regression analyses were performed to investigate the strength of the relationship between VA and the TTO values and to examine whether demographic or clinical characteristics or baseline TTO utility values influenced TTO values (specifically: gender, age, marital status, employment (Y/N), education, method of recruitment into the study; and whether long standing illness existed and baseline TTO values).

TTO values for the simulated ARMD states were compared to HUI3 and TTO values obtained from a previous ARMD patients' study[13]. These patients completed, among other measures, the HUI3, EQ-5D and TTO and had their VA and CS tested. Comparisons were made between the mean health state values produced by the participants in the simulation study and the values obtained from patients using the three measures. The differences were further examined by regression analysis fitting VA to each measure.

A p-value of ≤ 0.05 was considered statistically significant for all statistical tests. The statistical computer package STATA version 9.2 was used for all statistical analyses (StataCorp, 2007[17]).

Results:

Participants

A random sample of 2000 people yielded a response from only 77 participants, of which 42 participants attended to complete the interviews. In order to achieve the required sample size, a further 66 were recruited by word of mouth from household members and colleagues of study participants. The background characteristics of the sample reflect this. The mean age of the 108 participants was 32 years (SD=12.5 years), with the oldest being 68 years. Sixty-six percent were in employment at the time of the study and 28% had a university degree. There were 25 participants (23%) with a long standing illness. Overall participants were in good health, with a mean TTO value at baseline of 0.960 (SD = 0.109 range 0.30 to 1) and a mean HUI3 utility at baseline of 0.934 (SD = 0.105 range 0.33 to 1).

One hundred and seven (99%) had best-seeing eye VA of <0.30 LogMAR (<20/40), with those needing glasses being asked to wear them for the test. One person had a VA of between 0.31 and 0.60 (actual value 0.5) (20/40 and 20/80; actual value 20/63). The majority of participants had excellent vision, as best corrected VA was measured (i.e. corrected with own glasses at baseline). This is also reflected in the responses to the five VF-14 items, where all participants had no problems with the activities. One person had moderate difficulty reading a newspaper or book, and seven had either a little or moderate difficulty reading small print.

Four of the 108 did not proceed to wearing all three sets of custom-made contact lenses. For three recruits, the optometrist was unable to instill the contact lenses due to small eyes, and another withdrew during testing due to a headache caused by the pilocarpine drops.

An OLS linear regression showed that ordering did have a significant impact on utility values ($F_{6,306} = 3.44$, $p = 0.003$). Therefore, adjustments were made for the ordering effect using the results from the regression analysis. The results for the six possible orderings of the lenses support the hypothesis that participants who valued the milder state first tended to give lower values overall. It can be seen in Table 1 that orderings without lens 1 first (i.e. the mildest) have positive coefficients compared to a baseline of ordering 1, 2, 3 (Table 1).

Table 1: Adjustments for ordering effect made to TTO values (N = 313)

Ordering of lenses	Adjustments
Order 1: 1,2,3 (N = 48)	
Order 2: 1,3,2 (N = 63)	-0.0236
Order 3: 2,1,3 (N = 42)	0.1406
Order 4: 2,3,1 (N = 63)	0.0088
Order 5: 3,2,1 (N = 66)	0.1955
Order 6: 3,1,2 (N = 27)	0.1817
Order 7: did not receive all three lenses (N = 4)	0.0002

The distribution of the 104 participants across the three lenses and the four VA best-seeing eye groups can be seen in Table 2. A total of 41 participants achieved VA of ≤ 0.30 (≤20/40) despite wearing the lenses. This may be attributable to slippage of the lens, allowing the central opacity to move away from the visual axis. This group is important for estimating the impact of VA on TTO.

For each lens there was a distribution across the VA groups, and the distributions varied in the expected direction with VA. For example, the most severe lens had more participants in the poor VA group. This variation of VA score within each lens type may also have arisen from contact lens slippage (which allowed the visual axis to become uncovered due to eye movement) or incomplete pilocarpine effect, which would have allowed the natural accommodation of the eye to occur.

Table 2 presents mean TTO values by lens and VA group (with 95% confidence intervals) after adjusting for ordering of lenses by VA groups in the better-seeing eye. The overall decline in mean TTO scores by VA group is significant ($P<0.001$). The difference in mean values between the lowest and highest group is 0.392. The difference in mean value between the groups is not the same, and this is partly because the groups are not equal in size.

Table 2: Mean TTO scores (adjusted for ordering) with 95% CI by lens type and visual acuity group (Best seeing eye)

VA LogMAR group	Lens 1	Lens 2	Lens 3	Overall
≥ 1.31 (≥ 20/400)	N = 0	N = 0	N = 56 0.314 (0.217 to 0.410)	N = 56 0.314 (0.217 to 0.410)
0.61 to 1.30 (20/80 to 20/400)	N = 46 0.653 (0.563 to 0.743)	N = 41 0.486 (0.389 to 0.583)	N = 38 0.366 (0.246 to 0.486)	N = 125 0.511 (0.449 to 0.573)
0.31 to 0.60 (20/40 to 20/80)	N = 40 0.731 (0.662 to 0.801)	N = 40 0.649 (0.561 to 0.736)	N = 9 0.603 (0.295 to 0.912)	N = 89 0.681 (0.623 to 0.740)
≤ 0.30 (≤ 20/40)	N = 18 0.778 (0.706 to 0.851)	N = 23 0.649 (0.531 to 0.767)	N = 0	N = 41 0.706 (0.606 to 0.805)
Total	N = 104 0.705 (0.654 to 0.755)	N = 104 0.585 (0.283 to 0.433)	N = 103 0.358 (0.283 to 0.433)	N = 311 0.550 (0.526 to 0.644)

Score by VF-14 item response

Table 3 presents the mean utility values, adjusted for lens ordering, from participants' responses to the five questions taken from the VF-14. For all five VF-14 questions the average responder's utility values decreased the more they were unable to undertake an everyday activity. The overall decline in mean TTO scores by VF-14 item response was significant (P<0.001).

Table 3: Mean TTO scores (adjusted for ordering) by VF-14 question response (N = 311)

	Reading small print	**Reading a newspaper or book**	**Reading large print books**	**Recognising people**	**Watching television**
No	N = 13 0.786 (0.664 to 0.908)	N = 11 0.835 (0.700 to 0.971)	N = 34 0.696 (0.595 to 0.7968)	N = 92 0.705 (0.657 to 0.752)	N = 32 0.740 (0.669 to 0.811)
Yes with a little difficulty	N = 56 0.699 (0.627 to 0.770)	N = 49 0.719 (0.650 to 0.788)	N = 80 0.682 (0.628 to 0.737)	N = 88 0.645 (0.590 to 0.700)	N = 83 0.694 (0.643 to 0.745)
Yes with a moderate amount of difficulty	N = 56 0.628 (0.560 to 0.697)	N = 70 0.626 (0.562 to 0.689)	N = 57 0.671 (0.604 to 0.738)	N = 28 0.513 (0.354 to 0.672)	N = 65 0.589 (0.510 to 0.667)
Yes with a great deal of difficulty	N = 55 0.595 (0.521 to 0.669)	N = 47 0.607 (0.527 to 0.688)	N = 39 0.447 (0.344 to 0.549)	N = 18 0.432 (0.282 to 0.582)	N = 43 0.539 (0.448 to 0.629(
Yes and am unable to do	N = 131	N = 134	N = 101	N = 85	N = 88

	0.410 (0.342 to 0.478)	0.405 (0.339 to 0.471)	0.367 (0.290 to 0.444)	0.321 (0.238 to 0.404)	0.321 (0.237 to 0.405)
F-test (p-value)	11.47 (< 0.001)	13.40 (< 0.001)	16.46 (< 0.001)	19.49 (< 0.001)	18.98 (< 0.001)

Background characteristics

Socio-demographic characteristics and long standing illness were not significantly related to TTO values, after adjusting for visual acuity (Table 4). The mode of recruitment, i.e. postal or word of mouth represented by a dummy variable, was also not statistically significantly different. However, there was a significant relationship between baseline TTO and subsequent TTO values. Participants who gave a baseline TTO below one tended to give a lower value to simulated ARMD states (p=0.01).

Table 4: ANOVA results for demographic characteristics after adjusting for visual acuity (distant)

	Regression coefficient (standard error)	**F-test (P-value)**
Gender:		
Male	Baseline group	0.73 (0.394)
Female	-0.03 (0.036)	
Age	-0.0003 (0.0015)	0.04 (0.844)
Marital Status:		
Single	Baseline group	1.30 (0.275)
Married	0.07 (0.042)	
Separated	0.14 (0.131)	
Divorced	-0.01 (0.066)	
Employment:		
Yes	Baseline group	1.77 (0.184)
No	-0.05 (0.037)	
Education:		
O level/GCSE	Baseline group	0.91 (0.459)
A level	-0.003 (0.050)	
Diploma	-0.046 (0.074)	
Degree	-0.046 (0.049)	
Masters and above	0.124 (0.095)	
Method of recruitment:		
Post	Baseline group	1.17 (0.281)
Word of mouth	-0.04 (0.036)	
Long standing illness:		
Yes	Baseline group	0.58 (0.447)
No	0.03 (0.042)	
Baseline utility:		

Less than one	-0.135 (0.052)	2.59 (0.01)

Comparison with patient survey

Mean TTO values by VA group from the general population sample for simulated ARMD states were compared to those obtained from the patient survey using TTO, HUI3 and EQ-5D (Table 5). The differences in mean TTO values for simulated states and patient HUI3 were significant for three of the four VA groups. Differences were also significant between TTO values for simulated states and patient own TTO valuations and EQ-5D in two VA groups. An overall test of the differences between the four sources of values was performed by modeling dummy variables for patients' own TTO, HUI3 and EQ-5D (with simulated TTO as the baseline) alongside VA group in a regression model. The patient TTO and HUI3 dummies were found to be significant.

Table 5: Comparison of TTO values for ARMD simulated states (adjusted for ordering) compared to patient data HUI3 and TTO values by VA group with 95% CI by visual acuity group (Best seeing eye)

VA LogMAR group	TTO values for ARMD simulated states	TTO from ARMD patients[a]	HUI3 from ARMD patients[a]	EQ-5D from ARMD patients[a]
> 1.31 (≥ 20/400)	N = 56 0.314 (0.217 to 0.410)	N=74 0.613*** (0.542 to 0.680)	N=76 0.233 (0.180 to 0.287)	N=75 0.695*** (0.647 to 0.743)
0.61 to 1.30 (20/80 to 20/400)	N = 125 0.511 (0.449 to 0.573)	N=58 0.665** (0.588 to 0.741)	N=58 0.355** (0.289 to 0.420)	N=58 0.746*** (0.693 to 0.799)
0.31 to 0.60 (20/40 to 20/80)	N = 89 0.681 (0.623 to 0.740)	N=39 0.688 (0.573 to 0.763)	N=40 0.251*** (0.298 to 0.457)	N=41 0.697 (o.635 to 0.759)
≤ 0.30 (≤ 20/40)	N = 41 0.706 (0.606 to 0.805)	N=32 0.757 (0.655 to 0.858)	N=32 0.498*** (0.376 to 0.620)	N=33 0.746 (0.6528 to 0.839)

Total	N = 311 0.550 (0.511 to 0.589)	N=203 0.665 (0.623 to 0.707)	N=206 0.337 (0.298 to 0.375)	N=207 0.718 (0.688 to 0.748)

Source: [a] Espallargues et al, 2005[12].

Note: Significance of difference with TTO values for simulated ARMD states: * at 0.05 level, ** at 0.001 and *** at 0.001.

Differences between the TTO values for simulated ARMD states and the three sources of utility values from patients can be better seen by modeling the relationship by regression. A number of possible relationships were explored between simulated TTO and VA, these included linear, logarithmic, inverse, quadratic and cubic. Of the relationships explored, the best was the linear relationship between TTO and VA (adjusted $R^2 = 0.171$). The same model (Model 1) was fitted to patient own TTO, HUI3 and EQ-5D (Table 6). Previous modeling of patient TTO and HUI3 data had found age to be a significant covariate[13], so a further model (Model 2) was fitted to the three utility values with age as an explanatory variable.

Table 6: Estimated relationship between VA LogMAR and measures of health state values (Best seeing eye)

	TTO values for simulated states **B (SE)**	**TTO from ARMD patients** **B (SE)**	**HUI3 from ARMD patients** **B (SE)**	**EQ-5D from ARMD patients** **B (SE)**
Model 1				
Constant	**0.828 (0.039)**	**0.753 (0.038)**	**0.479 (0.033)**	**0.745 (0.027)**
VA LogMAR	**-0.359 (0.045)**	**-0.087 (0.031)**	**-0.140 (0.027)**	-0.027 (0.023)
Adj. R^2	0.171	0.032	0.110	0.002
Model 2				
Constant	**0.860 (0.068)**	**1.737 (0.217)**	**1.078 (0.198)**	**0.753 (0.164)**
VA LogMAR	**-0.368 (0.046)**	-0.036 (0.032)	**-0.109 (0.028)**	-0.027 (0.024)
Age	-0.001 (0.002)	**-0.013 (0.013)**	**-0.008 (0.003)**	0.000 (0.002)
Adj. R^2	0.172	0.121	0.147	0.003

Estimates shown in bold are significant at $t_{0.01}$ SE is standard error

The estimated coefficients for VA across the models show clear differences between them. The coefficient in the first model for TTO values for simulated states was more than twice the size of the one for HUI3 and over four times the size of the patients' own TTO coefficient and 13 times the coefficient for EQ-5D (which was not significant ($P>0.05$)). The addition of age increased the differences between the coefficients on VA for the TTO values from simulated ARMD states and for those from patients.

Discussion:

The rationale for this study was that existing generic preference-based measures of health do not adequately capture the impact of ARMD on visual function and its consequences. Even the most appropriate preference-based measure, the HUI3, uses a crude generic description of visual function that does not reflect the specific impact of ARMD on health-related quality of life[12].

This study developed a unique method of simulating the visual impairment associated with age-related macular degeneration (ARMD) through the use of custom-made contact lenses. For many conditions the use of simulation would be unethical. However, the development of the contact lenses allowed us to reproduce the condition in a convincing way with minimal risk and discomfort. It enabled the study to obtain informed preferences in a way that is rarely achieved in studies using verbal descriptions. A previous study undertaken by Aballéa and Tsuchiya[14] sought to simulate retinopathy using specially prepared spectacles which represented visually impaired health states. They found that the simulation was more effective than written descriptions of health states in allowing participants to imagine themselves with the condition without cognitive overload. However, Aballéa and Tsuchiya[14] allowed their participants to remove the spectacles while completing the valuation questionnaires and so this would have reduced this benefit. Not all participants chose to remove the spectacles. Our contact lens study allowed participants to experience more fully the visual restrictions of ARMD, and by completing the health state valuation whilst still experiencing the effects of the condition our study differs from Aballéa and Tsuchiya[14]. We have shown that it is possible to simulate an eye condition where spectacles would not have been able to reproduce the visual impairment specific to ARMD.

We acknowledge that the contact lenses, or the pilocarpine, may have had an impact on participants' valuations of the states, in addition to an impact on vision per se. There was some reported blurring of vision on instillation of the pilocarpine drops and the lenses were uncomfortable for some participants. The instructions given to participants when completing the health state valuations specifically asked them to ignore the sensation of the contact lens, and any potential slight headache induced by the pilocarpine drops. Nonetheless, participants may be responding to the wearing of lenses rather than simply the impact on their vision. For this reason all baseline assessments were excluded from the analyses. Another concern is that there may have been an ordering effect. Whilst the order of lenses was randomised, those participants who valued a mild state first gave it a lower value than participants who valued a more severe lens first. The TTO values used in the analysis were adjusted for ordering effects.

The results of this study indicate a significant relationship between the visual impairment caused by the lenses, as measured by visual acuity, and TTO values from a general population sample. However, the study sample was not representative of the general population. Given the invasive nature of the task described in the invitation letter, it was difficult to recruit for this study from a cold sample, so it was necessary to supplement with a word of mouth sample. Analysis found no significant impact from the socio-demographic characteristics of the participants and their source of recruitment, but baseline TTO utlity was important. Participants with worse baseline TTO values tended to give lower values to the simulated visual states. This result confirms the findings of Aballéa and Tsuchyia[14] that the background health of a participant can alter their responses to the questions. However, this effect was quite modest compared to VA and only affected a minority in this study.

The argument for using condition specific descriptive systems is that they better reflect the impact of the condition on a patient's quality of life. The use of condition specific measures in economic evaluation has been criticised for failing to achieve the comparability across conditions required to inform resource allocation[18]. Differences between the generic and condition-specific measures may be a result of differences in the methods of valuation rather than their descriptive system. Provided the descriptive system is valued on the same full health – death scale using the same variant of the same valuation technique and a comparable population sample, the valuations should be comparable[19].

Therefore any remaining differences in values should be a consequence of the descriptive system. There is a remaining concern that the value given to ARMD states might depend on other aspects of health arising from co-morbidities. This problem must be weighed against the advantages of having a better description of the impact of the condition (in this case a simulated experience of the state) than offered by the crude visual function scale of the HUI3.

The simulation approach used in this study partly overcomes one explanation for the differences observed between patient and general population valuations that the descriptions provided to the latter tend to be poor[3]. Previous work on this issue has tended to rely on the provision of verbal descriptions to members of the general public, whereas the sample in this study actually experienced the state for a short time before being asked to value it. The difference found between the general population sample and patients' TTO values, particularly for poorer vision states, better reflects actual differences between the samples than previous studies using verbal descriptions.

This study found that ARMD has a major impact on general population TTO health state values. Differences across four visual health states appear larger than those found for a generic preference-based measures and patient TTO values. Socio-demographic characteristics were not found to be significant factors in influencing the simulated utility values, though baseline TTO utility values were positively associated with subsequent TTO values for simulated states. For conditions that are difficult to describe and imagine, such as ARMD, simulation methods may offer an important method for obtaining better informed general population preferences.

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