

Limitations of Current PRO Measures

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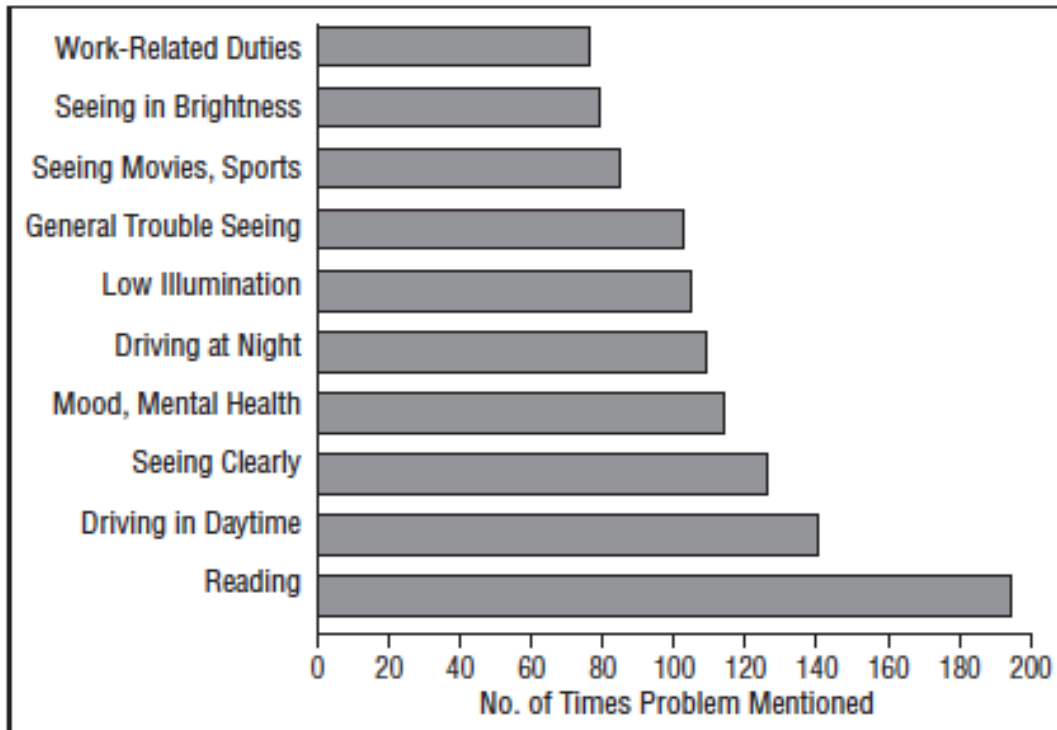
Financial Disclosures

C – Roche Diagnostics, Union Pacific; P – University of Alabama at Birmingham; S – Centers for Disease Control & Prevention, Genentech Inc, National Eye Institute, National Institute on Aging

Issue One.

Focus on visual function may not be sensitive to some of the concerns of patient population

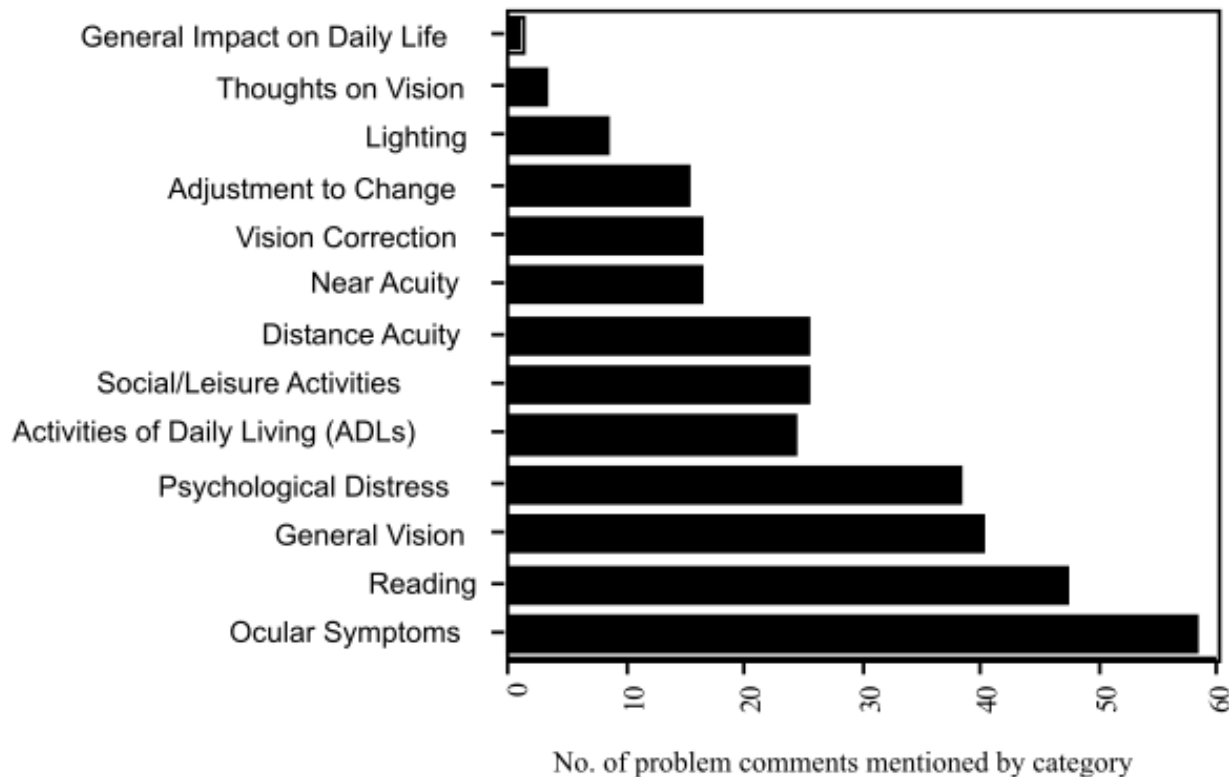
Patients' thoughts, beliefs and attitudes about their vision not just based on VA, CS, VF etc.



- Performing instrumental tasks of daily living.
- Fear, embarrassment.
- Employment.

Mangione, Berry, Spritzer, Janz, Klein, Owsley, Lee.
Arch Ophthalmol 1998; 116:227.

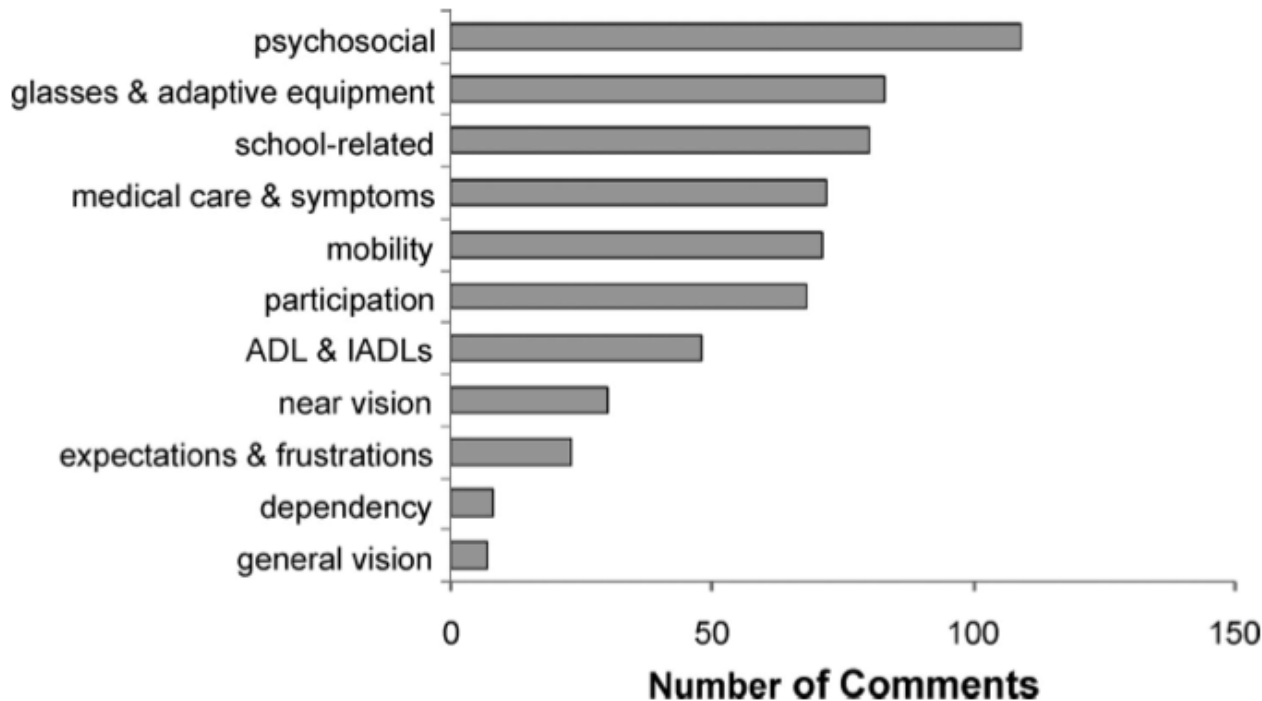
Depends on the subpopulation you ask: Nursing home residents



- Ocular symptoms.
- Psychological distress.
- Basic ADLs.

Scilley, Owsley. *Quality of Life Research* 2002; 11: 449.

Depends on the subpopulation you ask: Children



- Psychosocial.
- Glasses, adaptive devices.
- School issues.
- Mobility

DeCarlo, McGwin, Bixler, Wallander, Owsley.
Optometry & Vision Science 2012; 89: 1409.

Issue Two.

Measurement Scales

Different types of response scales: Difficulty

5. How much difficulty do you have reading ordinary print in newspapers? Would you say you have:

(READ CATEGORIES AS NEEDED)

(Circle One)

- | | |
|--|----------|
| No difficulty at all..... | 1 |
| A little difficulty..... | 2 |
| Moderate difficulty..... | 3 |
| Extreme difficulty..... | 4 |
| Stopped doing this because of your eyesight.... | 5 |
| Stopped doing this for other reasons or not interested in doing this..... | 6 |

Mangione, Lee, Gutierrez, Spritzer, Berry, Hays, NEI VFQ Test Investigators.
Arch Ophthalmol 2001; 119; 1050.

Different types of response scales: Bothersomeness

	Definitely True	Mostly True	Not Mostly Sure	Definitely False	Definitely False
<u>I stay in my room most of the time because of my eyesight.....</u>	1	2	3	4	5
Does this bother you?					
Not at all.....	0				
A little.....	1				
A lot.....	2				

Dreer, McGwin, Scilley, Meek, Dyer, Seker, Owsley.
Aging & Mental Health 2007; 11: 722.

Other measurement scales

- Frequency
- Agree Disagree
- True False
- Choices usually 5 but for children fewer.

Instruments with different response scales may give similar answers.

What do Different Visual Function Questionnaires Measure?

Robert W. Massof and

Lions Vision Research and Rehabilitation Center, Wilmer Eye Institute

ABSTRACT

Purpose: There are dozens of visual function questionnaires, each with different items, item content, and response categories. Do they all measure vision-related functional ability in visually impaired patients? We determined whether four popular VFQs measure the same vision-related functional ability variable in low vision patients. **Methods:** Two of four VFQs (ADVS, NEI-VFQ, VF-14, VAQ) plus the SF-36 were administered to 407 consecutive low vision clinic patients. Thus, each instrument was administered to just over 200 patients, and there were over 67 patients for each of the 6 pairings of VFQs. Separate Rasch analyses were performed on patient responses to each VFQ and to the physical and mental health domains in the SF-36. **Results:** Person measure estimates from the four VFQs were highly correlated. Person measures estimated from the mental health and physical domains of the SF-36 were uncorrelated with each other and with person measures estimated from the VFQs. From principal components analysis we concluded that three factors were necessary and sufficient: the first principal component accounts for 62% of the variance, the other two factors account for 16% and 14% of the variance, respectively. The VFQs load most heavily on the first factor; the mental health component of the SF-36 loads most heavily on the second; and the physical limitations component of the SF-36 loads most heavily on the third. **Conclusions:** The four VFQs measure the same vision-related functional ability variable in low vision patients that is separate from and independent of the physical and mental health variables measured by the SF-36.

“The four visual function questionnaires measure the same vision-related functional ability variable in low vision patients . . .”

Massof, Ahmadian. *Ophthalmic Epidemiology* 2007, 14: 198.

And instruments may or may not perform similarly in different ethnic/racial groups – empirical Q.

Visual Field Defects and Vision-Related Quality of Life in African Americans and Whites With Glaucoma

Lillian Ringsdorf, MD,* Gerald McGwin, Jr, MS, PhD

Purpose: To examine the relationship of visual field impairment to vision-specific health-related quality of life and symptoms in a large cohort (N = 345) of African Americans and Whites of non-Hispanic origin diagnosed with glaucoma.

Materials and Methods: Participants consisted of persons ≥ 55 years of age recruited from university-affiliated ophthalmology

For both African Americans and Whites with primary open angle glaucoma, the NEI VFQ-25 subscales demonstrated good construct validity, and sub scale scores were similar in both racial groups, except for general vision and ocular pain.

diagnosed with African Americans and Whites, the VFQ subscales for the most part demonstrated good construct validity with respect to the extent of visual field impairment. Results imply that the NEI VFQ-25 and the GSS are appropriate instruments for studying the personal burden of glaucoma in studies whose samples involve both African American and White adults.

Ringsdorf, McGwin, Owsley. *J Glaucoma* 2006; 15: 414.

Issue Three.

Novel lens designs may be associated with symptoms that current questionnaires do not assess.

Probably so.

blotchy shadowy hazy
just-can't-see-right vision-is-smearred
halos distance-vision-could-be-clearer
problems-seeing-at-night had-to-give-up-night-driving
something-is-just-weird still-need-readers
washed-out. circles-around-things
cloudy uneven-vision frustrating glare
double-vision unclear blurry

However . . .

- Refractive error correction PRO questionnaires may be useful resource in developing items for novel lens designs – many of the symptom types are similar.

Vitale, Schein, Meinert, Steinberg. *Ophthalmology* 2000; 107: 1529.

Hays, Mangione, Ellwein, Lindblad, Spritzer, McDonnell, NEI-RQL Research Group. *Ophthalmology* 2003; 110: 2292.

Pesudovs, Garamendi, Elliott. *Optometry & Vision Science* 2004; 81: E769

Issue Four.

Patient understanding of medical terminology such as glare, halo etc. may be inadequate or at least different than that of the ophthalmologists and scientists who develop PROs.

Yes. These types of symptoms, particularly “glare,” are complicated both psychologically and scientifically.

- What patients mean by “glare” is unclear.
- However, literature suggests that those who report glare problems on questionnaire more likely to have higher disability glare scores on lab/clinical tests of disability glare.

Example

Impact of cataract surgery on visual difficulties

Comparison with a no-surgery reference group

Gerald McGwin Jr., MS, PhD, Kay Scilley, PhD, Jay Brown, PhD, Cynthia Owsley, PhD, MSPH

Purpose: To examine the impact of cataract surgery on older adults' self-reported visual difficulties and compare them with those of patients with cataract who declined surgery over the same period.

Setting: Twelve area practices.

Methods: This was a consecutive chart review over a 6-month period. Primary inclusion criteria were 55 years or older, cataract in 1 or both eyes with 20/40 visual acuity or worse (best corrected, distance), and no previous cataract surgery in either eye. The Activities of Daily Vision Scale (ADVS) and visual acuity, contrast sensitivity, and disability glare tests were administered at baseline and at a 1-year follow-up visit.

A reduction in disability glare in the second eye was independently linked to increases in . . . the night driving, near vision, and glare disability subscales [of the ADVS].

McGwin, Scilley, Brown, Owsley. *J Cataract Refract Surg* 2003; 29: 941.

A “must read” on Glare.

PERSPECTIVE

Glare's Causes, Consequences, and Clinical Challenges After a Century of Ophthalmic Study

MARTIN A. MAINSTER AND PATRICIA L. TURNER

- **PURPOSE:** To provide a multidisciplinary synthesis of scientific information on disability, discomfort, dazzling, and scotomatic (photostress) glare.

Mainster & Turner. *Am J Ophthalmology*
2012; 153: 587.

Issue Five.

**Concerns about adequacy of development,
testing, and application**

Importance of deriving content from patients

- Begin with focus groups or structured interviews and subsequent content analysis.
- Critical for not only content of items but also for relevant response scales.
- “Expert” opinion can be used but cautiousness needed in straying from or over-riding what the patients are tell you.
- Cognitive interviews about items important.

Who pays for questionnaire development?

- NIH study sections not terribly excited about exercises to develop questionnaires.
- Expense of developing PROs non-trivial.
- Many agencies expect you to have them before the beginning of a project but do not fund the exercise.
- Is it solely industry's responsibility to develop PROs?
- Many scientists use them in many other research contexts, not just in examining safety and efficacy of products.

Issue Six.

Obstacles to incorporating PROs in clinical studies

Some problems

- Take too long to administer
 - A good PRO measure is brief.
- Too much missing data.
 - Good quality control procedures built into MOP avoid this.
- No good PRO instrument for my research question.
 - See previous slide on Who Pays?
- They are too unreliable.
 - If properly designed, they are not.

Frequent misunderstanding about PROs

- Often heard: they don't reflect the actual objective data.
- The proper expectation is that they will be related to clinical and laboratory measures in some modest to moderate way, but they aren't supposed to be strongly related.
- They are meant the patient's perspective, and as such, can't be criticized for not being objective.

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