

Clinical Considerations about Quality of Life Assessments: Implications for Rhinitis Treatment

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- What is QOL
- Why measure QOL in rhinitis?
- How to measure?
- How do QOL assessments compare to other subjective and objective measures of rhinitis?

Quality of Life (QOL)

- Includes multiple factors (eg health, financial security, spiritual contentment), and their interrelation
- Portion of overall QOL that pertains to an individual's health is "health-related quality of life" (HRQL)
 - "Functional effects of an illness and its consequent therapy as perceived by the patient" [Juniper EF. JACI 1997;99:S742-9.](#)

HRQL vs Objective Measures

- Unlike objective clinical measures, HRQL focuses on *patients' perceptions* of their disease and measures impairments that patients consider important.

[Meltzer. JACI 2001;108:S45-53](#)

HRQL vs Subjective Symptom Measures

- Consider: Similar level of symptom severity may have different impact on HRQL in different patients - because individuals vary in their tolerance levels.
- Certain individuals may be significantly bothered by mild AR symptoms, whereas a greater level of nasal symptoms may cause less HRQL impairment in others

[Meltzer. JACI 2001;108:S45-53](#)

QOL Impairments from Rhinitis

- Impairments in ability to conduct and enjoy activities of daily living including sleep
- Work (absenteeism, presenteeism, productivity), school performance, recreation, social and sexual well being
- One goal of therapy should be to reduce QOL impairments that patients consider important.

Meltzer E. Quality of life in rhinitis management. New York:Adelphi, 2001.

Benefits of monitoring health related QOL in allergic rhinitis

1. Uncovering problems that would not otherwise be volunteered
2. Facilitating physician-patient dialog on the subjective aspects of the disease and treatment effects
3. Helping to develop a management strategy that accomplishes more than reducing symptoms
4. Encouraging patient adherence to treatment by the positive feedback of sharing questionnaire results
5. Providing managed care organizations with documentation of the effectiveness of various interventions

Measuring HRQL

1. Standardized questionnaires that assess HRQL, including work performance & productivity, school performance, validated (for populations – generally not for individuals)
2. Less formalized assessments of the impact of rhinitis and its management on QOL.

Meltzer E. JACI 2001;108:S45-S53

- Standardized questionnaires to assess HRQL can be measured with generic or specific questionnaires.
- Generic instruments of more limited use in focused clinical trials and clinical care, may lack detail needed to detect small but important changes in HRQL
- Specific questionnaires may be more sensitive and are much more likely to detect clinically important changes in patients' impairments.

Advantage of a generic questionnaire: burden of rhinitis can be compared with other diseases, such as asthma.

⇒ In adults, moderate-to-severe perennial rhinitis and moderate-to-severe asthma have equal functional impairment.

Bousquet J, et al. JACI 1994;94: 182
Bousquet J, et al. AJRCCM 1994;149:371

Generic Instruments Measuring QOL

Representative Generic QOL Questionnaires

TABLE 10. Representative generic QOL questionnaires

Questionnaire	Web site for information	Contact for noncommercial use
Generic QOL index (Economic 1 and 2) (SF-12) (Economic 1 and 2)	http://www.med.org/health/healthcare/medicare/medicare_survey_index.html	For: http://www.med.org/health/healthcare/medicare/medicare_survey_index.html
Health Utilities Index Mark 2 and 3 (HUI2 and 3)	http://www.healthutilities.com/hi2.htm http://www.healthutilities.com/hi3.htm	Contact: http://www.healthutilities.com/hi2.htm
Functional Status Questionnaire (FSQ)	http://www.josephgagan.com/fsq.html	http://www.josephgagan.com/fsq.html
Health Utilities Index Mark 2 and 3 (HUI2 and 3)	http://www.healthutilities.com/hi2.htm http://www.healthutilities.com/hi3.htm	Contact: http://www.healthutilities.com/hi2.htm
Generic QOL index (Economic 1 and 2) (SF-12) (Economic 1 and 2)	http://www.med.org/health/healthcare/medicare/medicare_survey_index.html	For: http://www.med.org/health/healthcare/medicare/medicare_survey_index.html
Health Utilities Index Mark 2 and 3 (HUI2 and 3)	http://www.healthutilities.com/hi2.htm http://www.healthutilities.com/hi3.htm	Contact: http://www.healthutilities.com/hi2.htm

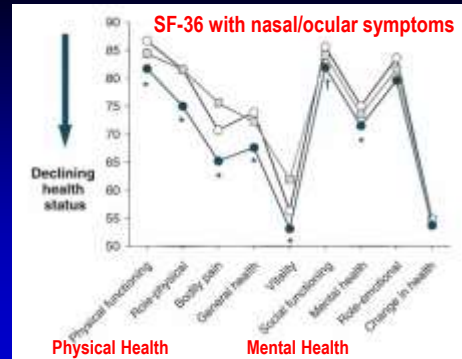
Wallace DV, Dykewicz MS et al. JACI 2008;122:S1-84.

Generic instruments

EXAMPLE: The Medical Outcomes Study Short-Form Health Survey (SF-36)

- 36 items, assess 3 major health attributes:
 1. Functional status
 2. Well-being
 3. Overall evaluation of health
- Used in many medical conditions, including AR.

With nasal/ocular sx (black circles; n = 312) vs healthy controls (white circles; n = 139). Squares: mean values (n = 2474). *P < .01, †P < .05 vs controls



Meltzer EO. JACI 1997;99:S805

“Use of generic QOL measurements in individual patients when studied in other areas of medicine has not led to changes in practice style and has not improved patients’ health outcomes.”

Wallace DV, Dykewicz MS et al. JACI 2008;122:S1-84.

Specific QOL instruments for rhinitis

TABLE IV. Representative rhinitis QOL questionnaires

Questionnaire	Web site for information
Rhinitis QOL adult	
RQLQ	http://www.qoltech.co.uk/Rhinocor.htm#rqlq
Standardized Rhinocorconjunctivitis Quality of Life Questionnaire	http://www.qoltech.co.uk/Rhinocor.htm#rqlq
Mini Rhinocorconjunctivitis Quality of Life Questionnaire	http://www.qoltech.co.uk/Rhinocor.htm#miniqlq
Nocturnal Rhinocorconjunctivitis Quality of Life Questionnaire	http://www.qoltech.co.uk/Rhinocor.htm#noctqlq
Rhinitis Quality of Life Questionnaire	http://www.qoltech.co.uk/Rhinocor.htm#rhinqolq
Rhinitis Symptom Utility Index	
Rhinitis QOL pediatric and adolescent	
Paediatric Rhinocorconjunctivitis Quality of Life Questionnaire	http://www.qoltech.co.uk/PaedRhinocon.htm#prqlq
Adolescent Rhinocorconjunctivitis Quality of Life Questionnaire	http://www.qoltech.co.uk/PaedRhinocon.htm#arqlq

Questionnaires have been validated for research groups but not for an individual.

Wallace DV, Dykewicz MS et al. JACI 2008;122:S1-84.

Adult

[Rhinocorconjunctivitis Quality of Life Questionnaire \(RQLQ\) - original](#)

[Standardized Rhinocorconjunctivitis Quality of Life Questionnaire \(SRQLQ/S\)](#)

[Mini Rhinocorconjunctivitis Quality of Life Questionnaire \(MiniRQLQ\)](#)

[Nocturnal Rhinocorconjunctivitis Quality of Life Questionnaire \(NRQLQ\)](#)

Children

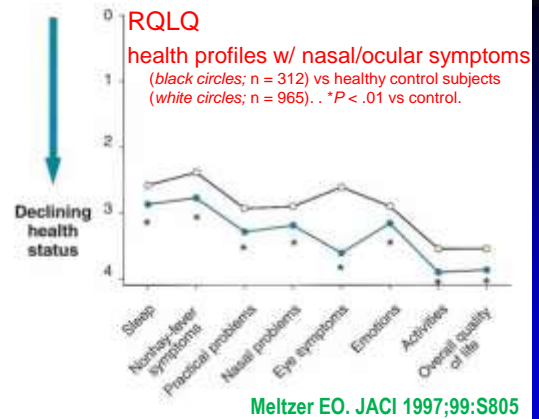
[Adolescent Rhinocorconjunctivitis Quality of Life Questionnaire \(ARQLQ\)](#)

[Paediatric Rhinocorconjunctivitis Quality of Life Questionnaire \(PRQLQ\)](#)

RQLQ by Elizabeth Juniper

- 28 questions in 7 domains (activity limitation; sleep; nose, eye, non-nose/eye sx, practical problems, emotional function).
- 3 'patient-specific' questions in activity domain, allow patients to select 3 activities in which they are most limited by their rhinoconjunctivitis.
- Recall how bothered by during the previous wk
- Respond to each question on a 7-point scale (0 = not impaired at all - 6 = severely impaired).
- Overall RQLQ score = mean of all 28 responses ; individual domain scores = means of items in those domains

<http://www.qoltech.co.uk/questionnaires.htm>



- “Only the RQLQ allows calculating the MID, namely how much a score must change so that it is perceived as such by the patient, irrespective of its statistical significance. This has not been calculated for the other instruments, and the studies that use RQLQ do not always indicate whether statistical significance has been achieved.”

Baiardini I et al. Allergy 2008; 63: 660

Mini-RQLQ

- 14 questions
- 5 domains
 - activity limitations (standardized)
 - practical problems
 - nose symptoms
 - eye symptoms
 - other symptoms

Juniper EL. Clinical Exp Allergy 2000;30:132-140

History of rhinitis guideline statements about QOL

1998 Joint Task Force on Practice Parameters: AAAAI/ACAAI

Dykewicz, Fineman et al. Ann Allergy Asthma Immunol 1998;81:478-518.

Taking History of Impact on Quality of Life “Summary Statement 24.

Symptoms of rhinitis may significantly impact the patient's quality of life, by causing fatigue, headache, cognitive impairment and other systemic symptoms. An assessment of the degree to which these symptoms interfere with the patient's ability to function should be made.”

1998 Joint Task Force

Dykewicz, Fineman et al. *Ann Allergy Asthma Immunol* 1998;81:478-518.

- “In patients with rhinitis, loss of sleep and concomitant fatigue, headache, poor concentration, (symptoms) ... all impact negatively on their ability to carry out physical, social and work/school responsibilities effectively.”

2001 ARIA

Bousquet J, Van Cauwenberge P, Khaltaev N et al. *JACI* 2001;108(Suppl. 5):S147–S334.

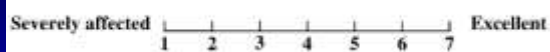
- Introduction of formal severity rating including QOL considerations



2003 Joint Task Force

Recommendation for rating QOL & symptoms by VAS for individuals

Spector SL et al. *Ann Allergy Asthma Immunol* 2003;91:105-14.



2008 Joint Task Force

Wallace & Dykewicz et al. *JACI* 2008; 122: S1-S84

36. Evaluation of rhinitis therapy should include assessment of quality of life (QOL). C

Quality of life is *QUANTIFY IMPACT AFFECTED** in terms of sleep disturbance at night and/or impairment of work performance and/or impairment of social and/or recreational activities

* 1 TERRIBLY

2 AFFECTED ALMOST ALL THE TIME

3 AFFECTED OFTEN

4 OCCASIONALLY BUT IS TOLERATED

5 HARDLY AFFECTED

6 SO MILDLY AFFECTED IT IS HARDLY NOTICED

7 EXCELLENT

Joint Task Force on Practice Parameters

Spector et al. *Ann Allergy* 2003;91:105

Wallace & Dykewicz et al. *JACI* 2008; 122: S1-S84

2008 Joint Task Force

Wallace & Dykewicz et al. *JACI* 2008;122(#2,Aug): S1

36. Evaluation of rhinitis therapy should include assessment of quality of life (QOL).

The use of a modified visual analog (graphic rating) scale for assessing the severity of allergic rhinitis has been recommended for the clinician **when assessing the individual patient** for nasal and nonnasal symptom severity, global nasal and nonnasal severity, and QOL assessment of rhinitis severity

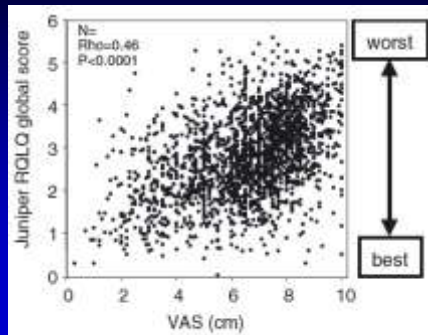
2007 ARIA V.A.S.

Bousquet PJ et al. *Allergy* 2007; 62: 367–372

- VAS ranging from 0 (“nasal symptoms, not at all bothersome”) to 10 cm (“nasal symptoms, extremely bothersome”) used to assess the severity of combined nasal symptoms.
- Did not use VAS for individual symptoms such as nasal obstruction, as previously proposed
- VAS and RQLQ global score correlated ($\rho = 0.46$; $P < 0.0001$).

Bousquet PJ et al. *Allergy* 2007; 62: 367–372

Distribution of global RQLQ score depending on VAS



What is more sensitive, subjective symptoms, objective measurements or HRQL? It depends...

In some studies, clinical evaluation did not discriminate between 2 different treatments, whereas a difference was noted with QOL assessment.

Ciprandi G et al. Effects of budesonide and fluticasone propionate in a placebo-controlled study on symptoms and quality of life in seasonal allergic rhinitis. *Allergy* 2002;57:986-91189.

Juniper EF et al. Clinically important improvements in asthma-specific quality of life, but no difference in conventional clinical indexes in patients changed from conventional beclomethasone dipropionate to approximately half the dose of extrafine beclomethasone dipropionate. *Chest* 2002;121:1824

Wallace & Dykewicz et al. *JACI* 2008;122(#2,Aug): S1

- Conversely, some studies document clear clinical improvement after antihistamines or bronchodilators in respectively rhinitis or asthma, but not accompanied by detectable changes in the HRQL

Van Cauwenberge P, Juniper EF. *Clin Exp Allergy* 2000;30:891
van der Molen T et al. *Eur Respir J* 1998;12:30

Nasal hyperreactivity, QOL and nasal symptoms

de Graaf-in 't Veld T et al. *JACI* 1996 ;98:508

- 48 patients with PAR
- Only moderate correlation between
 - Histamine responsiveness and total daily nasal symptoms ($r = 0.51$, $p = 0.001$).
 - Total daily nasal symptoms with overall QOL score ($r = 0.59$, $p < 0.001$)
 - Nasal response to histamine and overall QOL score ($r = 0.43$, $p = 0.002$).

“It may be helpful to question the patient about symptoms of fatigue, irritability, poor quality sleep, absenteeism and presenteeism at work and/or school, and general QOL problems during their symptomatic periods.”

Wallace & Dykewicz et al. *JACI* 2008; 122: S1-S84

Summary

- Impact of rhinitis on QOL significant
- Assessment of QOL recommended for guiding treatment, may be of increasing importance for making decisions about resource allotment
- Both the generic and disease-specific QOL questionnaires are used in research trials for assessing responses of a study group, their sensitivity and precision for use with individual patients questionable
- QOL and clinical measurements (subjective and objective) not fully interchangeable
- QOL VAS instruments recommended