Development of the National Eye Institute Refractive Error Quality of Life Instrument (NEI-RQL-42)

Ron D. Hays, UCLA/RAND March 20, 2002

www.gim.med.ucla.edu/Faculty/Pages/Hays/ (hays@rand.org)

Co-Investigators

- Peter McDonnell, UC Irvine/USC
- Sandra Berry, RAND
- Carol Mangione, UCLA
- Karen Spritzer, UCLA
- Leon Ellwein, NEI
- Anne Lindblad, EMMES
- Paul Lee, Duke

NEI-RQL-42 Site Investigators

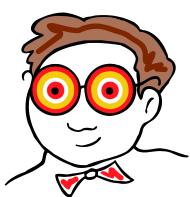
- Cynthia Owsley, U Alabama Birmingham
- David Hwang, UCSF
- Loretta Szczotka, Case Western
- Robert Kennedy, Southwestern—U of Texas
- Steven Schallhorn, Naval Medical Center
- Rhett Schiffman, Henry Ford Health System

Technical Advisory Group

- Richard Abbott, UCSF
- Anthony Adams, UC Berkeley
- Ralph Rosenthal, FDA
- Sally Shumaker, Bowman Gray
- Robert Sperduto, NEI
- Anita Stewart, UCSF

4-Year History of NEI-RQL-42

- December 1997--> March 1998
- 52 focus groups at 5 academic medical centers
 - University of Alabama, Birmingham
 - Massachusetts Eye and Ear Infirmary, Boston
 - University of Illinois, Chicago
 - UCSF
 - USC
- 414 participants with myopia or hyperopia
- Berry, S. et al. (submitted for publication)



History (continued)

- June 1998 TAC meeting suggestions
- Survey revised and re-circulated
- Revised again and 20 cognitive interviews
- Revised into 94-item pilot survey (n = 221)
- January 1999 TAC meeting
- Revised into 63-item field test survey

Field Test Design

- June 1999 -> October 2000
- 6 medical centers
 - University of Alabama, Birmingham
 - UCSF
 - Henry Ford, Detroit
 - University of Texas Southwestern Medical Center
 - Naval Medical Center, San Diego
 - Case Western Reserve University, Cleveland

Inclusion and Exclusion Criteria

- Inclusion criteria:
 - 18 years or older; read English
 - 20/32 or better visual acuity in worse eye with correction
 - Using current form of correction for 3+ months
- Exclusion criteria:
 - Chronic ocular disease or kerato-conjunctivitis sicca
 - Diabetes
 - Cognitive impairment
 - Unable to walk up stairs unassisted
 - Neurologic disease that limits activities

Sample Characteristics

- 665 Myopes; 375 Hyperopes; 114 Emmetropes
- N = 1154 (7 refused: 2 myopes, 5 hyperopes)
- 278 test-retest; 286 NEI VFQ-25 and SF-36
- 185 completed pre-post keratorefractive surgery
- <u>61%</u> female
- 69% white; 16% AA; 9% Asian; 4% Hispanic, 2% other
- Mean age = 44 (range = 18-81)
- 86% at least some college; \$15k-50k median income
- 76% working full-time

Sample Characteristic (cont.)

- Myopia (better eye)
 - -42% < 3.0 diopters
 - -13% > 6.0 diopters
- Hyperopia (better eye)
 - -84% < 2.5 diopters

Measures

- Uncorrected and corrected near and distance visual acuity (monocular and binocular)
 - ETDRS charts
- Refractive error and spherical equivalent

What's a Good Measure?

• Same person gets same score (reliability)

• Different people get different scores (validity)

• People get scores you expect (validity)

• It is practical (feasibility)

Variability

- All scale levels are represented
- Distribution approximates bell-shaped "normal"



Error in Measures

Sources of Variance in Reliability Formulas

Source	dfs	MS	
People (N)	9	628.67	(BMS)
Within	10	17.70	(WMS)
Items or raters (K)	1	57.80	(JMS)
People x Items/rate	er 9	13.24	(EMS)
Total	19		

Intraclass Correlation and Reliability

Model	Reliability	Intraclass Correlation
One-Way	MS _{BMS} - MS _{WMS}	MS_{BMS} - MS_{WMS}
	MS BMS	$MS_{BMS} + (K-1)MS_{WMS}$
Two-Way	MSBMS - MS EMS	MS_{BMS} - MS_{EMS}
Fixed	MS _{BMS}	$MS_{BMS} + (K-1)MS_{EMS}$
Two-Way	$N(MS_{BMS} - MS_{EMS})$	MS_{BMS} - MS_{EMS}
Random	$NMS_{BMS} + MS_{JMS} - MS_{EMS}$	$MS_{BMS} + (K-1)MS_{EMS} + K(MS_{JMS} - MS_{EMS})/N$

13 NEI-RQL-42 Scales

• Clarity of vision (k = 4, alpha = 0.72)

At this time, how clear is your vision using the correction you normally use, including glasses, contact lenses, a magnifier, surgery, or nothing at all?

Perfectly clear; Pretty clear; Somewhat clear; Not clear at all

(http://www.gim.med.ucla.edu/FacultyPages/Hays/NEI.htm)

• Expectations (k = 2, alpha = 0.90)

If you had perfect vision without glasses, contact lenses, or any other type of vision correction, how different would your life be?

No difference; Small difference for the better; Large difference for the better; I have this already

• Near vision (k = 4, alpha = 0.85)

How much difficulty do you have doing work or hobbies that require you to see well up close, such as cooking, fixing things around the house, sewing, using hand tools, or working with a computer?

No difficulty at all; A little difficulty; Moderate difficulty; A lot of difficulty; Never try to do these activities because of vision; Never do these activities for other reasons

• Far vision (k = 5, alpha = 0.81)

How much difficulty do you have judging distances, like walking downstairs or parking a car?

No difficulty at all; A little difficulty; Moderate difficulty; A lot of difficulty

- Diurnal fluctuation (k = 2, alpha = **0.73**)
- Activity limitations (k = 4, alpha = **0.76**)
- Glare scale (k = 2, alpha = 0.75)
- Symptoms (k = 7, alpha =**0.78**)
- Dependence/correction (k = 4, alpha = 0.74)
- Worry (k = 2, alpha = 0.80)
- Suboptimal correction (k = 2, alpha = 0.64)
- Appearance (k = 3, alpha = 0.66)
- Satisfaction with correction (k = 1, r = 0.64)

Reliability Minimum Standards

- For Group Comparisons
 - 0.70+
- For Individual Assessment
 - ().9()+
- Nunnally, J. C., & Bernstein, I. H. (1994). <u>Psychometric theory, 3rd edition</u>. McGraw-Hill.: New York.

Multitrait Scaling Analysis

- Internal consistency reliability
 - Item convergence
- Item discrimination

Fake Multitrait/Multi-Item Correlation Matrix

	Trait #1	<u>Trait #2</u>	<u>Trait #3</u>
• Item #1	0.80*	0.20	0.20
• Item #2	0.80*	0.20	0.20
• Item #3	0.80*	0.20	0.20
• Item #4	0.20	0.80*	0.20
• Item #5	0.20	0.80*	0.20
• Item #6	0.20	0.80*	0.20
• Item #7	0.20	0.20	0.80*
• Item #8	0.20	0.20	0.80*
• Item #9	0.20	0.20	0.80*

^{*}Item-scale correlation, corrected for overlap.

Scoring NEI-RQL-42 Scales

- Average items within scale
- Transform linearly to 0-100 possible range
- 0 = worse HRQOL; 100 = better HRQOL

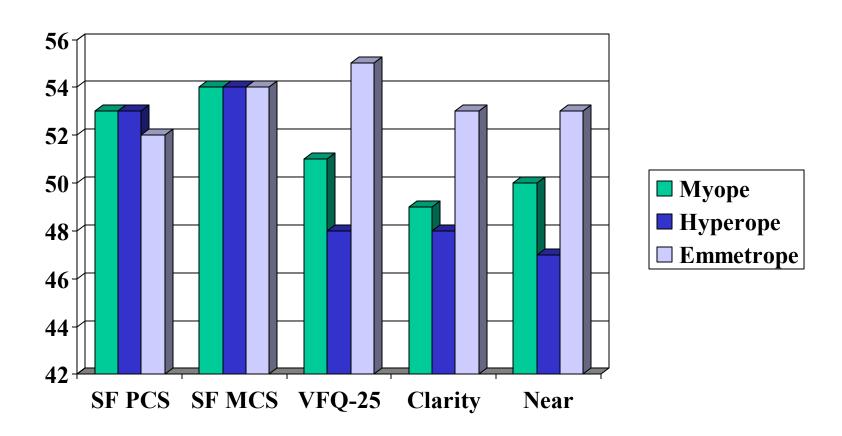
Note: T-scores (mean = 50, SD = 10) used for most of lecture.

NEI-RQL-42 for Myopes, Hyperopes and Emmetropes

- No differences on SF-36
- Emmetropes score significantly better than
 - hyperopes on VFQ-25
 - myopes for 12 and hyperopes for 13 NEI-RQL scales
- Dependence on correction scale most sensitive to differences

Adjusted for age, gender, education, race/ethnicity and work status

HRQOL for Myopes, Hyperopes and Emmetropes

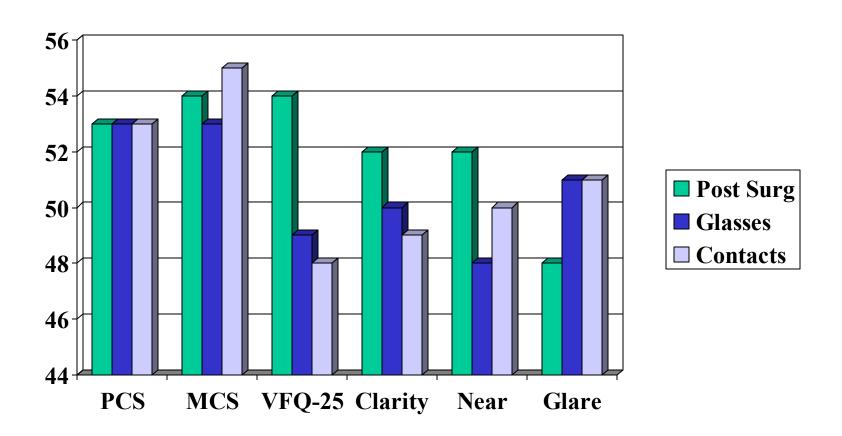


NEI-RQL-42 by Type of Correction

- No differences on SF-36
- No correction significantly better than wearing glasses or contact lenses on
 - VFQ-25
 - 8 of 13 NEI-RQL-42 scales
- Post-surgery no correction group significantly worse on *glare* scale

Adjusted for age, gender, education, race/ethnicity and work status

HRQOL by Type of Correction



NEI-RQL-42 by Spherical Equivalent Refractive Error

- No differences on SF-36 or VFQ-25
- Refractive error among myopes associated with worse scores for several NEI-RQL-42 scores
- Refractive error among hyperopes related to more dependence on correction

Adjusted for age, gender, education, race/ethnicity and work status

Satisfaction with Correction

- How satisfied are you with the glasses, contact lenses, magnifier, or other type of correction (including surgery) you have?
- Completely satisfied; Very satisfied; Somewhat satisfied; Somewhat dissatisfied; Very dissatisfied; Completely dissatisfied
- Variance in satisfaction with correction explained
 - About 27% by SF-36 and VFQ-25
 - Additional 26% by NEI-RQL (53% overall)

Mean Scores of NEI RQL Scales Before and After Surgery (n = 185)

Scale	Before	After	Change	t-statistic	p-value	Ratio of F-statistics
Clarity of vision	83.31	84.95	1.64	1.17	0.2431	0.003
Expectations	14.05	55.81	41.76	13.4	<.0001	0.203
Near vision	78.40	87.72	9.32	5.88	<.0001	0.039
Far vision	81.92	89.38	7.46	6.75	<.0001	0.052
Diurnal fluctuations	72.21	76.62	4.41	2.18	0.0305	0.005
Activity limitations	64.28	93.46	29.18	14.68	<.0001	0.244
Glare scale	74.73	67.09	-7.64	-3.13	0.0020	0.011
Symptoms	78.53	84.76	6.23	4.70	<.0001	0.025
Dependence on correction	26.08	83.85	57.77	29.71	<.0001	1.000
Worry	64.53	77.64	13.11	7.90	<.0001	0.071
Suboptimal correction	86.21	96.55	10.34	5.90	<.0001	0.040
Appearance	64.28	91.79	27.52	10.80	<.0001	0.132
Satisfaction with correction	56.41	82.61	26.20	11.41	<.0001	0.147

Responsiveness to Change (n=185)

Scale	Effect Size (ES)	Standardized Response Mean (SRM)	Responsiveness Statistic (RS)	t-statistic
Clarity of vision	0.11	0.09	0.15	1.17
Expectations	1.77	0.99	1.66	13.40
Near vision	0.45	0.43	0.86	5.88
Far vision	0.53	0.50	0.85	6.75
Diurnal fluctuation	0.19	0.16	0.26	2.18
Activity limitation	1.18	1.08	2.23	14.68
Glare	-0.29	-0.23	-0.38	-3.13
Symptoms	0.36	0.35	0.74	4.70
Dependence on correction	2.29	2.18	2.92	29.71
Worry	0.62	0.58	0.93	7.90
Suboptimal correction	0.46	0.45	0.67	5.90
Appearance	0.90	0.80	1.25	10.80
Satisfaction	1.10	0.84	1.68	11.41

Questions



