Development of Pediatric Eye Questionnaires for Children With Eye Conditions

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• PURPOSE: To develop patient-derived Pediatric Eye Questionnaires (PedEyeQ) to separately assess eye-related quality of life (ER-QOL) and functional vision in children with eye conditions.

• DESIGN: Questionnaire development study.

• METHODS: A total of 444 children (0 to $<$18 years old), across 10 diagnostic categories, were enrolled at 2 sites. All parents (n = 444) and 277 children (5 to $<$18 years old) completed master questionnaires, developed from patient-derived concerns. Factor analysis was performed to identify unidimensional domains (eigenvalue $>$1.0) and Rasch analyses (differential item functioning, targeting, fit) to reduce items (separate analyses for subjects aged 0-4, 5-11, and 12-17 years and for each factor).

• RESULTS: The Child 5- to 11-year-old PedEyeQ consisted of 4 unidimensional domains/questionnaires: functional vision, bothered by eyes/vision, social, frustration/worry (10 items each). The Child 12- to 17-year-old PedEyeQ consisted of the same 4 domains (total 39 items). The Proxy 0- to 4-year-old PedEyeQ consisted of 3 questionnaires/domains: functional vision, bothered by eyes/vision, social (total 29 items). The Proxy 5- to 11-year-old PedEyeQ consisted of 5 questionnaires/domains: functional vision, bothered by eyes/vision, social, frustration/worry, eye care (total 39 items), as did the Proxy 12- to 17-year-old PedEyeQ (total 42 items). The Parent PedEyeQ consisted of 4 questionnaires/domains: impact on parent/family, worry regarding child's eye condition, worry regarding child's self-perception and interactions, worry regarding child's visual function (total 35 items). Rasch look-up tables were created for scoring.

• CONCLUSIONS: By following a rigorous approach, we have developed Pediatric Eye Questionnaires for separately assessing functional vision and ER-QOL domains in children of any age and with any eye condition. (Am J Ophthalmol 2019;200:201–217. © 2019 Elsevier Inc. All rights reserved.)

Accepted for publication Jan 4, 2019.

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WE PREVIOUSLY REPORTED THE IDENTIFICATION of specific functional vision and eye-related quality of life (ER-QOL) concerns of children with eye conditions, derived from individual interviews. Based on the complete interview data set for children with a broad spectrum of eye conditions, we created a large pool of potential questionnaire items.[1] In the present study, we describe the second stage in the process, using these patient-derived items in a new cohort of patients, to develop new patient-reported outcome measures (in accordance with following Food and Drug Administration guidelines[2]), ensuring content validity. A subsequent third stage, evaluating construct validity, reliability, and responsiveness of the derived questionnaires in a new patient population, will be described separately. The goal in developing these questionnaires was to meet the need for patient-derived, eye-specific instruments that can be used across the spectrum of childhood eye disorders, in children of any age, with child self-report, proxy-report, and parent components. Our specific aim was to develop short forms, representing individual, analysis-driven, unidimensional domains within the separate constructs of functional vision and ER-QOL, for administration in any clinical setting.

METHODS

APPROVAL FOR THIS QUESTIONNAIRE DEVELOPMENT STUDY was obtained from Institutional Review Boards (IRBs) at the Mayo Clinic (Rochester, Minnesota, USA) and the University of Texas Southwestern Medical Center (Dallas, Texas, USA). All procedures and data collection were conducted in a manner compliant with the Health Insurance Portability and Accountability Act and all research procedures adhered to the tenets of the Declaration of Helsinki. Informed consent and informed assent were obtained as required by local IRBs. Both the child and 1 of the child's parents were enrolled.

• PATIENTS: As described previously,[1,3–6] patients were enrolled at 2 sites: Mayo Clinic (Rochester, Minnesota, USA) and Retina Foundation of the Southwest (Dallas, Texas, USA). Eligible children were aged 0-17 years, with any eye condition.

The medical record was reviewed to establish the current primary diagnosis. Based on this diagnosis, each subject was

0002-9394/$36.00
https://doi.org/10.1016/j.ajo.2019.01.001

TABLE 1. Demographics of Children and Parents Completing Master Questionnaires

Characteristic	N (%)
Sex of child	
Female	224 (50)
Male	220 (50)
Age	
0-4	167 (38)
5-11	156 (35)
12-17	121 (27)
Race	
White (including Hispanic/Latino)	339 (76)
Asian	35 (8)
More than 1 race	35 (8)
Black/African American	19 (4)
American Indian/Alaskan Native	5 (1)
Native Hawaiian/other Pacific Islander	1 (<1)
Other	8 (2)
Unknown/not reported	2 (<1)
Ethnicity	
Not Hispanic/Latino and not Middle Eastern/North African and not Indian Subcontinent	349 (79)
Hispanic/Latino	62 (14)
Indian Subcontinental	18 (4)
Middle Eastern/North African	7 (2)
More than 1	4 (1)
Unknown/not reported	4 (1)
Developmental delay	
No delay	365 (82)
Delay	79 (18)
Parent/legal guardian interviewed	
Mother	367 (83)
Father	71 (16)
Legal guardian	6 (1)
Parent/legal guardian age	
Under 21	5 (1)
21-30	55 (12)
31-40	218 (49)
41-50	129 (29)
51-60	31 (7)
Over 60	4 (1)
Not reported	2 (<1)
Parent/legal guardian highest level of education	
Attended high school	28 (6)
High school graduate	29 (7)
Attended college	80 (18)
College graduate	175 (39)
Postgraduate/professional degree	126 (28)
Not reported	6 (1)
Housing	
Own	366 (82)
Rent	65 (15)
Other	10 (2)
Not reported	3 (1)
Number of parents/legal guardians in home	
1	45 (10)
2	398 (90)
Not reported	1 (<1)
Care of child	
Parents/legal guardians only	189 (43)
Day care	47 (11)
Babysitter	37 (8)
Other relative	76 (17)
Other	21 (5)
After-school program	19 (4)
More than 1 source of assistance	50 (11)
Not reported	5 (1)
Visual acuity of worse eye	
-0.1 to 0.54 logMAR (20/16 to 20/70)	287 (65)
<0.54 to 1.0 logMAR (<20/70 to 20/200)	77 (17)
<1.0 logMAR (<20/200)	28 (6)
Not recorded	52 (12)
Visual acuity of better eye	
-0.2 to 0.54 logMAR (20/12 to 20/70)	340 (77)
<0.54 to 1.0 logMAR (<20/70 to 20/200)[a]	52 (12)
<1.0 logMAR (<20/200)[b]	13 (3)
Not recorded	39 (9)

Continued on next column

[a]World Health Organization criteria for moderate visual impairment (https://www.icd10monitor.com/looking-at-new-icd-10-cm-codes-for-blindness).

[b]World Health Organization criteria for severe visual impairment or blindness (https://www.icd10monitor.com/looking-at-new-icd-10-cm-codes-for-blindness).

then allocated to 1 of 10 broad diagnostic categories (esotropia, exotropia, hypertropia, nystagmus, amblyopia, refractive error, orbital and external conditions, anterior segment, retina and optic nerve, and central nervous system conditions affecting vision). Other diagnoses were listed as "additional." In an attempt to adequately represent the concerns of children with less common as well as those with more common eye conditions, we aimed to enroll equal numbers into each of the 10 diagnostic categories (480 overall; 48 into each of the 10 categories, 16 to each of 3 age bins [0-4, 5-11, and 12-17 years], at least 8 being from a racial/ethnic minority). We also aimed to cover a range of different disease severities. We attempted to enroll consecutive subjects and almost no invitees declined enrollment.

• **PHASE 1: CREATING MASTER QUESTIONNAIRES:** *Item Selection*. We previously described the process of identifying a large pool of 614 candidate child and proxy questionnaire items and 589 candidate parent items.[1] We planned to add any additional items that could be

TABLE 2. Diagnostic Categories of Children Enrolled for Completion of Master Questionnaires

		Secondary Diagnoses									
Current Primary Diagnosis		Esotropia	Exotropia	Hypertropia	Amblyopia	Nystagmus	Refractive Error	Orbital	Anterior Segment	Retina/Optic Nerve	Central Nervous System
Esotropia	56	-	1	6	16	0	45	1	0	3	0
Exotropia	52	10	-	11	7	1	35	0	2	5	1
Hypertropia	34	12	12	-	8	3	21	4	0	2	0
Amblyopia	44	13	3	2	-	2	42	2	1	2	0
Nystagmus	37	12	8	3	3	-	28	2	1	17	2
Refractive error	50	2	2	0	3	0	-	1	0	1	0
Orbital	38	4	3	4	5	1	21	-	6	2	0
Anterior segment	51	9	6	7	11	6	40	4	-	4	0
Retina/optic nerve	55	9	11	5	10	10	38	5	9	-	0
Central nervous system	27	5	15	2	4	4	20	2	1	13	-

Data indicate number of children.

identified in existing English-language, pediatric vision questionnaires, to be sure that our final, comprehensive list included all areas of concern. Review of the literature identified 14 previously published vision-specific questionnaires addressing the child's experience,[7–20] and 1 that assessed the parent's own experience,[15] with some parent-related items within proxy questionnaires.[9,11,20] On review of these published questions we did not find any additional areas of concern that we had missed, and therefore no additional questions derived from published questionnaires were added to our pool of candidate items.

Before commencing the process of item reduction, we had determined to segregate items within the 2 distinct constructs of functional vision and ER-QOL. To reduce items within these constructs to smaller subsets, we used a previously described process of winnowing.[21,22] All questions had been previously grouped by thematic content,[1] and these bins of questions were reviewed, and questions were removed if (1) they were similar to another question; (2) the question's content was too narrow, reducing applicability across socioeconomic and cultural groups; or (3) the question was confusing or unclear.[22] This process was repeated until the team agreed that the reduced number of questions formed a balance between adequate representation of concerns and reasonable burden of testing. Questions addressing the experience of the children themselves (expressed by the child or by the parent as proxy reporter) were grouped within either functional vision or ER-QOL. For the current project, we chose to exclude questions that only addressed symptoms, and focused on the 2 specific constructs of functional vision and ER-QOL. Child- and proxy-reported questions were collated separately from those addressing the experience of the parents themselves. While we collected concerns related to the treatment of pediatric eye conditions and formulated some candidate questions based on these concerns,[1] only a fraction of the children in the present study were undergoing treatment, so the development of treatment-related questionnaires was deferred, pending a larger sample size.

Formatting Master Questionnaires. Questions were formatted to create 3 different questionnaires: Child (for completion by the child), Proxy (parallel to the Child questionnaire but phrased in the third person), and Parent (the parent's own experience).

In a previous study,[5] we established that a frequency rating scale performed better than difficulty or severity scales for both children and parents, and therefore we used a 4-point frequency scale ("Never," "Sometimes," "Most of the time," "All of the time") for responses on each questionnaire. Questionnaires were also translated into Spanish and independently back-translated to ensure consistency of content.

• **PHASE 2: ADMINISTERING MASTER QUESTIONNAIRES:** Children aged 5-17 years completed Child questionnaires and 1 parent of each child aged 0-17 years completed Proxy and Parent questionnaires. No enrolled children or parents had been involved in previous phases of the study. Simple verbal and written instructions directed participants to select 1 response per question, and to indicate if the question was confusing or unclear. Questions were read to 5- to 7-year-old children by a trained examiner; 8- to 17-year-olds were given the option of completing on their own.

• **PHASE 3: DEVELOPING PEDIATRIC EYE QUESTIONNAIRE MODULES:** Our goal was to create short-form questionnaires, representing each of several analysis-driven

TABLE 3. Child 5- to 11-Year-Old Pediatric Eye Questionnaires

PedEyeQ-Functional vision: Child 5-11 years
1. Do your eyes make it hard to learn?
2. Do you have a hard time seeing?
3. Do you have to do things differently than other people because of your eyes?
4. Do your eyes make it hard to concentrate?
5. Do your eyes make it hard to do certain things?
6. Do you have trouble reading close up?
7. Do you have to do certain things to help you see better?
8. Is it hard to see the board at school?
9. Do you run into things because of your eyes?
10. Do your eyes get tired easily?
PedEyeQ-Bothered by eyes/vision: Child 5-11 years
1. Does it bother you because your eyes make it hard to learn?
2. Does it bother you because your eyes make it hard to play sports?
3. Does it bother you because you have a hard time seeing?
4. Does it bother you that you can't do certain things because of your eyes?
5. Does it bother you because your eyes make it hard to do certain things?
6. Does it bother you because it's hard to see the board at school?
7. Does it bother you because it's hard to see steps when you walk?
8. Does it bother you that bright light makes it hard to do things outside?
9. Is taking care of your eye condition hard for you?
10. Does it bother you because your eyes hurt?
PedEyeQ-Social: Child 5-11 years
1. Does it bother you that it's hard to play/interact with others because of your eyes?
2. Does your eye condition cause problems in your family?
3. Are you shy because of your eyes?
4. Do other people get frustrated with you because of your eyes?
5. Do you get teased because of your eyes?
6. Do you worry about getting hurt because of your eyes?
7. Do you worry about your eyes getting worse?
8. Do you worry about what other people think about you because of your eyes?
9. Do you worry about getting teased because of your eyes?
10. Do you worry about your eyes?
PedEyeQ-Frustration/worry: Child 5-11 years
1. Are you bothered by the things you have to do to make your eyes better?
2. Do your eyes make you feel unsure of yourself?
3. Are you frustrated because your eyes aren't getting better?
4. Does it bother you when other people say things or ask questions about your eyes?
5. Do you feel "different" because of your eyes?
6. Does it bother you that you get extra attention because of your eyes?
7. Do you feel left out because of your eyes?
8. Do you worry that your eyes will make it hard to do things when you're older?
9. Do you worry about not being able to do things because of your eyes?
10. Do you worry about what you might have to do to make your eyes better?

PedEyeQ = Pediatric Eye Questionnaire.

Formatted questionnaires with response options, instructions, and Rasch scoring are freely available at www.pedig.net. Each domain can be administered separately or in any combination, and is scored separately.

unidimensional domains, with no more than 10 items per factor (to minimize testing burden). Item reduction was accomplished in a series of analytical steps (described below). Child, Proxy, and Parent questionnaires were analyzed separately. For analysis, "Never" responses were scored as 3, "Sometimes" as 2, "Most of the time" as 1, and "All of the time" as 0.

Initial Item Reduction. Prior to performing factor analysis and Rasch analysis we excluded questionnaires with >10%

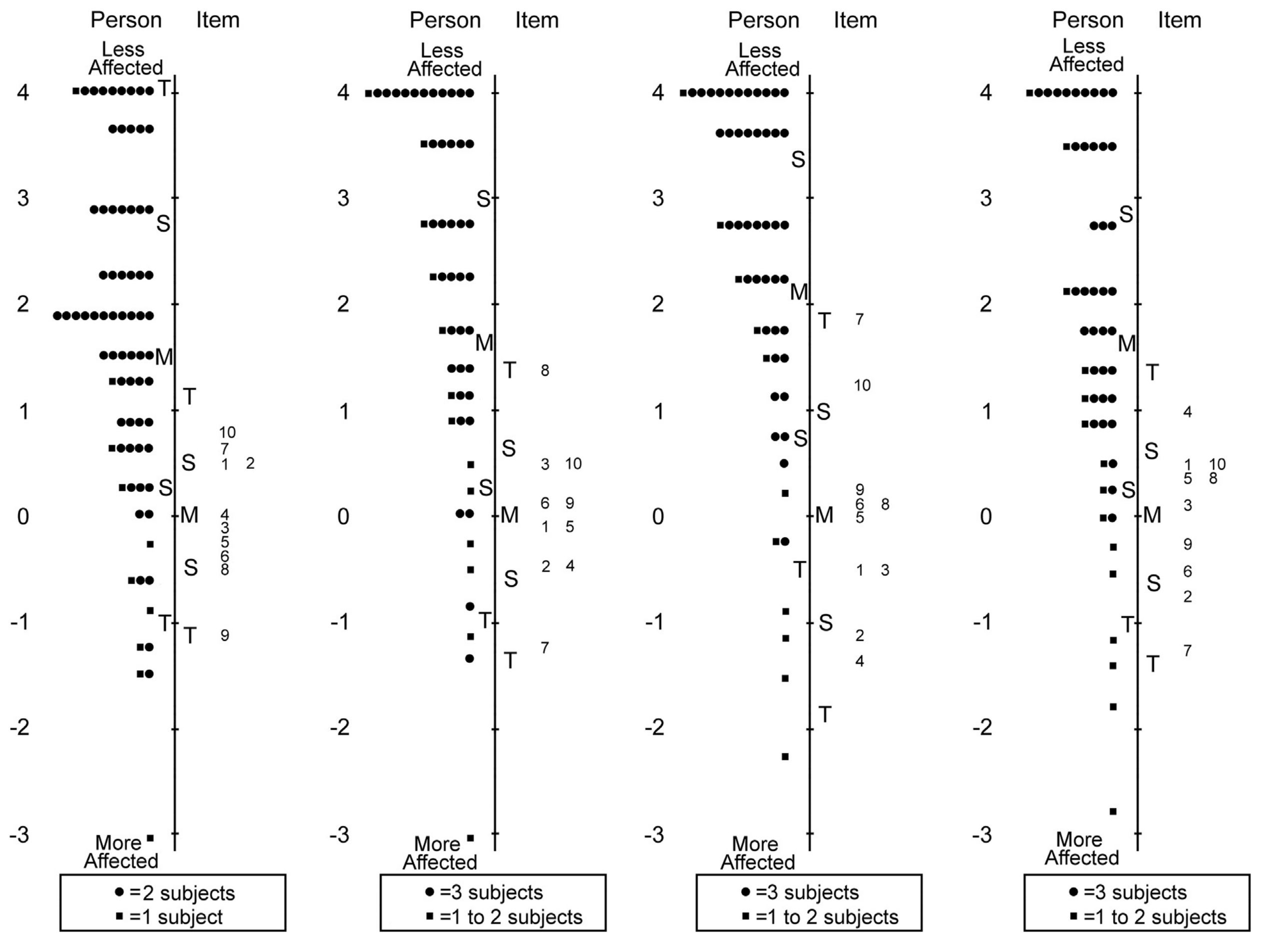

FIGURE 1. Person-item maps for the Child 5 to 11 Years Old Pediatric Eye Questionnaires: (First column) 10 items in a functional vision domain, (Second column) 10 items in a bothered by eyes/vision domain, (Third column) 10 items in a social domain, and (Fourth column) 10 items in a frustration/worry domain (see Table 3 for items). Items higher on the scale are less frequently endorsed as "never."

missing responses and questions with ≥20% "not applicable" responses, or questions where >10% of respondents found it unclear or confusing (analyzed separately for age groups 0-4, 5-11, and 12-17 years). For questionnaires with <10% of responses missing, we calculated Spearman rank correlations across questionnaires within the same age bin, and imputed the highest-correlated response, to allow use of all the nonimputed data for these children and parents (proportion of imputed responses: Child 8%, Proxy 4%, Parent 2%).

Factor Analysis. Factor analysis was performed to identify latent variables within each construct (Child and Proxy: functional vision and ER-QOL separately; Parent: ER-QOL). Analyses were performed separately by age group for Child (5-11, 12-17 years) and Proxy (0-4, 5-11, 12-17 years) questionnaires. There were no separate analyses by child age for Parent questionnaires. Similar to previous analyses for other eye-related questionnaire instruments,[23] varimax rotation methods were used with a threshold eigenvalue of 1.0 for identifying factors. Each factor analysis was initially performed unconstrained, and then constraining to fewer factors, based on review of thematic content, eigenvalues, and the inflection point on the scree plot. Items that loaded on more than 1 factor were initially retained on the factor with the highest loading threshold, but if an item cross-loaded (at a threshold of 0.3 or more) on another factor, we reviewed thematic content and if the thematic fit was better we moved it to the other factor for subsequent analyses. No items were removed for low loading. Identified latent traits were assigned descriptive titles according to their thematic content.

Rasch Analysis. Separate Rasch analyses were performed for each latent trait and, for Child and Proxy questionnaires, also by age group. All Rasch analyses were performed using Winsteps software version 4.0.1 (Winsteps

TABLE 4. Child 12- to 17-Year-Old Pediatric Eye Questionnaires

PedEyeQ-Functional vision: Child 12-17 years
1. Do your eyes make it hard to learn?
2. Do your eyes make it hard to play sports?
3. Do you have a hard time seeing?
4. Do you need special help at school because of your eyes?
5. Do you need help with certain things because of your eyes?
6. Do you have to do things differently than other people because of your eyes?
7. Do your eyes make it hard to concentrate?
8. Is it hard to see the board at school?
9. Is it hard to see steps when you walk?
10. Do you run into things because of your eyes?

PedEyeQ-Bothered by eyes/vision: Child 12-17 years
1. Does it bother you that you need help with certain things because of your eyes?
2. Does it bother you to have to do things differently because of your eyes?
3. Does it bother you because your eyes make it hard to learn?
4. Does it bother you because your eyes make it hard to play sports?
5. Does it bother you because you have a hard time seeing?
6. Does it bother you to need special help at school because of your eyes?
7. Does it bother you because your eyes make it hard to concentrate?
8. Does it bother you because your eyes make it hard to do certain things?
9. Does it bother you because it's hard to see the board at school?
10. Are you bothered by the things you have to do to make your eyes better?

PedEyeQ-Social: Child 12-17 years
1. Are you bothered by how your eyes look?
2. Do your eyes make you feel unsure of yourself?
3. Does it bother you when other people say things or ask questions about your eyes?
4. Do you feel "different" because of your eyes?
5. Does it bother you that you get extra attention because of your eyes?
6. Does it bother you when people look/stare at you because of your eyes?
7. Are you shy because of your eyes?
8. Do you get teased because of your eyes?
9. Do you worry about what other people think about you because of your eyes?
10. Do you worry about getting teased because of your eyes?

PedEyeQ-Frustration/worry: Child 12-17 years
1. Do you hate going to the eye doctor?
2. Is taking care of your eye condition hard for you?
3. Are you frustrated because your eyes aren't getting better?
4. Do you worry about getting hurt because of your eyes?
5. Do you worry about your eyes getting worse?
6. Do you worry that your eyes will make it hard to do things when you're older?
7. Do you worry about not being able to do things because of your eyes?
8. Do you worry about your eyes?
9. Do you worry about what you might have to do to make your eyes better?

PedEyeQ = Pediatric Eye Questionnaire.

Formatted questionnaires with response options, instructions, and Rasch scoring are freely available at www.pedig.net. Each domain can be administered separately or in any combination, and is scored separately.

Software Technologies, Seattle, Washington, USA) using the Masters Partial-Credit Model. All statistical analyses were performed using SAS version 9.4 (SAS Institute Inc, Cary, North Carolina, USA). Response option category utilization was evaluated and categories combined for subsequent analyses if there was underutilization of a response option. Principal component analysis was performed to assess dimensionality of the individual components. If any of the components was found to be multidimensional, items were removed until it became unidimensional.

For each identified factor (by age group), we then evaluated differential item functioning, fit (outside a range of 0.7 to 1.3), targeting, and local dependence (outside a range of

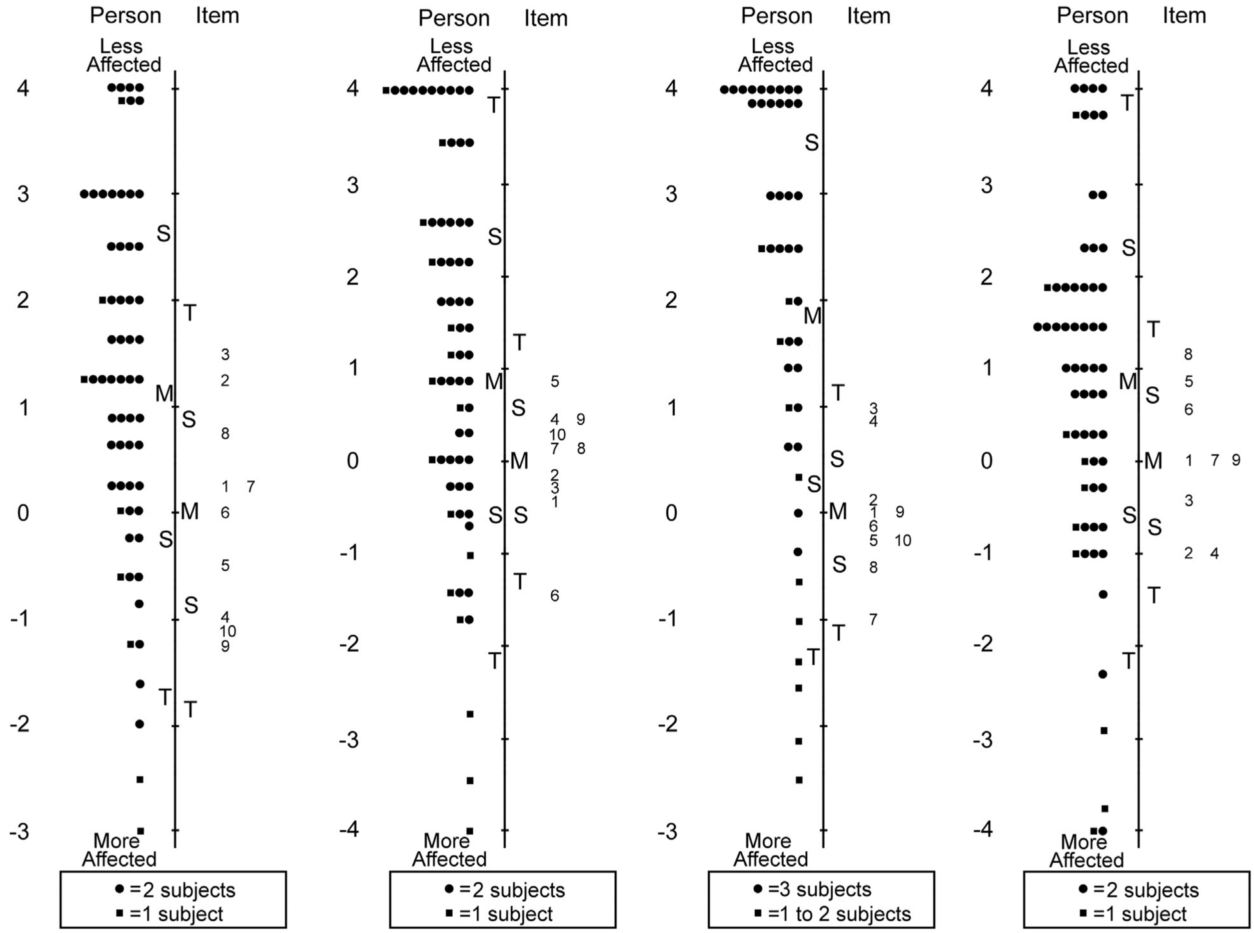

FIGURE 2. Person-item maps for the Child 12 to 17 Years Old Pediatric Eye Questionnaires: (First column) 10 items in a functional vision domain, (Second column) 10 items in a bothered by eyes/vision domain, (Third column) 10 items in a social domain, and (Fourth column) 9 items in a frustration/worry domain (see Table 4 for items). Items higher on the scale are less frequently endorsed as "never."

-0.5 to 0.5). We prioritized removal of items owing to differential item functioning (Child/Proxy questionnaires: child sex [male vs female]; child race/ethnicity [non-Hispanic white vs other]; Proxy/Parent questionnaires: person completing [mother vs not mother]; Parent questionnaires: parent race/ethnicity [non-Hispanic white vs other]). Items with a differential item functioning contrast of >1.0 logit were removed. We also iteratively reviewed the Rasch maps to decide which items to remove and which to retain, with the aim of achieving a good spread across item difficulty and to maintain optimal targeting. Item removal continued through iterative reevaluation of Rasch indices and review of the Rasch maps until we arrived at 10 or fewer items per factor, optimizing person and item separation indices (aim ≥2.0) and person and item reliability indices (aim ≥0.8). If a factor had fewer than 10 items from the outset, we removed items for multidimensionality and differential item functioning but accepted some degree of misfit and somewhat suboptimal targeting overall. Unidimensionality of each factor was reconfirmed once a final set of items had been derived.

RESULTS

• **PHASE 1: CREATING MASTER QUESTIONNAIRES:** The predetermined criteria for eliminating questions were applied to the 462 functional vision and general ER-QOL questions in the Child and Proxy item pool[1] (152 treatment-related questions not included in the current study). The predetermined criteria were also applied to the 367 general ER-QOL questions in the Parent item pool[1] (222 treatment-related questions not included in

TABLE 5. Rasch Indices for Each Unidimensional Domain Within Each Questionnaire, by Age Group

	Separation		Reliability		
	Person	Item	Person	Item	Mean Person Measure
Child 5-11 years					
Functional vision	1.55	2.86	0.71	0.89	1.47
Bothered by eyes/vision	1.33	3.07	0.64	0.90	1.67
Social	1.00	4.06	0.50	0.94	2.10
Frustration/worry	1.27	3.19	0.62	0.91	1.56
Child 12-17 years					
Functional vision	1.91	4.40	0.78	0.95	1.18
Bothered by eyes/vision	1.81	2.83	0.77	0.89	0.88
Social	1.43	2.04	0.67	0.81	1.88
Frustration/worry	1.99	3.43	0.80	0.92	0.87
Proxy 0-4 years					
Functional vision	2.11	4.30	0.82	0.95	1.73
Bothered by eyes/vision	1.81	3.92	0.77	0.94	3.08
Social	0.95	3.85	0.48	0.94	5.16
Proxy 5-11 years					
Functional vision	2.39	4.06	0.85	0.94	1.49
Bothered by eyes/vision	1.91	4.84	0.78	0.96	3.34
Social	1.35	2.22	0.65	0.83	2.59
Frustration/worry	1.15	2.16	0.57	0.82	3.22
Eye-care	1.40	2.48	0.66	0.86	1.32
Proxy 12-17 years					
Functional vision	2.30	5.40	0.84	0.97	1.51
Bothered by eyes/vision	2.24	3.91	0.83	0.94	1.38
Social	1.97	3.78	0.79	0.93	2.84
Frustration/worry	2.03	2.46	0.81	0.86	2.40
Eye-care	1.25	3.58	0.61	0.93	2.95
Parent					
Impact on parent and family	1.27	4.99	0.62	0.96	3.20
Worry about child's eye condition	2.27	6.64	0.84	0.98	0.15
Worry about self-perception/interactions	1.96	7.17	0.79	0.98	0.86
Worry about functional vision	2.02	8.70	0.80	0.99	1.70

the current study). Child (and parallel Proxy) questions were reduced to 63 items for a master questionnaire (399 eliminated), and Parent questionnaires were reduced to 47 items for a master questionnaire (320 eliminated).

• **PHASE 2: ADMINISTERING MASTER QUESTIONNAIRES:** Four hundred and forty-four children were enrolled, along with 1 of their parents, to complete master questionnaires. All parents completed Proxy and Parent master questionnaires (83% mothers, 16% fathers, 1% legal guardians), and 277 5- to 17-year-old children completed Child master questionnaires (22 [8%] 5- to 17-year-old children were unable to complete the questionnaires owing to cognitive impairment). Demographics of enrolled children and their parents are provided in Table 1: 220 of 444 children (50%) were male, and race/ethnicity was non-Hispanic white for 296 (67%). One hundred and sixty-seven (38%) children were 0-4 years old, 156 (35%) were 5-11 years old, and 121 (27%) were 12-17 years old (Table 1). The numbers of children in each primary diagnostic category, along with associated diagnostic categories, are shown in Table 2.

• **PHASE 3: DEVELOPING PEDIATRIC EYE QUESTIONNAIRE MODULES:** *Factor Analysis.* For Child, Proxy, and Parent master questionnaires, no items were removed in the master questionnaire item reduction phase (>10% missing, ≥20% questions "not applicable," >10% found questions unclear or confusing). Factor analysis was then performed, yielding unidimensional domains described below for Rasch analysis.

Rasch Analysis. Child Questionnaires

Analysis of both Child 5- to 11-year-old and Child 12- to 17-year-old items showed that 1 response category ("most of the time") was consistently underutilized, and therefore

TABLE 6. Proxy 0- to 4-Year-Old Pediatric Eye Questionnaires

PedEyeQ-Functional vision: Proxy 0-4 years

1. Do your child's eyes make it hard for them to learn?
2. Does your child have a hard time seeing?
3. Are there certain things your child can't do because of their eyes?
4. Does your child need help with certain things because of their eyes?
5. Does your child have to do things differently than other people because of their eyes?
6. Do your child's eyes make it hard for them to concentrate?
7. Do your child's eyes make it hard for them to do certain things?
8. Is it hard for your child to play/interact with others because of their eyes?
9. Is it hard for your child to see steps when they walk?
10. Does your child run into things because of their eyes?

PedEyeQ-Bothered by eyes/vision: Proxy 0-4 years

1. Does it bother your child that they need help with certain things because of their eyes?
2. Does it bother your child because they have to do things differently than other people because of their eyes?
3. Does it bother your child because their eyes make it hard to learn?
4. Does it bother your child because they have a hard time seeing?
5. Does it bother your child that they can't do certain things because of their eyes?
6. Does it bother your child because their eyes make it hard to concentrate?
7. Does it bother your child because their eyes make it hard to do certain things?
8. Does it bother your child to have to do certain things to help them see better?
9. Is your child bothered by the things they have to do to make their eyes better?
10. Does your child get upset because of their eyes?

PedEyeQ-Social: Proxy 0-4 years

1. Does it bother your child that bright light makes it hard to do things outside?
2. Is your child bothered by how their eyes look?
3. Do your child's eyes make them feel unsure of themself?
4. Does your child feel "different" because of their eyes?
5. Does it bother your child that they get extra attention because of their eyes?
6. Does it bother your child when people look/stare at them because of their eyes?
7. Is it hard for your child to make friends because of their eyes?
8. Is your child shy because of their eyes?
9. Does your child feel left out because of their eyes?

PedEyeQ = Pediatric Eye Questionnaire.

Formatted questionnaires with response options, instructions, and Rasch scoring are freely available at www.pedig.net. Each domain can be administered separately or in any combination, and is scored separately.

the response scale was collapsed to 3 response options for subsequent analyses, combining "most of the time" with "sometimes." After removing 23 of 63 items for either misfit or differential item functioning, and/or to improve targeting, the final Child 5- to 11-year-old Pediatric Eye Questionnaires (PedEyeQ) had 4 unidimensional domains: 10 of 18 items in functional vision, 10 of 22 in bothered by eyes/vision, 10 of 12 in social, and 10 of 11 in frustration/worry (Table 3 and Figure 1).

For the Child 12- to 17-year-old PedEyeQ, 24 of 63 items were removed across 4 unidimensional domains, retaining 10 of 18 items in functional vision, 10 of 21 in bothered by eyes/vision, 10 of 15 in social, and 9 of 9 in frustration/worry (Table 4 and Figure 2). Separation and reliability indices for both Child 5- to 11-year-old and 12- to 17-year-old questionnaires are shown in Table 5. Formatted questionnaires and look-up tables with Rasch scoring for Child 5- to 11-year-old and 12- to 17-year-old PedEyeQs are freely available at www.pedig.net.

Proxy Questionnaires

Across all Proxy questionnaires (0-4, 5-11, and 12-17 years) the response "most of the time" was consistently underutilized, and therefore the scale was collapsed to 3 response options, combining "most of the time" with "sometimes." After further Rasch analysis of the Proxy 0- to 4-year-old questionnaire, 18 of 47 items were removed across 3 unidimensional domains, retaining 10 of 14 items in functional vision, 10 of 19 in bothered by eyes/vision, and 9 of 14 in social (Table 6 and Figure 3).

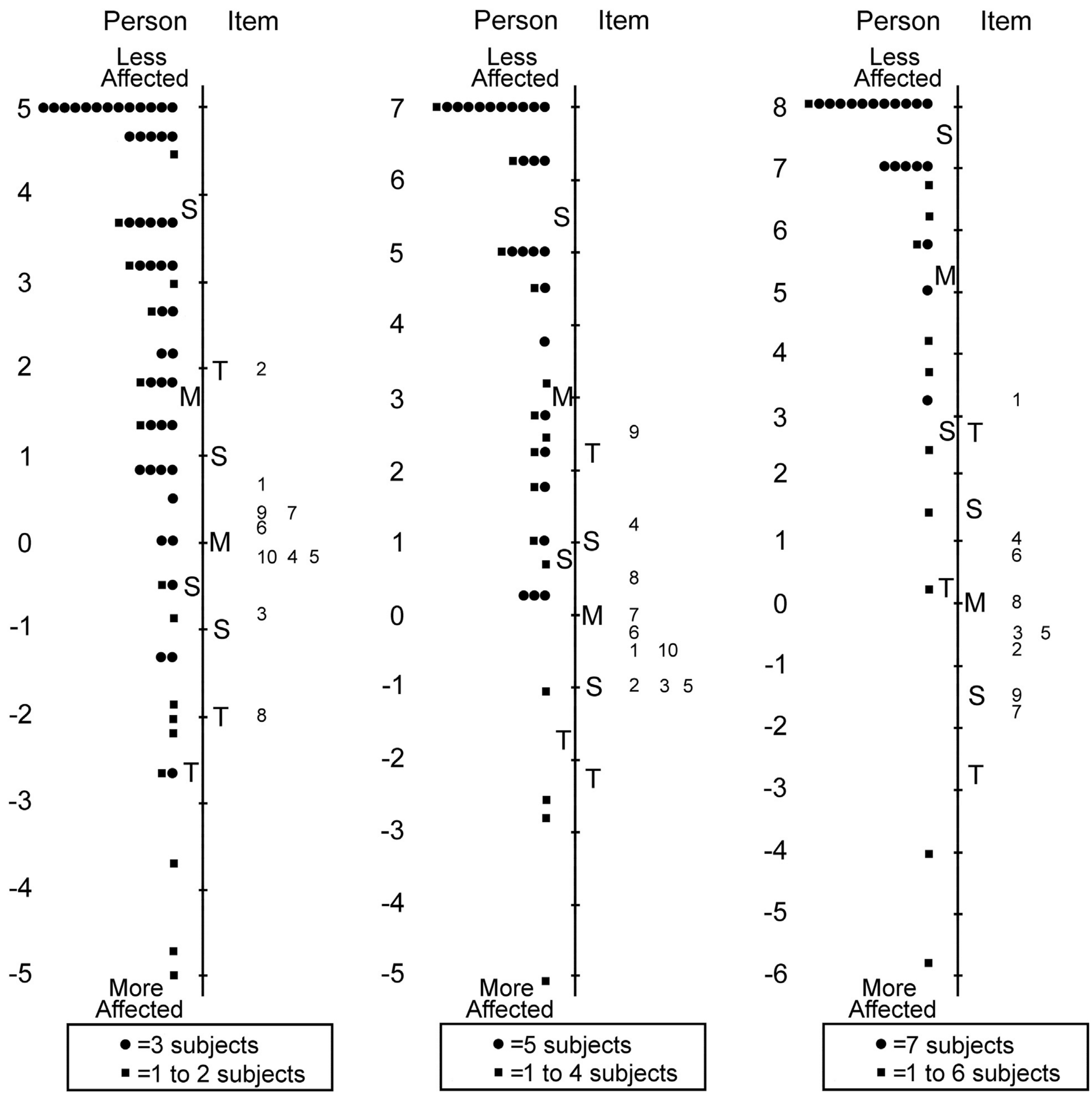

FIGURE 3. Person-item maps for the Proxy 0 to 4 Years Old Pediatric Eye Questionnaires: (First column) 10 items in a functional vision domain, (Second column) 10 items in a bothered by eyes/vision domain, and (Third column) 9 items in a social domain (see Table 6 for items). Items higher on the scale are less frequently endorsed as "never."

For Proxy 5- to 11-year-old items, 24 of 63 items were removed across 5 unidimensional domains, retaining 10 of 18 items in functional vision, 10 of 23 in bothered by eyes/vision, 8 of 11 in social, 5 of 5 in frustration/worry, and 6 of 6 in eye care (Table 7 and Figure 4).

For Proxy 12- to 17-year-old items, 21 of 63 items were removed across 5 unidimensional domains, retaining 10 of 18 items in functional vision, 10 of 19 in bothered by eyes/vision, 8 of 12 in social, 8 of 8 in frustration/worry, and 6 of 6 in eye care (Table 8 and Figure 5). Separation and reliability indices for Proxy 0- to 4-year-old, 5- to 11-year-old, and 12- to 17-year-old questionnaires are shown in Table 5. Formatted questionnaires and look-up tables with Rasch scoring for Proxy 0- to 4-year-old, 5- to 11-year-old, and 12- to 17-year-old PedEyeQs are freely available at www.pedig.net.

Parent Questionnaires

For Parent questionnaires the "most of the time" response option was once again underutilized, and

TABLE 7. Proxy 5- to 11-Year-Old Pediatric Eye Questionnaires

PedEyeQ-Functional vision: Proxy 5-11 years
1. Do your child's eyes make it hard for them to play sports?
2. Does your child have a hard time seeing?
3. Are there certain things your child can't do because of their eyes?
4. Does your child need help with certain things because of their eyes?
5. Does your child have to do things differently than other people because of their eyes?
6. Do your child's eyes make it hard for them to concentrate?
7. Do your child's eyes make it hard to do certain things?
8. Is it hard for your child to see the board at school?
9. Does your child run into things because of their eyes?
10. Do your child's eyes get tired easily?
PedEyeQ-Bothered by eyes/vision: Proxy 5-11 years
1. Does it bother your child because they have to do things differently than other people because of their eyes?
2. Does it bother your child because their eyes make it hard to play sports?
3. Does it bother your child because they have a hard time seeing?
4. Does it bother your child to need special help at school because of their eyes?
5. Does it bother your child that they can't do certain things because of their eyes?
6. Does it bother your child that they run into things because of their eyes?
7. Does it bother your child because their eyes get tired easily?
8. Does it bother your child because their eyes make it hard to do certain things?
9. Does it bother your child that it's hard to play/interact with others because of their eyes?
10. Does your child feel left out because of their eyes?
PedEyeQ-Social: Proxy 5-11 years
1. Do your child's eyes make them feel unsure of themself?
2. Does it bother your child when other people say things or ask questions about their eyes?
3. Does your child feel "different" because of their eyes?
4. Does it bother your child that they get extra attention because of their eyes?
5. Does it bother your child when people look/stare at them because of their eyes?
6. Does your child get teased because of their eyes?
7. Does your child worry about what other people think about them because of their eyes?
8. Does your child worry about getting teased because of their eyes?
PedEyeQ-Frustration/worry: Proxy 5-11 years
1. Is your child frustrated because their eyes aren't getting better?
2. Does your child worry about their eyes getting worse?
3. Does your child worry that their eyes will make it hard to do things when they're older?
4. Does your child worry about not being able to do things because of their eyes?
5. Does your child worry about their eyes?
PedEyeQ-Eye care: Proxy 5-11 years
1. Does it bother your child to have to protect their eyes?
2. Does it bother your child to have to do certain things to help them see better?
3. Is your child bothered by the things they have to do to make their eyes better?
4. Does your child hate going to the eye doctor?
5. Is taking care of their eye condition hard for your child?
6. Does your child worry about what they might have to do to make their eyes better?

PedEyeQ = Pediatric Eye Questionnaire.

Formatted questionnaires with response options, instructions, and Rasch scoring are freely available at www.pedig.net. Each domain can be administered separately or in any combination, and is scored separately.

therefore the response scale was collapsed to 3 response options, combining "most of the time" with "sometimes." After further Rasch analysis of Parent questionnaires, 12 of 47 items were removed across 4 unidimensional domains, retaining 10 of 19 items in impact on parent, 10 of 13 in worry about child's eye condition, 7 of 7 in worry about child's self-perception/interactions, and 8 of 8 in worry about child's functional vision (Table 9 and Figure 6). Separation and reliability indices for Parent PedEyeQs are shown in Table 2. Formatted questionnaires and look-up

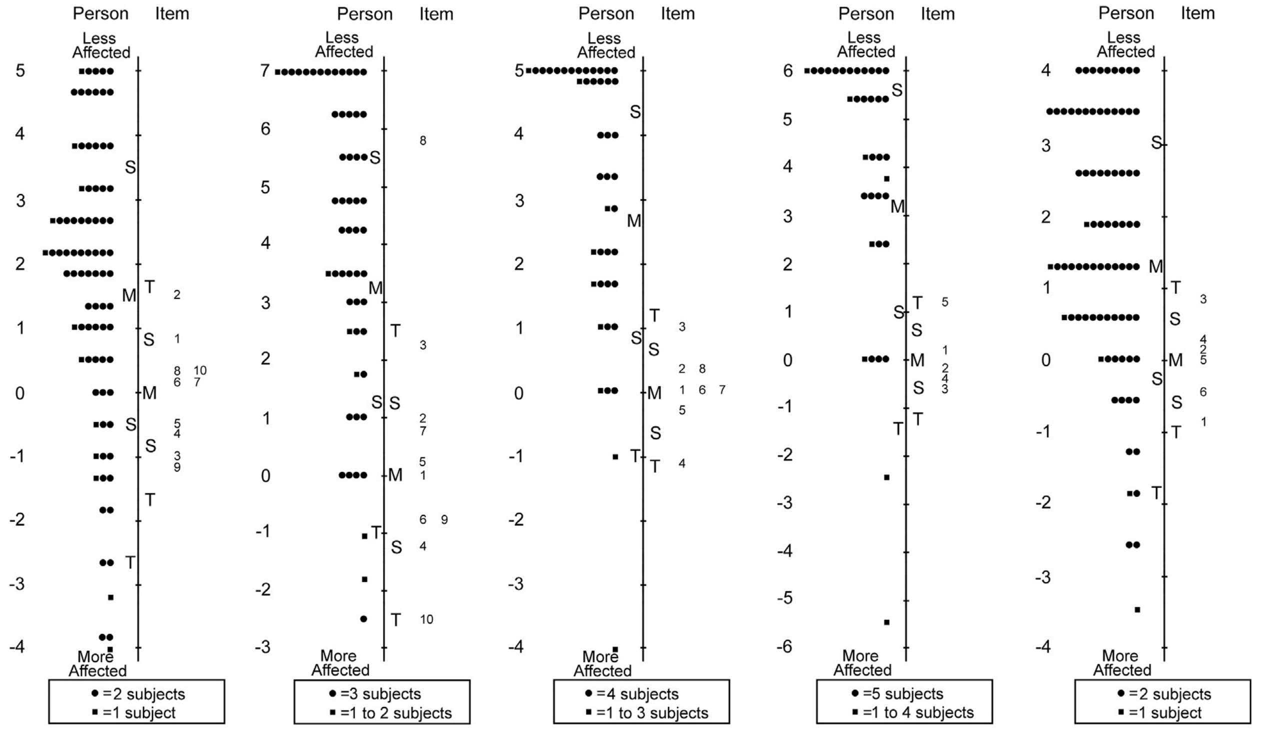

FIGURE 4. Person-item maps for the Proxy 5 to 11 Years Old Pediatric Eye Questionnaires: (First column) 10 items in a functional vision domain, (Second column) 10 items in a bothered by eyes/vision domain, (Third column) 8 items in a social domain, (Fourth column) 5 items in a frustration/worry domain, and (Fifth column) 6 items in an eye care domain (see Table 7 for items). Items higher on the scale are less frequently endorsed as "never."

tables with Rasch scoring are freely available at www.pedig.net.

DISCUSSION

USING RIGOROUS QUESTIONNAIRE DEVELOPMENT methods, we have created new PedEyeQs, with Child, Proxy, and Parent components, for use across the entire spectrum of childhood eye conditions. The PedEyeQs have been designed to enable age-appropriate assessment of the impact of any eye condition on the functional vision and ER-QOL of the children themselves (self-report and proxy), as well as the impact on the parent, with individual, separately scored domains that can be administered alone or in any combination, depending on clinical and/or research needs. By making the PedEyeQ questions, short forms, and Rasch scoring system freely available to the community, we hope to improve assessment and reporting of how various eye conditions affect children and their families in everyday life.

Existing pediatric questionnaires have been designed either as generic instruments (eg, the PedsQL[24,25]) or for specific eye conditions (eg, uveitis,[7,26] conjunctivitis,[8] amblyopia[10,11,17,18,27]) or for low vision.[12–14,16,20,28–30] While we recognize a role for evaluating concerns peculiar to a certain disease, as well as a role for evaluating more general quality-of-life concerns, we identified a need for instruments that would allow evaluation of eye-related concerns without being disease-specific, and would therefore be applicable across the entire spectrum of childhood eye conditions. By initially deriving potential questionnaire items from interviews with a large cohort of children with a diverse range of eye disorders,[1,3,4,6] and then using rigorous item-reduction methods, we believe the new PedEyeQs provide such a means of evaluating the functional vision and ER-QOL impact of any childhood eye disorder. In future studies the PedEyeQ domains will be evaluated for construct validity, reliability, and responsiveness and compared with other instruments.

It is impractical to administer a large number of questionnaire items to children; many have a limited attention span, making administration of more than 40-50 questions

TABLE 8. Proxy 12- to 17-Year-Old Pediatric Eye Questionnaires

PedEyeQ-Functional vision: Proxy 12-17 years

1. Do your child's eyes make it hard for them to play sports?
2. Does your child have a hard time seeing?
3. Does your child need special help at school because of their eyes?
4. Does your child have to do things differently than other people because of their eyes?
5. Do your child's eyes make it hard for them to concentrate?
6. Do your child's eyes make it hard to do certain things?
7. Is it hard for your child to play/interact with others because of their eyes?
8. Is it hard for your child to see steps when they walk?
9. Does your child run into things because of their eyes?
10. Do your child's eyes get tired easily?

PedEyeQ-Bothered by eyes/vision: Proxy 12-17 years

1. Does it bother your child that they need help with certain things because of their eyes?
2. Does it bother your child because they have to do things differently than other people because of their eyes?
3. Does it bother your child because their eyes make it hard to learn?
4. Does it bother your child because their eyes make it hard to play sports?
5. Does it bother your child because they have a hard time seeing?
6. Does it bother your child that they run into things because of their eyes?
7. Does it bother your child because their eyes get tired easily?
8. Does it bother your child because their eyes make it hard to concentrate?
9. Does it bother your child because they have trouble reading close-up?
10. Does it bother your child because it's hard to see the board at school?

PedEyeQ-Social: Proxy 12-17 years

1. Is your child bothered by how their eyes look?
2. Do your child's eyes make them feel unsure of themself?
3. Does it bother your child when other people say things or ask questions about their eyes?
4. Does it bother your child when people look/stare at them because of their eyes?
5. Is it hard for your child to make friends because of their eyes?
6. Is your child shy because of their eyes?
7. Does your child worry about what other people think about them because of their eyes?
8. Does your child worry about getting teased because of their eyes?

PedEyeQ-Frustration/worry: Proxy 12-17 years

1. Does your child get upset because of their eyes?
2. Is your child frustrated because their eyes aren't getting better?
3. Does your child worry about getting hurt because of their eyes?
4. Does your child worry about their eyes getting worse?
5. Does your child worry that their eyes will make it hard to do things when they're older?
6. Does your child worry about not being able to do things because of their eyes?
7. Does your child worry about their eyes?
8. Does your child worry about what they might have to do to make their eyes better?

PedEyeQ-Eye care: Proxy 12-17 years

1. Does your child hate going to the eye doctor?
2. Is taking care of their eye condition hard for your child?
3. Does it bother your child because their eyes hurt?
4. Does it bother your child that they get extra attention because of their eyes?
5. Does your child's eye condition cause problems in your family?
6. Do other people get frustrated with your child because of their eyes?

PedEyeQ = Pediatric Eye Questionnaire.

Formatted questionnaires with response options, instructions, and Rasch scoring are freely available at www.pedig.net. Each domain can be administered separately or in any combination, and is scored separately.

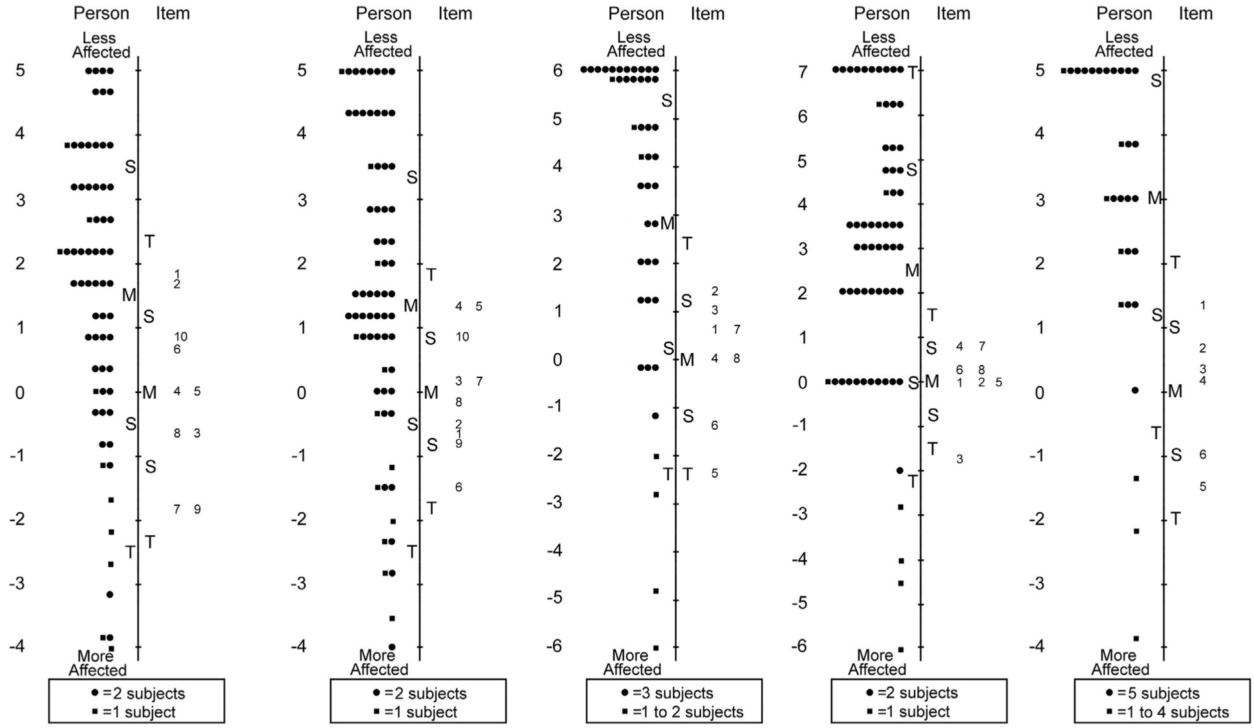

FIGURE 5. Person-item maps for the Proxy 12 to 17 Years Old Pediatric Eye Questionnaires: (First column) 10 items in a functional vision domain, (Second column) 10 items in a bothered by eyes/vision domain, (Third column) 8 items in a social domain, (Fourth column) 8 items in a frustration/worry domain, and (Fifth column) 6 items in an eye care domain (see Table 8 for items). Items higher on the scale are less frequently endorsed as "never."

unrealistic, particularly in a clinical setting. Various strategies can be adopted to reduce a large number of items to a smaller representative sample. We elected to use Rasch analysis to identify which items to exclude, in order to retain 10 items or fewer per unidimensional domain. We found that for older children and for parents, this approach to item reduction typically resulted in a final set of questions that had the desired precision as assessed by Rasch parameters. Nevertheless, for younger children we had several examples of relatively poor targeting and relatively low precision even before any items were removed. Published target Rasch indices[31,32] are based on typical performance in adult populations, and it is likely that these thresholds are unrealistic for young children.

There are some limitations to our study. Although we recruited a large, diverse cohort of children and parents to complete master questionnaires, we may have underrepresented certain socioeconomic and cultural groups, and final selection of items might have been different had we tested master questionnaires in other patient populations. Nevertheless, we included children and parents across a spectrum of socioeconomic, racial, and ethnic groups. In addition, some children had coexisting systemic health conditions, and the presence of such may have influenced responses. Nevertheless, we consistently used the qualifier "because of your eyes," and such responses are representative of children with eye conditions who have additional health concerns. We identified ER-QOL constructs using a data-driven approach, performing factor analysis and then labeling factors according to item content. However, alternative approaches include determining constructs a priori, and we may have created different constructs had we used this approach. We provide Rasch-based scoring look-up tables for derived questionnaires, but these scores were derived from our specific study population and scoring may differ in other populations, where a de novo Rasch analysis may be preferable.

By following a rigorous approach to questionnaire development and refinement, we have developed sets of Pediatric Eye Questionnaire short forms for separately assessing

TABLE 9. Parent Pediatric Eye Questionnaires

PedEyeQ - Impact on parent and family: Parent
1. Do you feel different from other parents because of your child's eye condition?
2. Does taking care of your child's eye condition cause stress on your family?
3. Is it difficult to ensure that your child receives the help they need because of their eye condition?
4. Is it hard because you need to be more involved in your child's schooling because of their eye condition?
5. Does it bother you to have to change how you do things because of your child's eye condition?
6. Does it bother you that you can't do certain things because of your child's eye condition?
7. Is it hard because it takes extra time to do things because of your child's eye condition?
8. Is it hard work having to explain your child's eye condition to others?
9. Is it hard because you have to attend frequent eye exams for your child?
10. Is it hard because your child needs more supervision because of their eye condition?
PedEyeQ-Worry about child's eye condition: Parent
1. Does it bother you that your child has an eye condition?
2. Does it bother you that your child doesn't see well out of one or both eyes?
3. Does it bother you that your child's eye condition causes physical discomfort?
4. Do you worry about your child getting upset because of their eye(s)?
5. Do you worry about your child's eye condition getting worse?
6. Do you worry about your child's future because of their eye condition?
7. Do you worry about protecting your child's eye(s)?
8. Do you worry about your child's safety because of their eye condition?
9. Do you worry about the treatment(s) your child may need for their eye condition?
10. Do you worry that you don't fully understand your child's eye condition?
PedEyeQ-Worry about self-perception and interactions: Parent
1. Are you bothered by your child's appearance because of their eye condition?
2. Does it bother you when others say things about your child's eye condition?
3. Does it bother you when others look/stare at your child because of their eye condition?
4. Do you worry about your child being "different" because of their eye condition?
5. Do you worry about your child getting teased because of their eye condition?
6. Do you worry about your child's eye condition affecting them socially?
7. Do you worry about your child's self-esteem because of their eye condition?
PedEyeQ-Worry about functional vision: Parent
1. Does it bother you that your child can't do certain things because of their eye condition?
2. Do you worry about your child being unable to do certain things because of their eye condition?
3. Do you worry about your child having a hard time reading because of their eye condition?
4. Do you worry about your child's eye condition affecting their development?
5. Do you worry about your child's eye condition affecting their learning?
6. Do you worry about your child's depth perception?
7. Does it bother you when others aren't patient with your child's eye-related needs?
8. Is it hard because your child's eye condition affects their behavior?

PedEyeQ = Pediatric Eye Questionnaire.

Formatted questionnaires with response options, instructions, and Rasch scoring are freely available at www.pedig.net. Each domain can be administered separately or in any combination, and is scored separately.

functional vision and individual ER-QOL domains in children of any age and with any eye condition. In future phases of this study these questionnaires will undergo reliability and validity testing in a new cohort of patients, and we will also separately report the development of treatment-related questionnaires.

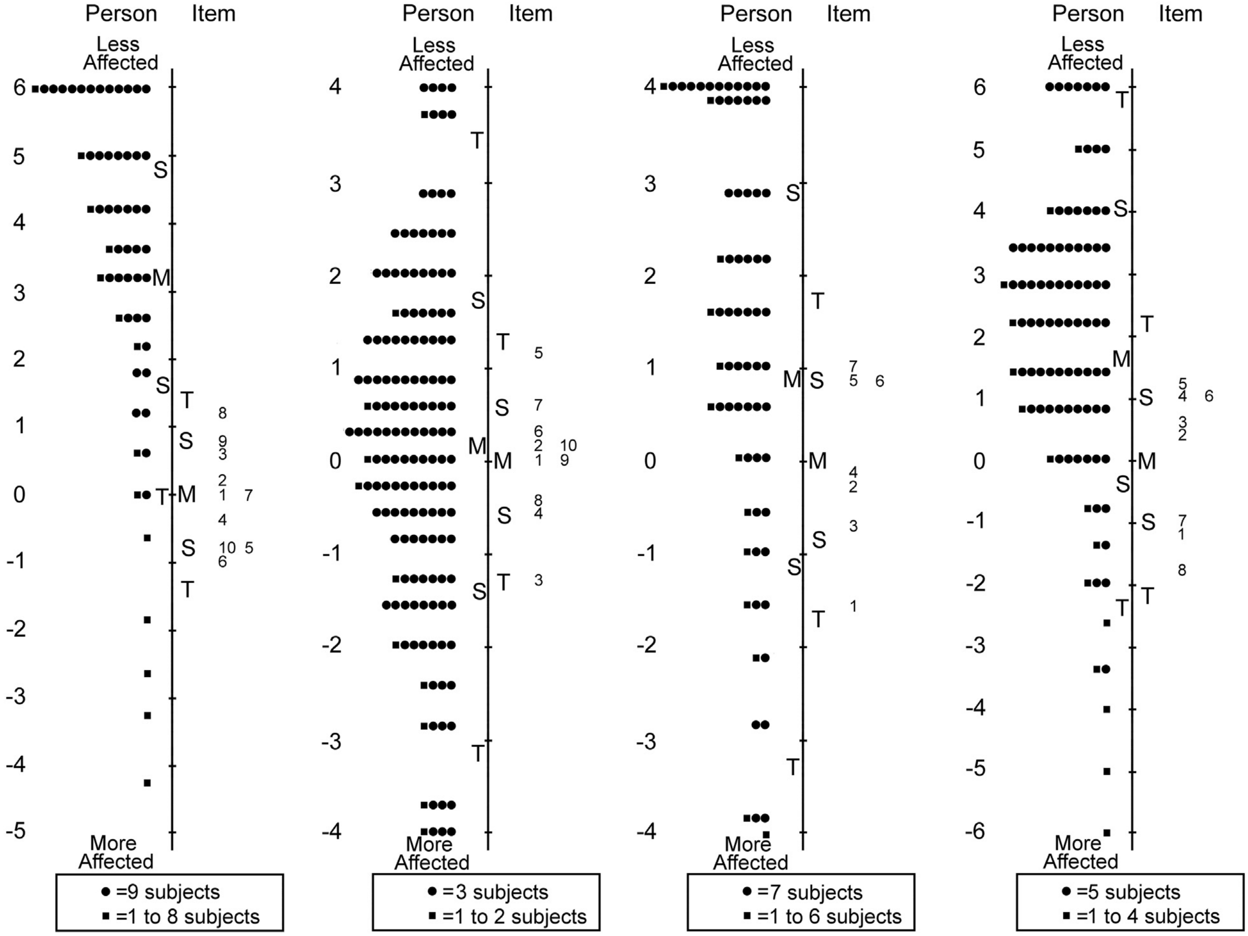

FIGURE 6. Person-item maps for the Parent Pediatric Eye Questionnaires: (First column) 10 items in an impact on the parent and family domain, (Second column) 10 items in a worry about the child domain, (Third column) 7 items in a worry about the child's self-perception/interactions domain, and (Fourth column) 8 items in a worry about the child's functional vision domain (see Table 9 for items). Items higher on the scale are less frequently endorsed as "never."

FUNDING/SUPPORT: FINANCIAL ASSISTANCE FOR THIS STUDY CAME FROM NATIONAL INSTITUTES OF HEALTH GRANTS EY024333 (J.M.H., P.I., E.E.B., Co-Investigators) and EY022313 (E.E.B.), and Mayo Foundation, Rochester, Minnesota, USA. Financial Disclosures: The following authors have no financial disclosures: Sarah R. Hatt, David A. Leske, Yolanda S. Castañeda, Suzanne M. Wernimont, Laura Liebermann, Christina S. Cheng-Patel, Eileen E. Birch, and Jonathan M. Holmes. All authors attest that they meet the current ICMJE criteria for authorship.

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