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Specific Health-Related Quality of Life Concerns in Children with Intermittent Exotropia

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Abstract

Purpose—To assess the frequency of specific health-related quality of life (HRQOL) concerns in children with intermittent exotropia (XT) using the Intermittent Exotropia Questionnaire (IXTQ).

Methods—80 children with intermittent XT (aged 5 to <17 years), plus one parent for each child, completed the Child and Proxy IXTQ respectively. Each item was scored from 0 to 100 (worst to best HRQOL). Mean scores were calculated for each item and items were ranked from lowest to highest impact (worst HRQOL). Analysis was repeated for sub-groups of 5- to <8- (n=46) and 8- to <17- (n=34) year olds.

Results—Highest impact Child IXTQ items were: “It bothers me that I have to shut one eye when it is sunny,” “I worry about my eyes,” and “It bothers me because I have to wait for my eyes to clear up.” Highest impact Proxy IXTQ items were: “It bothers my child because he/she has to shut one eye when it is sunny” and “My child worries about his/her eyes.” Lowest impact Child and Proxy items were “My eyes make it hard to make friends,” and “Kids tease me because of my eyes.” Ranking of items was similar for younger and older children.

Conclusions—The greatest HRQOL concerns for children with intermittent XT were shutting one eye when sunny, waiting for their eyes to clear up, and worrying about their eyes. Items related to teasing and making friends were of least concern. Evaluation of HRQOL concerns using the IXTQ may be helpful in the clinical care of individual patients.

Keywords

Intermittent Exotropia; Quality of Life; Strabismus

INTRODUCTION

In intermittent exotropia (XT), management decisions may be influenced by the presence or absence of health-related quality of life (HRQOL) concerns. In order to formally measure HRQOL in this population, we previously developed and validated the Intermittent Exotropia Questionnaire (IXTQ), a patient-derived HRQOL instrument for children with intermittent exotropia (XT). (Hatt et al., 2010a, Hatt et al., 2010b, Yamada et al., 2011a, Yamada et al., 2011b) In our previous initial study, Child IXTQ and Proxy IXTQ scores were found to be lower (worse HRQOL) in children with intermittent XT than in normal controls, (Hatt et al., 2010a) nevertheless, responses to individual questionnaire items have

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not been studied. The purpose of the present study was to assess responses to individual items on Child and Proxy IXTQ on a larger cohort of patients than used in the original validation studies in order to evaluate the impact of specific HRQOL concerns in children with intermittent XT.

MATERIALS AND METHODS

Institutional review board approval was obtained for this study. All procedures and data collection were conducted in a manner compliant with the Health Insurance Portability and Accountability Act. Informed consent was obtained for all participants and informed assent was obtained from children aged 7 to <18 years of age. All research procedures adhered to the tenets of the Declaration of Helsinki.

Subjects

Children aged 5 to <18 years with intermittent XT, defined as distance exodeviation measured by prism and alternate cover test (PACT) ≥ 10 prism diopters (pd) and distance control ≥ 1 , (Mohny & Holmes, 2006) were eligible for inclusion. Included subjects were consecutive children with intermittent XT in our clinical practice and were referred for a variety of reasons by their primary care giver (pediatrician or family practitioner) or for parental or child concerns. Children were required to have visual acuity of 20/40 or better in each eye and no previous eye muscle surgery. Children with co-existent near esodeviation were excluded. Children and one parent for each child were recruited during the child's eye examination at an outpatient clinic. Both the child and their parent were required to be conversant in English to be recruited.

Intermittent Exotropia Questionnaire (IXTQ)

The IXTQ has 2 components to assess the child's HRQOL: the Child IXTQ, a self-report of the child's own HRQOL completed by the child, and the Proxy IXTQ, a parent report of their child's HRQOL completed by the parent (questionnaires available from: <http://www.pedig.net/>, accessed October 31st, 2012, and items listed in Table 1). The Child and Proxy IXTQ contain 12 parallel questionnaire items addressing the child's HRQOL. The IXTQ also has a Parent questionnaire (evaluating the HRQOL of the parent themselves), but in the present study we were interested in evaluating the child's HRQOL from the perspective of the child (Child IXTQ) and parent (Parent IXTQ), so the Parent IXTQ is not reported. For the Child IXTQ, each item has either 3 response options ("Not at all," "Sometimes," and "A Lot" for 5- to <8-year-old children) or 5 response options ("Never," "Almost never," "Sometimes," "Often," and "Almost always" for 8- to <18- year-old children). For the Proxy IXTQ, each item has 5 response options. For both Child and Proxy questionnaires, each item is scored 0, 25, 50, 75, and 100 for the 5 response options and 0, 50, and 100 for the 3 response options (worst to best HRQOL).

Children and parents completed respective Child and Proxy components of the IXTQ during the clinic examination. Care was taken to minimize parental influence on their child's responses, with the child's back towards their parent whenever possible.

Data analysis

For Child and Proxy questionnaires, the mean score for each questionnaire item was calculated. Items were then ranked from highest impact (lowest mean score) to least impact (highest score). Comparison of child individual item scores and corresponding proxy individual item scores were made using Signed-rank tests. In addition, the proportion of high-frequency responses (defined for this study as "Sometimes," "Often," or "A Lot"/ "Almost Always") was calculated for each item and ranked. Analyses of mean item scores

and proportion of high-frequency responses were repeated for sub-groups of children aged 5 to <8 years and 8 to <17 years. Comparisons of scores between age groups were made using Wilcoxon rank-sum tests and comparisons of proportions of high-frequency responses between age groups for each item using Fisher's exact tests.

RESULTS

Eighty children with intermittent XT (aged 5 to <17 years, median age 7 years), plus one parent for each child, were prospectively enrolled. Forty-six children were aged 5 to <8 years and 34 were aged 8 to <17 years. Two parents failed to complete the proxy questionnaire, leaving 78 proxy questionnaires for analysis. Thirty (38%) of subjects wore spectacles habitually. Median angle of distance exodeviation measured by PACT was 25 pd (range 12 to 55 pd exo) and median near exodeviation was 16 pd (range 0 to 40 pd exo). Control ranged from 1 (tropia present only following dissociation and recovers within 1 to 5 seconds) to 5 (constant spontaneous tropia) (median 2, tropia present only following dissociation and doesn't recover within 5 seconds) in the distance. (Mohny & Holmes, 2006) Average Child and Proxy IXTQ scores have been previously reported in 45 (56%) of these subjects, but individual item scores have not been previously reported.

Clinical characteristics of the younger and older children were similar. Median visual acuity of the best eye was 20/20 (range 20/15 to 20/40) in younger children compared with 20/20 (range 20/20 to 20/40) in older children ($P=0.4$). Median visual acuity in the worse eye was 20/25 (range 20/15 to 20/40) in younger children and 20/20 (range 20/20 to 20/40) in older children ($P=0.2$). The angle of exodeviation was similar between younger and older children at both distance (median 25 pd, range 14 pd to 40 pd versus 25 pd, range 12 pd to 55 pd, $P=0.7$) and near (median 16 pd, range 0 pd to 40 pd versus 15 pd, range 2 pd to 40 pd, $P=0.8$). Control of the exodeviation was also similar for younger and older children both at distance (median 2, range 1 to 5 versus 2, range 1 to 5, $P=0.3$) and at near (median 1, range 0 to 5 versus 1, range 0 to 5, $P=0.5$).

Mean IXTQ item scores

For the Child IXTQ, the items with the highest HRQOL impact (lowest mean scores) were: "It bothers me that I have to shut one eye when it is sunny," (mean $\pm$ standard deviation, 60.3 ± 35.7) followed by "I worry about my eyes" (mean 74.1 ± 33.6), and "It bothers me that I have to wait for my eyes to clear up," (mean 74.7 ± 32.6) (Table 1). The items with the least HRQOL impact (highest mean scores) were: "My eyes make it hard to make friends" (mean 94.7 ± 18.5) and "Kids tease me because of my eyes" (mean 92.8 ± 20.7). (Table 1)

For the Proxy IXTQ, the items with the highest HRQOL impact (lowest mean scores) were: "It bothers my child because he/she has to shut one eye when it is sunny" (mean 71.1 ± 27.5) followed by "My child worries about his/her eyes" (mean 71.5 ± 23.7) and "My child finds it hard to concentrate because of his/her eyes" (mean 73.1 ± 24.4) (Table 1). The items with the least HRQOL impact (highest mean scores) were "My child's eyes make it hard for him/her to make friends" (mean 95.2 ± 11.4) and "Kids tease my child because of his/her eyes" (mean 89.1 ± 17.8) (Table 1)

Two of the items, "It bothers me that I have to shut one eye when it is sunny" and "It bothers me because I have to wait for my eyes to clear up" had significantly lower scores (worse HRQOL) on the Child IXTQ compared with the Proxy IXTQ (Table 1).

IXTQ items: high-frequency response proportions

For the Child IXTQ, the items with the greatest proportion of high-frequency responses ("Sometimes," "Often," or "A Lot"/"Almost Always") were, "It bothers me that I have to

shut one eye when it is sunny” (56%, Table 2), “It bothers me that people wonder what is wrong with my eyes” (39%), and “It bothers me because I have to wait for my eyes to clear up” (38%). The items with the lowest proportion of high-frequency responses were “My eyes make it hard for me to make friends” (6%) and “Kids tease me because of my eyes.” (11%, Table 2).

For the Proxy IXTQ, the items with the greatest proportion of high frequency responses were, “My child worries about his/her eyes” (40%) and “It bothers my child because he/she has to shut one eye when it is sunny” (39%, Table 2). The items with the lowest proportion of high-frequency responses were “My child’s eyes make it hard for him/her to make friends” (3%) and “My child feels different from other kids because of his/her eyes” (6%, Table 2).

Four items had a statistically higher proportion of high-frequency responses on the Child IXTQ compared with the Proxy IXTQ: “It bothers me that I have to shut one eye when it is sunny” ($P=0.03$), “It bothers me because I have to wait for my eyes to clear up” ($P=0.002$), “I worry about what other people think of me because of my eyes” ($P=0.03$), and “I feel different from other kids because my eyes go in and out” ($P=0.01$)(Table 2).

Younger vs older children: mean IXTQ scores

Mean Child IXTQ scores were mostly similar for younger (5 - <8 years) and older (8 - <17 years) children on most items, although there was a trend towards higher scores (better HRQOL) in older children (Table 3). Significant differences were observed between younger and older children for item #3, “It bothers me because I have to wait for my eyes to clear up” ($P=0.05$). For mean Proxy IXTQ scores, most scores were similar between younger and older children but there was a trend towards lower scores (worse HRQOL) in older children (Table 3), reaching statistical significance for worse HRQOL in older children on item #8, “My child feels different from other kids because of his/her eyes” ($P = 0.01$) and item #10, “My child finds it hard to look people in the eye,” ($P=0.02$, Table 3).

Younger vs older children: high-frequency response proportions

For the Child IXTQ, the proportion of high-frequency responses (“Sometimes,” “Often,” or “A Lot”/“Almost Always”) was numerically greater for younger children than for older children on 10 of 12 items (Table 4), with differences reaching statistical significance for 1 of the 12 items (#3, $P=0.01$, Table 4). For the Proxy IXTQ, the proportion of high-frequency responses was numerically greater for older children on 9 of 12 items, with differences reaching statistical significance for 1 of the 12 items (#10, “My eyes make it hard to look people in the eye,” $P=0.005$, Table 4).

DISCUSSION

By evaluating responses to individual IXTQ items, we found that the HRQOL concerns with the greatest impact reported by children with intermittent XT are shutting one eye when it is sunny, waiting for eyes to clear up, and worry about the eyes. Two of these concerns (shutting one eye and worry) were also the highest rated concerns reported by their parent (Proxy IXTQ).

There are few previous studies examining HRQOL concerns in children with intermittent XT. Using the IXTQ, we have previously reported overall decreased HRQOL in children with intermittent XT compared with controls. (Hatt et al., 2010b) A study by Buck et al (Buck et al., 2011) reported HRQOL in children with intermittent XT using the PedsQL, but the PedsQL is a generic instrument and has not been found to be optimal for detecting concerns specific to intermittent XT. (Hatt et al., 2010a) By using a condition-specific,

patient-derived HRQOL instrument, (Hatt et al., 2010a, Hatt et al., 2010b) we were able to identify the concerns with the highest impact affecting children with intermittent XT.

The main concern reported by both children and their parents, was shutting one eye in sunlight. Monocular eye closure in sunlight is a commonly reported symptom in children with intermittent XT. (Hatt et al., 2009, Wang & Chryssanthou, 1988) Wirtschafter and von Noorden have reported that bright light decreases fusional convergence, (Wirtschafter & Von Noorden, 1964) which may explain a tendency for the intermittent exotropia to become manifest in sunlight. (Wang & Chryssanthou, 1988) Lew et al found that a majority of patients with intermittent XT exhibit photophobia and that surgical correction alleviates this symptom in many patients. (Lew et al., 2007) We previously made the preliminary observation in a subset of the current cohort that the primary concern of children with intermittent XT appeared to be closure of one eye in sunlight. (Hatt et al., 2010b) Our current study confirms this finding in a larger cohort. The IXTQ may be a useful method for measuring the effects of treatment on frequently reported concerns such as monocular eye closure.

It is interesting that teasing and difficulty making friends were of least concern in children with intermittent XT. Manifest strabismus might be expected to result in negative social bias and teasing in children. (Paysse et al., 2001, Uretman et al., 2003) Nevertheless, some previous studies have shown a surprising lack of teasing and bullying in children with strabismus. (Horwood et al., 2005, Johns et al., 2005, Sabri et al., 2006) It is also possible that since children with intermittent XT are mostly able to control the exodeviation at conversational distances, the exodeviation largely goes unnoticed by peers.

Regarding the difference between the child report and proxy report, it is interesting that the children's score was lower (worse HRQOL) than the parent's score for the child on several items, particularly those that pertained to their primary concerns, e.g. "It bothers me that I have to shut one eye when it is sunny." Some studies comparing proxy reporting and self reporting of HRQOL in other conditions have also described differences between child and parent, (Eiser & Morse, 2001) with some indicating worse HRQOL when rated by the parents (White-Koning et al., 2007) while others report better or similar HRQOL by proxy rating. Both the proxy and the self-report contain valuable information from differing perspectives and should both be delivered if possible. (Erhart et al., 2009) Despite some differences observed between child and proxy scores in the present study, there are many points of agreement between child and proxy regarding concerns of most importance for children with intermittent XT.

The impact of intermittent XT on child HRQOL at different ages appears to differ whether it is assessed by the child themselves or by their parent. When assessed by the child themselves, younger children have lower scores (worse HRQOL) and a greater proportion of high-frequency responses (worse HRQOL) for most items. We were somewhat surprised that the younger children had lower HRQOL scores (worse HRQOL) than older children, because we predicted that older children would be more self-aware. It is possible that older children have learned to control their deviation better, and therefore the condition does not bother them as much, but further studies are needed to elucidate the reasons for these findings. In contrast to the child reports, when assessed by the parent, older children have lower scores (worse HRQOL) and a higher proportion of high-frequency responses (worse HRQOL) on most items. Nevertheless, this comparison is limited by the use of 3-level response options for younger children and 5-level response options for older children with slightly different wording. Older and younger children may interpret response options differently. In addition, parents and children may interpret response options differently, resulting in different scores.

Given the low impact of several items on the Child IXTQ and the Proxy IXTQ, consideration should be given to reducing the number of items on each questionnaire. Items demonstrating consistently low impact on the IXTQ contribute to ceiling effects, potentially leading to a questionnaire that is less responsive to change. These low impact items might therefore be excluded in future versions of the IXTQ. Such further refinement of the IXTQ should also include Rasch analysis.

Our study is not without limitations. Our sample population was predominantly white (91%) and it is possible that with a more mixed racial cohort, the impact of items may have been different. It is also unknown how responses may have differed if we had studied a population with a greater proportion of very severe intermittent XT. Our age analysis was limited by a relatively small number of subjects within each age group and therefore we may have missed differences between older and younger children on some items. It is possible that there were subtle differences in severity between our younger and older children which could account for our findings, although, based on our sample size, we found no statistically significant differences in clinical measurements for visual acuity, magnitude of deviation, or control of the exodeviation between older and younger subjects.

In summary, using the IXTQ, we have identified that children with intermittent XT are most bothered by needing to shut one eye when it is sunny, waiting for eyes to clear up, and worry about their eyes. Impact of concerns differs depending on whether assessed by the child themselves or their parent. Formal evaluation of specific HRQOL concerns using the IXTQ may be helpful clinically in identifying the impact of intermittent XT on individual patients.

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Individual Child Intermittent Exotropia Questionnaire (IXTQ) and Proxy IXTQ Items, showing mean item score $\pm$ SD for Child IXTQ and Proxy IXTQ.

Table 1

IXTQ item number	IXTQ item*	Item score (mean $\pm$ SD)			P value
		Child IXTQ	Proxy IXTQ		
7	It bothers me that I have to shut one eye when it is sunny	60.3 $\pm$ 35.7	71.1 $\pm$ 27.5		0.03
1	I worry about my eyes	74.1 $\pm$ 33.6	71.5 $\pm$ 23.7		0.6
3	It bothers me because I have to wait for my eyes to clear up	74.7 $\pm$ 32.6	84.0 $\pm$ 19.7		0.03
2	It bothers me that people wonder what is wrong with my eyes	76.6 $\pm$ 32.2	79.2 $\pm$ 25.3		0.7
11	It is hard to concentrate because of my eyes	76.6 $\pm$ 32.6	73.1 $\pm$ 24.4		0.4
10	My eyes make it hard to look people in the eye	82.2 $\pm$ 28.7	79.2 $\pm$ 25.0		0.4
6	I am bothered when my parents say things about my eyes	84.1 $\pm$ 27.3	77.9 $\pm$ 22.8		0.06
8	I feel different from other kids because my eyes go in and out	87.7 $\pm$ 25.3	88.1 $\pm$ 16.5		0.8
9	I worry about what other people think of me because of my eyes	86.9 $\pm$ 24.8	86.9 $\pm$ 20.8		1.0
5	I am bothered when grownups say things about my eyes	87.2 $\pm$ 23.2	81.4 $\pm$ 22.6		0.1
4	Kids tease me because of my eyes	92.8 $\pm$ 20.7	89.1 $\pm$ 17.8		0.1
12	My eyes make it hard for me to make friends	94.7 $\pm$ 18.5	95.2 $\pm$ 11.4		0.8

Ordered by Child IXTQ scores from lowest score to highest score (worst to best HRQOL).

* Proxy IXTQ items are identical but expressed in the third person, e.g., "My child worries about his/her eyes."

Bold values indicate numerically lower scores (worse HRQOL) when comparing Child IXTQ and Proxy IXTQ for that item.

Proportion of high-frequency responses on individual Child Intermittent Exotropia Questionnaire (IXTQ) and Proxy IXTQ items.

Table 2

IXTQ item number	IXTQ item*	Proportion with high frequency			P Value
		Child IXTQ	Proxy IXTQ		
7	It bothers me that I have to shut one eye when it is sunny	0.56	0.39		0.03
2	It bothers me that people wonder what is wrong with my eyes	0.39	0.26		0.1
3	It bothers me because I have to wait for my eyes to clear up	0.38	0.17		0.002
1	I worry about my eyes	0.36	0.40		0.7
11	It is hard to concentrate because of my eyes	0.34	0.37		0.7
6	I am bothered when my parents say things about my eyes	0.28	0.31		0.5
10	My eyes make it hard to look people in the eye	0.28	0.28		1.0
5	I am bothered when grownups say things about my eyes	0.21	0.26		0.4
9	I worry about what other people think of me because of my eyes	0.21	0.10		0.03
8	I feel different from other kids because my eyes go in and out	0.18	0.06		0.01
4	Kids tease me because of my eyes	0.11	0.10		1.0
12	My eyes make it hard for me to make friends	0.06	0.03		0.3

Ordered by proportion of high-frequency responses (“Sometimes,” “Often,” or “Almost always”) using Child IXTQ scores (highest proportion of high-frequency responses to lowest proportion of high-frequency responses).

* Proxy IXTQ items are identical but expressed in the third person, *e.g.*, “My child worries about his/her eyes.”

Bold values indicate numerically larger proportions of high-frequency responses (worse HRQOL) when comparing Child IXTQ and Proxy IXTQ for that item.

Table 3

Mean scores on individual Child Intermittent Exotropia Questionnaire (IXTQ) and Proxy IXTQ items in sub-groups of younger versus older children.

IXTQ item number	IXTQ item*	Child IXTQ			Proxy IXTQ		
		5-<8 years (n=46)	8-<17 years (n=34)	P value	5-<8 years (n=45)	8-<17 years (n=33)	P value
1	I worry about my eyes	75.0 ± 36.1	72.8 ± 30.4	0.4	73.3 ± 25.2	68.9 ± 21.7	0.4
2	It bothers me that people wonder what is wrong with my eyes	72.8 ± 34.5	81.6 ± 28.4	0.3	81.7 ± 26.3	75.8 ± 23.8	0.1
3	It bothers me because I have to wait for my eyes to clear up	67.8 ± 35.6	83.8 ± 26.0	0.05	84.4 ± 20.1	83.3 ± 19.4	0.7
4	Kids tease me because of my eyes	92.4 ± 23.5	93.4 ± 16.6	0.7	88.9 ± 18.1	89.4 ± 17.7	1.0
5	I am bothered when grownups say things about my eyes	88.0 ± 24.0	86.0 ± 22.4	0.4	83.9 ± 22.7	78.0 ± 22.3	0.2
6	I am bothered when my parents say things about my eyes	84.8 ± 27.6	83.1 ± 27.3	0.7	78.9 ± 23.8	76.5 ± 21.6	0.5
7	It bothers me that I have to shut one eye when it is sunny	56.5 ± 37.4	65.4 ± 33.2	0.3	71.0 ± 29.0	71.2 ± 25.9	0.9
8	I feel different from other kids because my eyes go in and out	88.0 ± 26.2	87.1 ± 24.3	0.5	91.7 ± 15.1	83.3 ± 17.3	0.01
9	I worry about what other people think of me because of my eyes	84.8 ± 27.6	89.7 ± 20.5	0.6	87.8 ± 22.4	85.6 ± 18.8	0.3
10	My eyes make it hard to look people in the eye	83.7 ± 28.0	80.1 ± 30.0	0.5	85.0 ± 22.2	71.2 ± 26.6	0.02
11	It is hard to concentrate because of my eyes	75.6 ± 33.1	77.9 ± 32.4	0.8	75.6 ± 22.9	69.7 ± 26.3	0.4
12	My eyes make it hard for me to make friends	92.4 ± 23.5	97.8 ± 7.2	0.7	96.7 ± 8.6	93.2 ± 14.4	0.3

* Proxy IXTQ items are identical but expressed in the third person, *e.g.*, "My child worries about his/her eyes."

Bold numbers indicate numerically lower mean item scores (worse HRQOL) when comparing children aged 8 to <17 years and children aged 5 to <8 years.

Table 4

Proportion of high-frequency responses on individual Child Intermittent Exotropia Questionnaire (IXTQ) and Proxy IXTQ items, in sub-groups of younger versus older children

IXTQ item number	IXTQ item*	Proportion with high frequency					
		Child IXTQ			Proxy IXTQ		
		5-<8 years (n=46)	8-<17 years (n=34)	P value	5-<8 years (n=45)	8-<17 years (n=33)	P value
1	I worry about my eyes	0.37	0.35	1.0	0.36	0.45	0.5
2	It bothers me that people wonder what is wrong with my eyes	0.43	0.32	0.4	0.24	0.27	0.8
3	It bothers me because I have to wait for my eyes to clear up	0.51	0.21	0.01	0.16	0.18	0.8
4	Kids tease me because of my eyes	0.11	0.12	1.0	0.13	0.06	0.5
5	I am bothered when grownups say things about my eyes	0.22	0.21	1.0	0.24	0.27	0.8
6	I am bothered when my parents say things about my eyes	0.26	0.29	0.8	0.29	0.33	0.8
7	It bothers me that I have to shut one eye when it is sunny	0.65	0.44	0.07	0.36	0.42	0.6
8	I feel different from other kids because my eyes go in and out	0.20	0.15	0.8	0.07	0.06	1.0
9	I worry about what other people think of me because of my eyes	0.26	0.15	0.3	0.11	0.09	1.0
10	My eyes make it hard to look people in the eye	0.28	0.26	1.0	0.16	0.45	0.005
11	It is hard to concentrate because of my eyes	0.40	0.26	0.2	0.36	0.39	0.8
12	My eyes make it hard for me to make friends	0.11	0.00	0.07	0.00	0.06	0.2

* Proxy IXTQ items are identical but expressed in the third person, e.g., "My child worries about his/her eyes."

Bold numbers indicate greater proportion of high-frequency (worse HRQOL) responses ("Sometimes," "Often," or "Almost always") when comparing children aged 8 to <17 years and children aged 5 to <8 years.