An External Control of Validity of the German EuroQol-5D Questionnaire[1]

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Background. In 1998, the validation study for the German version of the EuroQol index instrument ("Hannover Study") was published. In that study, 13 different health states were valued directly by a sample of the general German population. In that publication, a regression model was presented to derive index values from these 13 directly valued health states for each of the 243 health states possible within the EuroQol framework . The aim of our study ("Munich Study") was an external validation of the mathematical model and the estimated index values.

Methods. In a cross-sectional study the valuations for 16 health states, 14 of it different to those of the first study, were collected and compared with the estimated values from the Hannover study. Furthermore, the mathematical model was checked and new coefficients were computed for comparison with the values of the Hannover study.

Results. The comparison demonstrated a significant difference between the estimated values from the Hannover study and the direct valuation by the population in the Munich study. Neither the averages nor the median values were comparable. Moreover, the newly computed coefficients were significantly different from the formerly computed ones. The correlation of the direct valuations and the estimated values was only moderate.

Conclusions. The study shows that the index values for the EuroQol health states derived in the Hannover study do not seem to be valid and their use in economic trials cannot be recommended. Because of context-dependency between the different dimensions of the health states, the generalization of the values derived from a subset of only 13 health states to all of the 243 health states in order to establish general population weights, is problematic. As a regression model to derive index values for 243 health states has been applied not only in Germany

but also in many validation studies in other countries, the issue of validity of the index values is relevant there as well. For further work on the validation of the EuroQol index instrument, the crucial question is: How many health states will be needed to calculate valid index values through a regression model?

Key Words: EuroQol-5D; external; control; validity; Germany

Introduction

In 1987, the EuroQol-group was founded to develop a brief generic questionnaire for measuring the outcome of medical treatment. The instrument provides a composite index of health-related quality of life. Respondents are asked to describe their health state using the five dimensions of the EuroQol-5D (mobility, self-care, usual activity, pain and discomfort, anxiety, and depression) and the three answer levels (no problems, some or moderate problems, unable or extreme problems). Furthermore the participants are supposed to value their health state on a 200 mm visual analogue scale (VAS) between the value 100 (best imaginable health state) and the value 0 (worst imaginable health state). An example for a possible EuroQol health state is given in table 1. Corresponding to the answer levels of the five dimensions, it would be coded 12123.

To get estimated index values for all of the 243 (3^5) possible health states, general population samples in different countries were asked, in addition to the evaluation of their own health state, to value a certain number of hypothetical health states as well (Johnson et al., 1998; Dolan, 1997; Björk et al., 1999).

Estimated coefficients for each answer level of each dimension of health related quality of life were interpolated in these studies by multiple linear regression using the population valuations of the selected hypothetical health states.

In 1998, the German version of the EuroQol-5D, including a model to compute estimated values for all of the 243 EuroQol health states, was published (Schulenburg et al. 1998). In this study, henceforth called 'Hannover study', 13 different health states were valued directly by a sample of the German population (the best and the worst health state were asked twice). Estimated coefficients for each response level of all the five dimensions of health-related quality of life were computed to get index values for all health states. Also death and the state 'unconscious' were valued in that study by the respondents, but both states were not used in the calculation of index values.

The validity of these estimated values is an important but often neglected fact, for index values are used not only in economic studies but also in epidemiological and clinical trials. A context-dependency between the EuroQol dimensions may be supposed. The latter can be easily illustrated by the following two

examples: A limitation of self-care in a state of full mobility may be experienced totally different as when confined to bed. Pain, while still being mobile, might be easier to bear than in a state of immobility.

Insofar as context-dependency is relevant, it may be inadequate to draw conclusions from observed health states to other non-observed health states through a regression model. If, for instance, the regression analysis results in a difference in the valuation of some problems with pain (answer-level 2) and severe pain (answer-level 3) of 40 among the health states observed, this difference may not be true for comparisons of other health states. Therefore we decided to execute a new study to test the validity of the estimated coefficients and the index values of the German version of the EuroQol.

Research Design and Methods

DEVELOPMENT OF A NEW MODEL

The first and second part of the questionnaire were not changed for this new (Munich) study: As in the Hannover study, the respondents in these parts described their own health state by

using the five dimensions and valuing it on the VAS. The third part of the questionnaire, the valuation of other, hypothetical, health states, was completely revised.

The valuation of more than 16 different health states seems impossible. The respondent burden is high, as they have to identify the differences of the health states, to remember them in comparison and to weight them against each other. We excluded the state ‘unconscious’ (because it was not used in the Hannover model) and asked the best and the worst health state only once. In consequence 14 new health states different to the Hannover study could be included. In addition, we asked (like the Hannover study) for the evaluation of death, but did not include this information in the regression model presented in this paper, because the information was not used in the Hannoverian model either.

In order to select hypothetical health states for inclusion in our study, we tried to arrive at a system to avoid floor and ceiling effects without making use of the Hannoverian estimated values. Therefore we classified the health states by severity. The best response level of each dimension (no problems) was valued with

1, the second level (some problems) with 2 and the level of extreme problems with 3. Summing up these values over the five dimensions yielded a severity score ranging from 5 (for the best health state with the code 11111) to 15 (for the worst one, coded 33333). To present all grades of severity in the questionnaire, we selected by random a certain number of health states of each severity grade, corresponding to its frequency, and also the best and worst health state.

The selection of health states for the Munich study is shown in table 2. Except the best and the worst health state, they are all different to those used in the Hannover study. Though obvious floor or ceiling effects should be avoided, we did not reach an absolute equally divided distribution.

For comparison, the sums of severity grades of the Hannover study are illustrated in table 3. In the Hannover study ‘good’ answer levels, especially the level ‘no problem with’, appear twice as often than the worst level ‘extreme problems’.

In order to avoid any manipulation of the respondents, the 16 selected health states were displayed in a way to avoid uneven cumulation of good or poor states on the VAS. In addition, some

social-demographic data, questions about the experiences with illness and the own health related behaviour concerning to smoking were requested.

DATA COLLECTION

Data for the Munich study were collected in May and June 1999 using a mail survey design. A randomised sample of 3000 households was drawn by Infratest Burke. The official telephone directories were used while applying the municipality key developed for German-wide samples.Quasi-random selection of a household member was achieved by asking the person (aged 18 years or older) who was next to celebrate his or her birthday to complete the questionnaire.To maximise the response rate, every third household was called up four weeks after the initial mailing of the questionnaires and every sixth household was approached again after another two weeks by mail.

The returned questionnaires were anonymized and coded. The data input was performed in SAS (Version 6.12 for HP-UNIX). To look for random bias, the input was repeated for 10 percent of the data. According to the rules of the EuroQol-group, health

states not valued or valuations not doubtlessly recognizable were coded as missing values.

Results

RESPONSE RATE

Of the 3000 questionnaires that were mailed out, 162 (5.4%) were returned undeliverable and, affirmed by mail or telephone, 627 (22.1%) households refused participation. 469 questionnaires were returned, which corresponds to a response rate of 38.6% (table 4).

SOCIAL-DEMOGRAPHIC DATA

The gender distribution was not representative for Germany, but similar to the Hannover study. In both samples men dominated (table 5).

The study was restricted to people aged 18 years or older. The oldest respondent was 94 years old, the mean value was 51.9 years (STD = 16.7). Also the age groups, except three of them

(18 - 25, 31 – 35, and 36 - 40 years) accord with the Hannover study but not with the German population (table 6).

The level of education of the participants in the Munich study is higher than in the Hannover study and higher than in the German population (table 7).

VALUATION OF THE OWN HEALTH STATE

Part one and two of the questionnaire were almost always filled in completely. 98.3 % of the respondents described their health in all the five dimensions and 95.9 % valued their health state on the VAS. Only 33 (13.6 %) of the 243 combinations possible in theory were used for this description.

A vast majority evaluated their own health as quite good, even though it should also be mentioned that more than 20 % of the respondents indicated at least ‘some problems’ in the dimensions pain, discomfort, and anxiety/depression.

The valuation of the own health state showed a good accordance between the two German studies. We compared those health states, which were mentioned in both studies. All the means of the visual analogue scale of the Hannover study were situated

within the 95% confidence interval of the Munich values except the average of all valuations (table 8).

In contrast to the first and second part of the questionnaire, the analysis of the third part revealed a considerable number of missing values (not valued health states). 5303 (70.7%) of 7504 theoretically possible health states could be used for the comparison of the two studies and the interpolation of estimated values, whereas in the Hannover study 47.3% of the health states had been useable.

In a first step we compared the means and medians of the health states valued in the Munich study with the estimated values, computed by the weights of the regression model of Hannoverian study. The estimated values of 15 of the 16 health states lay outside the 95% confidence interval of the Munich study. Based on the assumption that a 10% interval deviation is acceptable for the medians and the estimated values, we could only find four health states which fullfilled this requirement (table 9).

In a second step we examined the correlation between the health state valuations of the Munich sample and the estimated values

for these 16 states from the Hannover study. On the horizontal axis we plotted the estimated values of the Hannover study for each of the 16 used health states, on the vertical axis the valuations of our sample. Obviously there exists a wide variation of valuations for all of the 16 health states (fig.1). The analysis revealed respondents, who valued each health state except the best one with zero as well as respondents, who valued even poor health states quite high.

To assess external validity we executed a linear regression. The values of the Munich study were taken as the dependent, the estimated values of the Hannover study as the independent variables of the regression. The results of the computed correlation are shown in table 10.

The intercept is significantly different from zero and the slope is significantly different from the ideal value 1 . We also computed the Intraclass Correlation Coefficient (Bland et al., 1996) yielding 0.59 signifying moderate agreement of actual valuations and estimated values.

In addition we estimated new coefficients using the mathematical model of the Hannover study:

$$LQI = \beta_0 * \beta_{12}^{b12} * \beta_{13}^{b13} * \beta_{22}^{b22} * \beta_{23}^{b23} * \beta_{32}^{b32} * \beta_{33}^{b33} * \beta_{42}^{b42} * \beta_{43}^{b43} * \beta_{52}^{b52} * \beta_{53}^{b53} * e$$

β_0 = constant factor, by definition 100

β_{xy} = estimated coefficient, x = EuroQol-dimension, y = answer level

bxy = dummy variable (0;1) coding response level y of dimension x

e = residuals

LQI = life quality index value

It had to be acknowledged that inconsistencies with the model's underlying standard statistical assumptions, e.g. no normal distribution, heteroscedasticity and no independence of the values, existed. These problems have been addressed in the literature before (Dolan et al., 1995; Johnson et al., 1998) and are not specific to the German version of the model. To compute the estimated coefficients by ordinary least square regression a log-transformation was necessary to get an additive model. The VAS-values were shifted by one, because otherwise all health states valued with zero would have been excluded

The coefficients estimated from the valuations of the Munich study were compared with those of the Hannover study. The outcome, a significant difference in eight of the ten values, underlines the results of the linear regression presented above (table 11).

Discussion

To our knowledge, this is the first external test of validity comparing the index values and estimated coefficients of the EuroQol with direct valuations derived from a population sample.

The response rate achieved in the Munich study was not satisfactory. Although the questionnaire is quite complex, the Hannover study showed a better response rate. This fact and the high number of missing or not useable values in the third part of the questionnaire suggests the use of another data collection

method, e.g. a personal interview, for the valuation of the EuroQol-5D.

The social-demographic data of the two samples are comparable by gender but show some differences in age structure and education level. Further research should standardize the populations either to the German data or the samples from Munich or Hannover. Although the index values should be useable for the population in general, a respondent bias is possible, particularly as we got no information about the non-respondents.

We propose further research in the field to create new possibilities for getting weights by other statistical methods, e.g. multi-level-models or conjoint analysis. These approaches are described in the literature and should be tested (Beacon et al., 1996).

Comparing the results of the two German studies, no accordance could be found between the values estimated using the Hannoverian coefficients and neither the means nor most of the medians from direct valuations by the population sample in the Munich study. Moreover, the estimated coefficients calculated in

the Hannover study were dissimilar from the corresponding estimates in the Munich study, computed with the same model but different health states. The different coefficients cause impressing variations of the index values. This is inacceptable for economic as well as clinical trials.

The Intraclass Correlation Coefficient shows a moderate agreement but the values for intercept and slope of the regression demonstrate the bias of the estimated values. These results and logical considerations about context dependency of the five dimensions, which represent the health states of the EuroQol, should provide sufficient incentives for further research.

The observed differences in age structure and educational level as well as the fact that in our study the best and the worst health state were asked only once, might partly explain the differences to the values generated in the Hannover study. However, we assume that context dependency between the different dimensions of the EuroQol is the main reason for the lack of validity. We are convinced that this lack of validity is not restricted to the German EQ5-D model: Since the models

developed for other countries are rather similar or even identical, we think that there is a general problem of validity of the EuroQol index values. We assume that a model has to be constructed with the usage of more than just 14 out of 243 health states. The question which health states should be included into such a model deserves substantial considerations. Up to the point in time when a valid model has been developed, the index values of the EuroQol model should be used with reservation.

Although we think that the EuroQol is a brief and useful instrument to measure health related quality of life, further research seems to be necessary. An increased validity of the EuroQol index values will enlarge the use of the questionnaire and improve the results of economic or epidemiological studies. External validity control of other countries should be executed to discuss the different results.

Table 1: ***Example of a health state***

Dimension	**Answer level**	**Description in the dimensions**
Mobility	1	No problems in walking about
Self-Care	2	Some problems with washing or dressing myself
Usual Activity	1	No problems with performing my usual activities
Pain Discomf ort	2	Moderate pain or discomfort
Anxiety Depression	3	Extremely anxious or depressed

Table 2: ***The health states of the Munich study***

Response Level	**Mobility**	**Self-Care**	**Usual Activity**	**Pain Discomfort**	**Anxiety Depression**	**Sum of Response Levels**
	1	1	1	1	1	
	1	1	2	2	1	
	2	1	1	2	2	
	2	1	1	3	1	
	1	2	1	2	3	
	1	2	3	2	1	
	1	3	2	1	3	
	2	3	1	2	2	
	3	1	1	3	2	
	3	3	1	2	1	
	1	3	1	3	3	
	3	2	3	1	2	
	3	1	2	3	3	
	3	2	1	3	3	
	1	3	3	3	3	
	3	3	3	3	3	
‘1’ no problems	7	6	9	3	5	30
‘2’ some problems	3	4	3	6	4	20
‘3’ extreme problems	6	6	4	7	7	30

Table 3: ***The health states of the Hannoverian study***

Response Level	Mobility	Self-Care	Usual Activity	Pain Discomfort	Anxiety Depression	Sum of Response Levels
'1' no problems	6	7	6	6	7	32
'2' some problems	4	4	4	4	3	19
'3' extreme problems	3	2	3	3	3	14

Table 4: ***Response rate***

	n	**Proportion in %**
Sample	**3000**	100
Undeliverable	162	5.4
Net sample	**2838**	100
Respondents	469	16.5
Refusals	627	22.1
Response rate	**1096**	**38.6**

Table 5: ***Distribution of sex***

	Proportion in % Munich study	**[95% CI]**	**Proportion in % Hannover study[1]**	**Proportion in % Germany[2]**
Male	62.4	[57.8;66.8]	64.6	48.7
Female	37.6	[33.2;42.2]	34.5	51.3
Missing values	6			

1 (v.d. Schulenburg et al., 1998) 2 German population aged 18 years and older (1998)

*Table 6: Age **distribution***

	Proportion in % Munich study	**[95% CI]**	**Proportion in % Hannover study[1]**	**Proportion in % Germany[2]**
18-25 years	4.5	[2.8;6.9]	8.9	9.4
26-30 years	5.6	[3.7;8.1]	5.9	9.1
31-35 years	10.0	[7.4;13.1]	4.9	11.0
36-40 years	10.4	[7.8;13.5]	4.9	10.3
41-50 years	16.5	[13.2;20.2]	16.8	17.3
51-60 years	17.5	[14.2;21.3]	21.1	15.8
> 60 years	35.5	[31.1;40.1]	37.6	27.1

1 (v.d. Schulenburg et al., 1998) 2 German population aged 18 years and older (1998)

Table 7: ***Level of education***

Level of education	**n**	**Proportion in % Munich study**	**[95 % CI]**	**Proportion in % Hannover study[1]**	**Proportion in % Germany[2]**
Primary education	151	32.6	[28.4;37.1]	57.7	46.4
Basic secondary schooling	131	28.3	[24.2;32.7]	14.6	24.4
Advanced secondary schooling	80	17.3	[13.9;21.0]	20.6	17.2
University graduate	85	18.4	[14.9;22.1]	--	6.4
Others	16	3.4	[2.0;5.6]	7.0	7.5
Missing values	6				

1 (v.d. Schulenburg et al., 1998) 2 German population aged 18 years and older (1998)

Table 8: ***The valuation of the own health state***

Code of the health state	Mean Munich study	SD	[95% CI]	Mean Hannover study[1]
11111	88.3	9.2	[86.9;89.7]	87.5
11112	83.0	11.5	[79.0;86.9]	80.4
11121	78.1	12.1	[75.9;80.4]	77.1
11122	74.2	13.2	[69.8;78.6]	77.3
21121	71.3	12.7	[65.0;77.6]	66.7
21122	45.0	25.2	[5.0;85.0	57.7
21221	61.3	19.3	[50.6;72.0]	55.0
21222	46.0	15.2	[30.1;61.9]	54.2
Total	77.7	18.4	[76.0;79.4]	75.4

1 (v.d. Schulenburg et al., 1998)

Table 9: ***Comparison of mean and median of the direct valuations in the Munich study with the estimated values from the Hannover study.***

Code of the health state	Median	Mean	SD	[95% CI of the mean]	Estimated value[1]
11111	100	95.7	8.9	[94.7;96.6]	100
11221	65	62.9	20.0	[60.8;65.1]	78.3
12123	50	51.7	22.7	[49.2;54.1]	42.2
12321	49	46.2	19.6	[44.1;48.3]	17.5
13133	24	28.1	20.7	[25.8;30.3]	18.2
13213	30	31.1	18.7	[29.1;33.2]	42.7
13333	10	17.2	20.7	[15.0;19.4]	5.7
21122	60	61.8	18.0	[59.8;63.7]	66.0
21131	39	39.3	21.6	[37.0;41.7]	38.0
23122	34	33.3	17.4	[31.4;35.2]	42.2
31132	25	27.4	20.0	[25.2;29.6]	12.3
31233	14.5	18.9	18.5	[16.9;20.9]	10.9
32133	13	17.3	16.8	[15.5;19.2]	7.8
32312	25	26.5	16.4	[24.7;28.3]	6.4
33121	30	30.4	20.2	[28.2;32.6]	24.2
33333	2	6.9	11.0	[5.7;8.1]	2.4

[1] computed by the estimated coefficients of the Hannoverian study

Figure 1: ***Scatterplot of the estimated values from the Hannover study (horizontalaxis) and the direct valuations in the sample (vertical axis)***

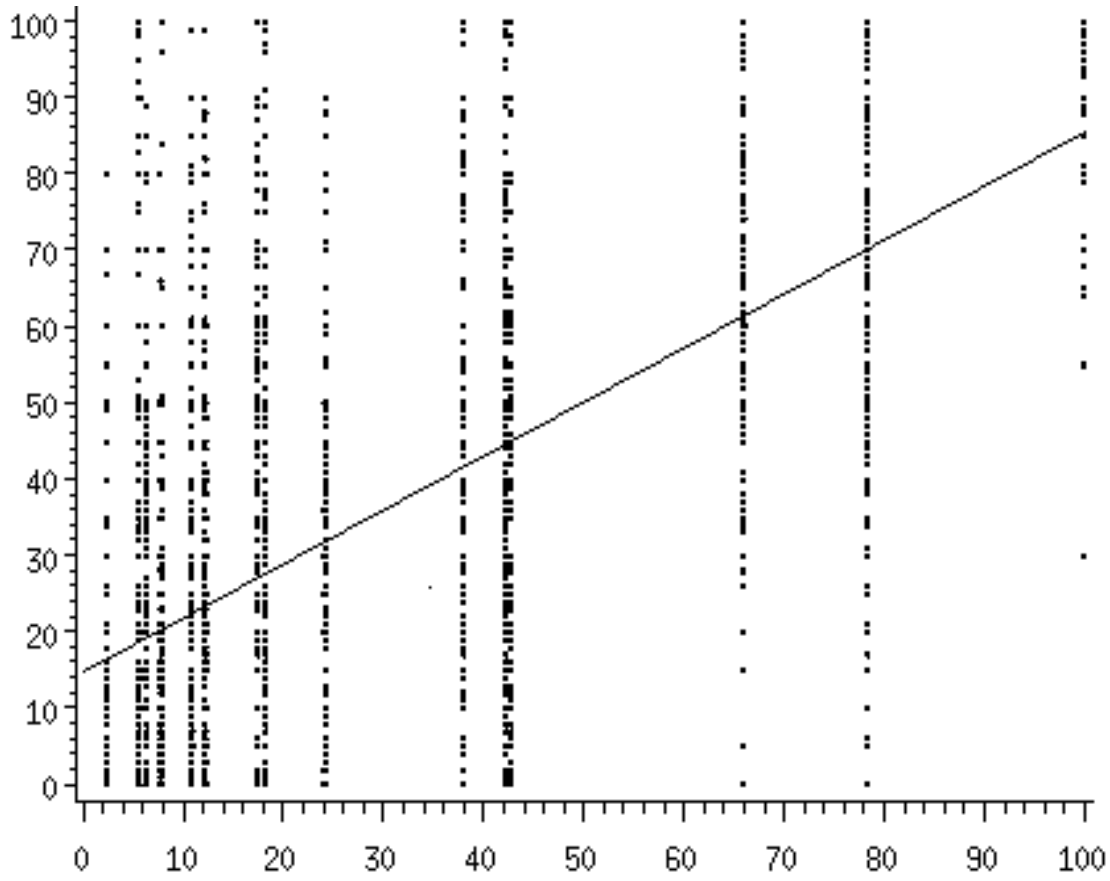

Table 10: ***The results of the regression and correlation***

	Computed value	**[95% CI]**
Intercept	14.1	[13.3;14.9]
Slope	0.7	[0.68;0.72]
Spearman –Correlation Coefficient	0.63	
Intraclass Correlation Coefficient	0.59	

Table 11: ***Comparison of the estimated coefficients from Munich and Hannover***

EuroQol Dimensions	Response-level 2 'some problems' Estimated coefficient Munich study	[95% CI]	Estimated coefficient Hannover Study[1]	Response-level 3 'extreme problems' Estimated coefficient Munich study	[95% CI]	Estimated coefficient HannoverStudy[1]
Mobility	0.64	[0.58;0.71]	1.00	0.43	[0.40;0.46]	0.43
Self-care	0.87	[0.79;0.97]	0.64	0.55	[0.51;0.60]	0.64
Usual activity	0.74	[0.68;0.80]	0.89	0.52	[0.48;0.56]	0.31
Pain	0.86	[0.80;0.92]	0.88	0.51	[0.47;0.55]	0.38
Anxiety	0.97	[0.90;1.05]	0.75	0.64	[0.58;0.71]	0.75

1 (v.d. Schulenburg et al., 1998)

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