

Selecting HRQOL Measures for Outcomes Research

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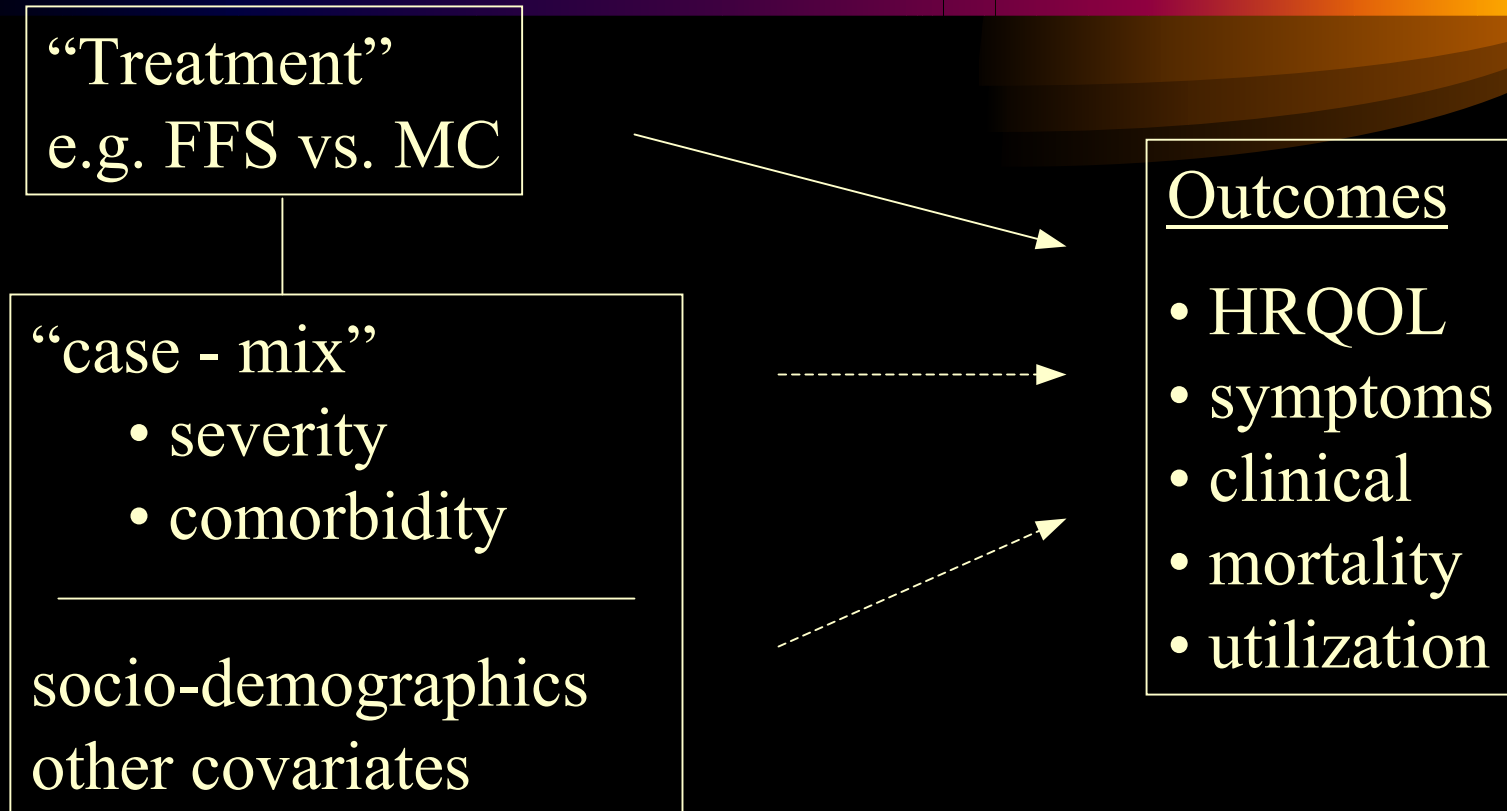
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Lecture Overview



- An approach to selecting measures for outcomes studies
- A “real” example of an outcomes study

Analytic Model for an Outcomes Study



Domains of Common HRQOL Measures

1. Physical functioning
2. Role functioning
3. Bodily pain
4. Energy/fatigue
5. General health perceptions
6. Social functioning
7. Psychological distress
8. Psychological well-being
9. Overall Quality of life?
10. Overall health?
12. Sleep
13. Cognitive Function
14. Sexual function

Plethora of Measures to Select From

- Arthritis Impact Measurement Scale
- COOP Charts
- Duke-UNC Health Profile
- Functional Status Questionnaire
- General Health Questionnaire
- McMaster Health Index Questionnaire
- MOS General Health Surveys
- Nottingham Health Profile
- OARS Multidimensional Functional Assessment Questionnaire
- Sickness Impact Profile
- Quality of Well-Being Scale
- EuroQol/ EQ5D

Domains Covered by Selected Multidimensional Measures (Kane)

	Physical Functioning	Emotional Functioning	Cognitive Functioning	Social Functioning	Pain	Vitality	Overall Well-Being
SF-36	✓	✓		✓	✓	✓	✓
SIP	✓	✓	✓	✓	✓		✓
NHP	✓	✓		✓	✓	✓	
DUKE	✓	✓	✓	✓	✓	✓	
QWB	✓			✓		✓	
COOP	✓	✓		✓			✓

Key:

SF-36 = 36-Item Short-Form Health Survey (Ware & Sherbourne, 1992).

SIP = Sickness Impact Profile (Bergner, et al. 1981).

NHP = Nottingham Health Profile (Hunt, McKenna, & McEwen, 1980).

DUKE = Duke-University of North Carolina Health Profile (Parkerson, Broadhead, & Tse, 1990; Parkerson et al, 1989).

QWB = Quality of Well-Being Scale (Kaplan, et al., 1989).

COOP = Dartmouth COOP Charts (Nelson & Berwick, 1989).

MOS-Derived Health Status Instruments

	<u>LF-116</u>	<u>SF-56</u>	<u>ESI-55</u>	<u>SF-38</u>	<u>SF-36</u>	<u>HAQ</u>	<u>SF-30</u>	<u>SF-20</u>
Physical Health								
Physical functioning	10	6	10	6	10	11	6	6
Mobility	2	0	0	0	0	0	0	0
Pain	11	2	2	1	2	0	1	1
Role limitations - physical	7	0	5	0	4	0	0	0
Mental Health								
Psychological distress	22	3	3	3	3	3	3	3
Psychological Well-being	10	2	2	2	2	2	2	2
Cognitive Functioning	6	6	5	6	0	5	4	0
Role limitations- emotional	3	0	5	0	3	0	0	0
Loneliness	0	8	0	0	0	0	0	0
Hopefulness	0	7	0	0	0	0	0	0
General Health								
Energy/fatigue	5	5	4	4	4	4	4	0
Sleep problems	9	0	0	0	0	0	0	0
Role limitations	2	2	0	2	0	0	2	2
Social activity limitations	4	2	2	1	2	3	1	1
Health perceptions	9	5	9	5	5	2	1	5
Health distress	6	0	0	0	0	0	4	0
Quality of life	0	7	2	7	0	0	1	0
Change in Health	1	1	1	1	1	0	1	0

AIMS: Questionnaire Concepts

- Mobility
- Physical activity
- Dexterity
- Household activity
- Activities of daily living
- Social activity
- Pain
- Depression
- Anxiety

AIMS Questionnaire Example Items

- **Physical activity (yes/no)**
Do you have any trouble either walking one block or climbing one flight of stairs because of your health?
- **Activities of daily living (no help, some help, don't do)**
How much help do you need to use the toilet?
- **Pain (very severe to none)**
During the past month, how severe has your pain been in your joints?
- **Depression (always to never)**
During the past month, how often did you feel that others would be better off if you were dead?

McMaster Health Index

Questionnaire (example items)

- **Physical Function**

Today, do you (or would you) have any physical difficulty at all with:

	Difficulty	No Difficulty
a) walking as far as a mile?	1	2
b) climbing up 2 flights of stairs?	1	2

- **General Health**

How would you say your health is today? Would you say your health is (Circle your answer)

1) Very Good 2) Pretty Good 3) Not Too Bad

- **Social Activities**

How would you say your *social* function is today? (By this we mean your ability to work, to have friends, and to get along with your family?)

1) Good 2) Good To Fair 3) Fair 4) Fair to Poor 5) Poor

MOS General Health Perception Measures

Current health
(alpha = 0.88)

My health is excellent
I am somewhat ill

Resistance to illness
(alpha = 0.79)

Body resists illness very well
Get sick easier than other people

Health Outlook
(alpha = 0.87)

Future will be unhealthy
Expect a very health life

Prior Health
(alpha = 0.74)

Never seriously ill
Sickly for a long time

Health Concern
(alpha = 0.73)

Concerned about my health
Often think about my health

MOS Cognitive Functioning Measure (alpha = 0.87)

How much time during the last 4 weeks:

- Become confused, start several actions at a time
- React slowly to things
- Have difficulty reasoning, solving problems
- Forget things that happened, appointments
- Have trouble keeping attention on any activity for too long
- Have difficulty concentrating, thinking

MOS Sleep Measures

Sleep Disturbance
(alpha = 0.84)

Sleep not quiet

(moving restlessly, feeling tense, etc.)

Trouble falling asleep

Awaken during sleep, have trouble falling asleep again

Sleep Adequacy
(alpha = 0.75)

Get enough sleep to feel rested upon waking

Get the amount of sleep you need

Somnolence
(alpha = 0.75)

Feel drowsy or sleepy during the day

Have trouble staying awake during the day

Take naps during the day

Snoring

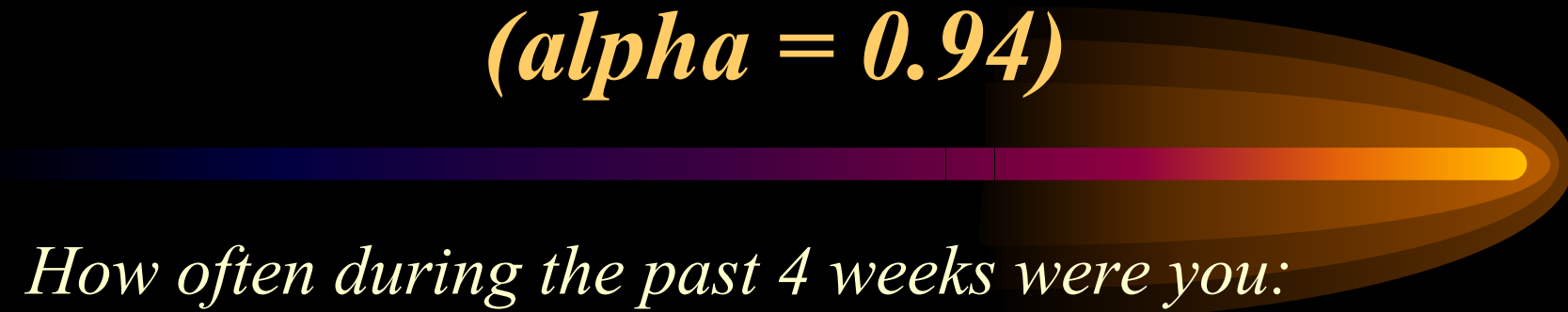
Snore during sleep

Sleep apnea

Awaken short of breath or with a headache

MOS Health Distress Measure

(alpha = 0.94)



How often during the past 4 weeks were you:

- Frustrated about your health
- Weighed down by health problems
- Afraid because of your health
- Despair over health problems
- Discouraged by health problems
- Health was a worry

Generic vs. Disease-Targeted Measures

- Generic - Measure is relevant to individuals generally
- Targeted (or “specific”)- Measure is tailored to a particular characteristic
- Disease-Targeted - Measure is targeted to a disease

Advantages of Generic Measures



- Allow Comparisons Across Different People
 - Across Disease Groups
 - Sick vs. Well
 - Young vs. Old

Advantages of Targeted Measures



- More sensitive to small, clinically-important changes
- May be necessary to get respondent cooperation

Recommendation Regarding Generic vs. Targeted Measures



- Generic Core
- Targeted supplement

Relationship between study question and measure selection

- Effect of physical therapy on recovery from sports knee injury (physical function).
- Effect of SS on bereavement of family member death (emotional well-being).
- Association of work-place noise pollution with HRQOL (hearing).

Criteria for Choosing a Generic Measure

(Kane)

- *Domains of health* Choice of domains affects the treatment effects observed.
- *Range of health* Range of measure affects the coverage of the spectrum of performance and change in health status.
- *Clinical relevance* The interpretation of score will be difficult if numbers do not have a logical ordering and connection to reality.
The emphasis determines the relative weight of each domain in the measure.
- *Level of emphasis* Unreliable measures yield inconsistent, uninterpretable results.
- *Reliability* Valid measures provide information about the dysfunction of interest. Includes sensitivity or responsiveness.
- *Validity* The burden of administration influences the responses from patients and providers and amount of information obtained.
- *Practical considerations*

Practical Considerations (Kane)

- The length of time required to administer the questionnaire.
- The appropriate format (for the survey) telephone, face-to-face, or self-administered.
- The use of proxy respondents.
- The cost of administration (data collection and data entry).
- The complexity of the measurement and scoring methods.
- The acceptability of the survey to patients/respondents and clinicians.
- The expected format for presenting the results.

Outcomes Study Mini-example

- Topic: the Effect of Dental Insurance on HRQOL in Persons with HIV

Objective



- To examine the prospective effect of having dental insurance coverage on physical, mental, and oral HRQOL outcomes in persons with HIV infection

Background

- HIV impacts oral, physical, and mental health
- Oral problems may be overlooked in HIV care
- Dental insurance enables dental care that may improve oral, physical, and mental HRQOL

Design Overview

- Design: prospective cohort study
- Setting: HCSUS study- national probability sample of patients with HIV infection, throughout U.S.
- Patients: 2864 patients with HIV receiving care at least every 6 months

Conceptualization of HRQOL

- Physical, mental health
- Oral health: ability to chew, swallow, speak, interact socially, work/school
 - Oral dysfunction/distress: tooth loss, dry mouth, sore throat, appearance of lesions
 - oral health perceptions, worry

Measurement of HRQOL



- Cover the concepts you decided were important!

Selection of HRQOL Measures



- Population/condition
- Independent var (main comparison or intervention)
- Instrument characteristics

Summary Table of Instruments Available for Assessing Oral HRQOL

	Number of Items			
	OHIP*	IOHS**	GOHAI***	HCSUS****
Domain				
Oral Functioning	2	0	5	2
Oral pain	2	0	2	2
Oral Psychological discomfort	2	0	2	0
Oral Psychological disability	2	0	0	0
Oral Social Function	2	0	1	1
Oral Handicap	2	0	0	1
Oral Handicap	0	0	0	1
General Oral Health	0	0	1	1
Oral Health Perceptions	0	0	0	1
Oral Role Function	0	0	1	1
Oral Health Worry	0	0	0	2
Oral Health Worry		0		
Tooth Survival		5		
Total Number of Items	12	5	12	11

*Oral Health Impact Profile. Slade GD, 1997; **Index of Oral Health Status. Marcus M, Koch A, Gershen KA, 1983; ***Geriatric Oral Health Assessment Index, Atchison K, 1992. ****HCSUS oral HRQOL measure, Marcus M, Freed J, Coulter I, 1999.

HRQOL Measures for HIV Research

(Number of Items in Each Domain)

SCALE	SF-56	SF-38	SF-36	SF-31	SF-30	SF-20	SF-20*	HOPES**
1. Physical Function/ Disability	6	6	10	11	6	6	4	8
2. Role Limitations	2	2	7	0	2	2	2	4
3. Pain	2	1	2	0	1	1	2	3
4. Emotional Distress/WB	22	5	5	5	5	5	3	6
5. Cognitive Distress	6	6	0	5	4	0	2	3
6. Social Function	2	1	2	3	1	1	2	18
7. Fatigue	5	4	4	4	4	0	2	1
8. Health Perceptions	5	5	5	2	5	5	3	0
9. Sexual Function/QOL	3	0	0	0	0	0	0	13
9. Overall Quality of Life	3	7	0	0	1	0	0	0

SF-56 = Hays, et al.; SF-38 = Bozzette et al.; SF-36 = Ware & Sherbourne;
 SF-31 = AIDS HAQ= Lubeck & Fries; SF-30 = MOS-HIV = Wu et al.; SF-20 = Stewart et al.;
 SF-20* = Bozzette et al.; **HOPES = Schag and Ganz

Analysis Plan

- Construct item, scale, summary scores: OH, PH, MH
- Assess the reliability and validity
- Evaluate the research question: does dental insurance impact HRQOL in patients with HIV?

Assessment of Reliability and Validity

- Internal consistency reliability (alpha = 0.82)
- Construct validity
 - compare OH, PH, MH scores by # oral symptoms (test difference in means)
 - assess relative validity of scores in detecting differences in HRQOL by # symptoms (F-ratios compared to category rating scale)

Hypothetical Mean HRQOL Scores at 6-Month Follow-Up by Oral Symptoms

Measures	Oral Symptoms Grouping			F statistic [F ratio]
	None	1-5 Symptoms	All 6 Symptoms	
Oral HRQOL	87	77	50	8 [4]
Physical HRQOL	75	73	68	2 [1]
Mental HRQOL	70	65	63	3 [1.5]
Categorical Rating Scale	75	73	70	2 [1]

Evaluate Effect of Dental Insurance on OH, PH, MH

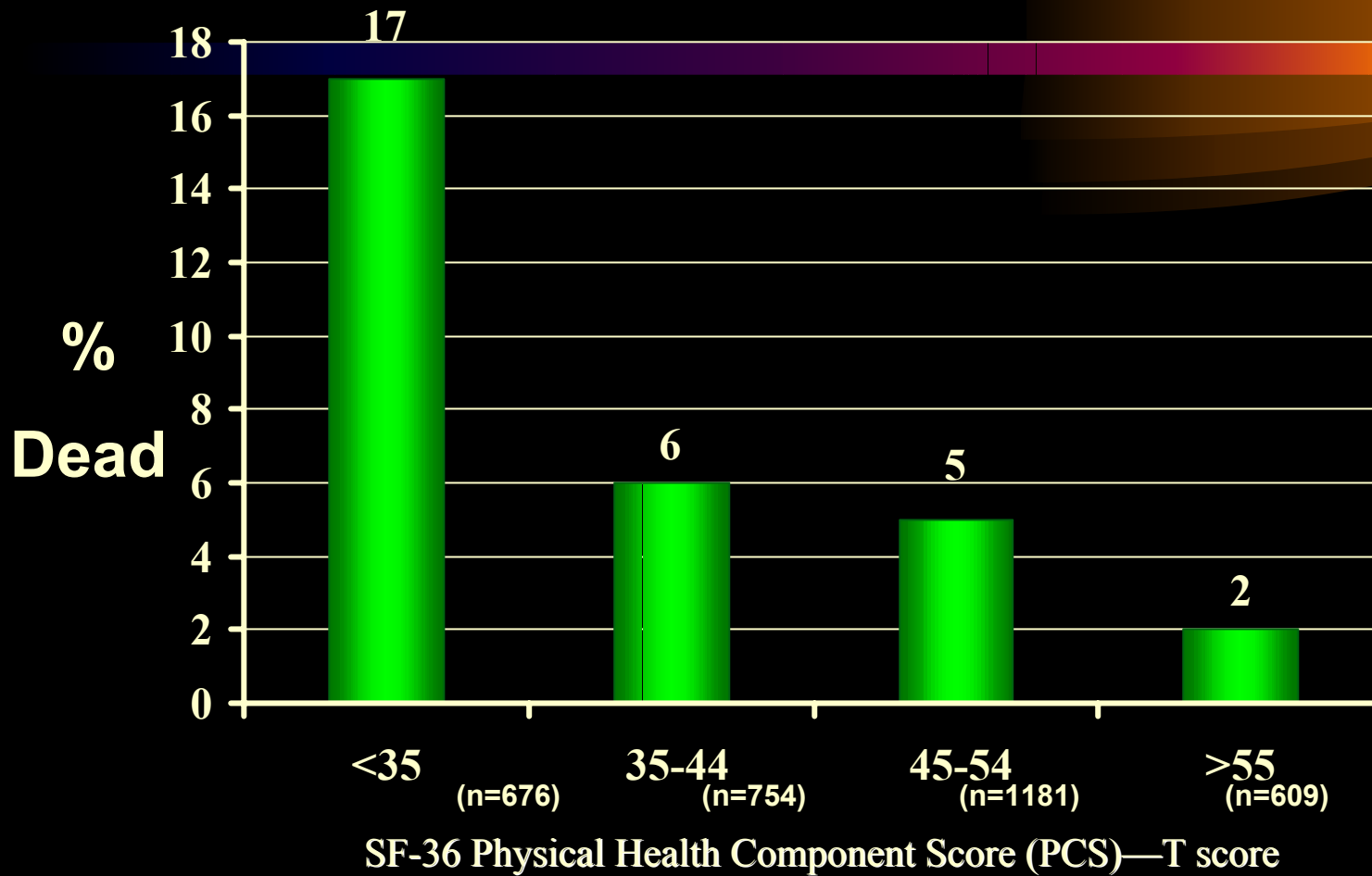
- Compute OH, PH, MH @ baseline, follow-up, and change (between baseline and FU)
- Compare (and test) change score by dental insurance
- Multivariate analysis controlling for age, gender, race, HIV exposure, education, living alone, income, CD4, AIDS DX, smoking, region, employment

Hypothetical Differences in Scores on Four Health Summary Scales between Patients With and Without a Usual Source of Dental Care

Measures	Dental Insurance	No Dental Insurance	Difference	95% C.I.*
Oral HRQOL**	90	60	30	(29.1, 30.2)
Oral Symptoms**	88	68	20	(19.9, 20.2)
Physical HRQOL**	85	75	10	(9.9, 11.0)
Mental HRQOL**	85	70	15	(14.1, 15.1)

*Confidence interval. **0-100 possible range.

Five-Year Mortality Rates by Levels of Physical Health



Ware et al. (1994). SF-36 Physical and Mental Health Summary Scales: A User's Manual.

Characteristics of HIV-infected persons represented by HCSUS, Part 1

Variable/subgroup	%	Oral HRQOL	Physical HRQOL	Mental HRQOL
Dx AIDS?				
a) No	62	50.7	51.7	50.7
b) Yes	38	49.5	47.9	49.3
Physical Symptoms Score				
a) 0	17	54.7	54.6	54.8
b) 1-3	43	52.4	52.1	52.1
c) 4-6	30	48.0	47.6	47.5
d) 7-9	30	41.5	43.1	42.8
		ab;ac;ad;bc;bd;cd	ab;ac;ad;bc;bd;cd	ab;ac;ad;bc;bd;cd

Mean scores on oral HRQO and physical and mental HRQOL; summary scores by subgroup of independent variables. *Lower-case letters indicate which pairs of subgroups had significantly different mean oral HRQOL scores at $p < 0.0007$ (initial α level of 0.05 adjusted for multiple comparisons).

Source: Coulter ID, Heslin KC, et al. Quality of Life Research 2002

Characteristics of HIV-infected persons represented by HCSUS, Part 2

Variable/subgroup	%	Oral HRQOL	Physical HRQOL	Mental HRQOL
Oral Symptoms Score				
a) 0	48	54.5	52.8	53.1
b) 1	28	50.3	49.5	49.6
c) 2	14	44.2	47.1	47.0
d) 3	8	40.9	44.8	43.4
e) 4	2	32.6	42.9	39.8
		ab;ac;ad;ae;bc;bd;be;ce;de	ab;ac;ad;bd	ab;ac;ad;bc;bd;cd

Mean scores on oral HRQO and physical and mental HRQOL; summary scores by subgroup of independent variables. *Lower-case letters indicate which pairs of subgroups had significantly different mean oral HRQOL scores at p<0.0007 (initial x level of 0.05 adjusted for multiple comparisons).

*Source: Coulter ID, Heslin KC, et al.
Quality of Life Research 2002*

Multivariate association on oral HRQOL (T-scores regression coefficients) measured at first follow-up

Variable	Category	Estimated coefficient	P
Oral symptoms score (first follow-up)	0-4	-3.97	0.0000*
Physical symptoms score (first follow-up)	0-9	-0.35	0.0010**
Physical functioning, (baseline)			
Emotional well-being, (baseline)	0-100	0.02	0.0310**
	0-100	0.05	0.0000*

Number of observations in the model is 2279.

*p<0.001; **p<0.05

*Source: Coulter ID, Heslin KC, et al.
Quality of Life Research 2002*