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QOL10 for clinical quality-assurance and research in treatment-efficacy: Ten key questions for measuring the global quality of life, self-rated physical and mental health, and self-rated social-, sexual- and working ability

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Abstract

Quality of life and self-rated health are important health measures. They are simple to use and highly efficient for accurate documentation of treatment effects and thus for securing the quality of a clinical practice. We have developed the 10-item QOL10 questionnaire measuring self-assessed quality of life, health and ability. We need to measure both self-rated physical health and self-rated mental health, to be certain that we know how the patients are in both these dimensions. The QOL10 combined with the Square Curve Paradigm data-collecting-procedure seem to be an extremely efficient, fast, in-expensive and valid method of documenting total treatment effect and securing high quality of a treatment facility. In this paper we demonstrate how easy data are collected and analyzed. The time consumption of administering, collecting and analyzing the QOL10 was only 10 minutes per patient. The QOL10 is free for all to use. People even without statistical training can make the statistics in a few hours. The use of QOL10 and its 10 key questions makes it possible to group the patients into treatment groups according to their health/QOL/functional problems, and follow the development of each group to see how well they are helped in the clinic. We found the following dimensions to be of primary interest in quality assurance and documentation of treatment effect: 1) Health: Self-assessed physical health, self-assessed mental health, 2) Quality of life: Self-assessed QOL (QOL1), QOL measured with a small questionnaire (i.e. QOL5) 3) Ability: Self-assessed sexual ability, self-esteem social ability and working ability.

Keywords: Quality assurance, treatment effect, research methodology, global quality of life, CAM, holistic medicine

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Introduction

During the last two decades a large number of papers have documented that the most important factor and

most significant endpoint in studies of effects of medical treatments is the self-rated health (1-11).

- "Self-rated health (SRH) is considered a valid measure of health status as it has been shown to predict mortality in several studies" (4)
- "Self-assessed health status has been shown to be a powerful predictor of mortality, service use, and total cost of medical care treatment" (5)
- "Self-rated health contributes unique information to epidemiologic studies that is not captured by standard clinical assessments or self-reported histories" (7)
- "Self-evaluations of health status have been shown to predict mortality, above and beyond the contribution to prediction made by indices based on the presence of health problems, physical disability, and biological or life-style risk factors" (8)
- "The results suggest that poor self rated health is a strong predictor of subsequent mortality in all subgroups studied, and that self rated health therefore may be a useful outcome measure" (11)

Self-rated health has been documented to predict survival time and future health better than any other known health parameter. This means that self-rated health has been found to be a valid and possibly the most valid health measure. To document improvement of health we need to measure self-rated health; and to measure health we need to measure self-rated health. Most unfortunately the research has worked with a single item questionnaire of self-assessed health, making it very difficult to understand what is measured by the questionnaire. We have as a part of the validated QOL5 questionnaire included two items on self-assessed physical health and self-assessed mental health (see appendix 1). We have found that these two items function extremely well in quality assurance and in documentation of treatment effect (12,13). We therefore recommend that these two measures, together with measures of self-assessed global quality of life (like the single item QOL1 (14) or QOL5 (14)) and self-assessed measures of ability are used for quality assurance and documentation of research effect. We have combined ten key questions into the QOL10-battery measuring self-assessed health, quality of life, and ability in general, and found this to be of immense value.

The use of QOL10 and its ten key questions makes it possible to group the patients into treatment groups according to their health/QOL/functional problems, and follow the development of each group to see how well they are helped in the clinic setting (12,13,15-18).

The QOL10

The idea behind QOL10 is the *sense of coherence (SOC),* a very important dimension in life developed by Aaron Antonovsky (1923-1994). The subjective experience of sense of coherence stem from a line going from life inside us to reality outside us (19). Sense of coherence is thus closely related to the concept of meaning of life and global QOL, as we find it for example in the IQOL theory (20). You can say that sense of coherence is the experience of being an integrative part of the world. The world is your home, you have come home in the world. Psychologically the secure base that your mother was, when you were a child has become the whole world. In religious terms, you live in God, or in Sunya (the great emptiness), and no longer in Maya, the illusionary world.

QOL is determined by the global state of the person, while self-assessed health is determined by the inner state of this person. Self-assessed ability in the relevant dimensions (work, social, sex, love) is determined by the social state of the person. In our experience health, QOL and ability are improved simultaneously, when the person is healing his existence though the process of salutogenesis.

Due to our experience with the symmetric 5-point Likert scales for psychometric research (21), we selected this scale for all items. The QOL5 and QOL1 questionnaire was validated earlier (14) and we also plan to validate the QOL10 questionnaire.

Analysing the data

For research in treatment effects and quality assurance you need about 20 patients in each group for a valid test. You need according to our experiences to measure the patients before and after treatment with a one year follow-up questionnaire. If the treatment is taking place over a long period of time you need to measure before treatment, then three months later and then again a year after treatment. If you do it this way, you can measure a change in health that is highly likely to be the effect of your treatment, meaning that you can use the patients as their own control (we call this the Square Curve Paradigm) (22).

The simplest way to analyze data is by dichotomizing the scale in a "bad" and "well" part. We normally use the bottom values [4 and 5] on the Likert scale as an indication of "bad" and the top part of it [1,2 and 3] as "well". You include all starting participants in the study. Only patients who comply with the treatment and answer the questionnaire in the end of the study, and report that they are well now, are included in the "cured" group; all the dropouts, non-responders of questionnaires, and not-cured are treated as not cured. We finally used a statistical table (23) to establish the confidence interval.

The time consumption of administering, collecting and analyzing the QOL10 were only ten minutes per patient. The QOL10 is free for all to use. The statistics can be made in e few hours and by people with no statistical education. We found in our study of the treatment effects of clinical holistic medicine (CHM) (24-58) that the six following dimensions measured by the QOL10 questionnaire were of primary interest:

1. Self-assessed physical health (12)
2. Self-assessed mental health (13)
3. Self-assessed QOL (measure with QOL1) (17)
4. Self-assessed sexual ability (16)
5. Self-assessed self-esteem (relation with self) (15)
6. Self-assessed working ability (18)

1) and 2) are the self-assessed physical and mental health, and the average of this corresponds well to the single item questionnaire of self-assessed health (statistical validation of this statement is planed).

An example

Data is taken from one of our studies (13). 54 patients felt mentally ill before treatment (rating 4 or 5 on the 5-point Likert scale of self-assessed mental health of QOL5). 31 Patients did not feel mentally ill any more after treatment (rating 1, 2 or 3 on the Likert scale). Six patients still felt mentally ill after treatment (rating 4 or 5). 17 patients were non-responders upon follow-up of withdrew during the study.

We thus treated 54 patients, who rated themselves mentally ill before treatment, 31 patients did not do so after treatment. From this we calculate a curing rate of 57,4%. The table (23) gives us 95% CI: 43.21% - 70.77%). From this we estimated: $1.41<NNT<2.31$. We then analysed the changes in all QOL10 measures for the treatment responders using paired samples T-test, and found that all measured aspects of life improved significantly, simultaneously, and radically (see table 1): somatic health (from 2.9 to 2.3), self-esteem/relationship to self (from 3.5 to 2.3), relationship to partner (from 4.7 to 2.9 [no partner was rated as "6"]), relationship to friends (from 2.5 to 2.0), ability to love (from 3.8 to 2.4), and self-assessed sexual ability (from 3.5 to 2.4), self-assessed social ability (from 3.2 to 2.1), self-assessed working ability (from 3.3 to 2.4), and self-assessed quality of life (from 4.0 to 2.3) (see table 1). Quality of life as measured with QOL5 improved (from 3.6 to 2.3 on a scale from 1-5 ($p<0.001$)). Most radically the self-rated mental health improved by 1.97 steps on the Likert scale, from a bad mental health to a good mental health. This documents that the patients were not just "flipped" over the artificially defined border between the two dichotomised groups, but their mental health were actually radically improved.

All this data documents a general improvement that strongly indicates that the patient had healed existentially and experienced what Antonovsky called "salutogenesis" (59,60), defined as the process exactly the opposite of pathogenesis.

Table 1. 31 patients who changed from feeling mentally ill to mentally well (defined as "not ill"), healed all measured aspects of life due to Antonovsky salutogenesis: Somatic health, relationship to self, relationship to partner, relationship to friends, ability to love, and self-assessed sexual ability, self-assessed social ability, self-assessed working ability, and self-assessed quality of life. Paired samples T-test

	Paired Differences					t	df	Significance (2 – tailed)
	Mean	Std. Deviation	Std. Error mean	95% confidence interval of difference				
				Lower	Upper			
Physical health	.6000	.89443	.16330	.2660	.9340	3.674	29	.001
Mental health	1.9677	.79515	.79515	1.6761	2.2594	13.778	30	.000
Self esteem	1.2258	1.11683	1.11683	.8161	1.6355	6.111	30	.000
Relation to friends	.5161	.92632	.92632	.1764	.8559	3.102	30	.004
Relation to partner	1.8065	2.27185	2.27185	.9731	2.6398	4.427	30	.000
Ability to love	1.3548	1.60309	1.60309	.7668	1.9429	4.706	30	.000
Sexual ability	1.0323	1.35361	1.35361	.5358	1.5288	4.246	30	.000
Social ability	1.1613	1.12833	1.12833	.7474	1.5752	5.730	30	.000
Work ability	.9000	1.06188	1.06188	.5035	1.2965	4.642	29	.000
Quality of life	1.7097	1.03902	1.03902	1.3286	2.0908	9.162	30	.000

As reference value we have "2" (good) on the 5-point Likert scale, which corresponds to being well and normal (this is in accordance with what have been found empirically in large population surveys in Denmark) (61). We therefore see that the 31 mentally ill patients, that where helped with holistic therapy, actually almost normalised all their scores, signifying that they were indeed cured, not only improved.

It is very important to have a system to collect side effects and we therefore observed for brief reactive psychosis, suicide attempts, suicide, and signs of re-traumatisation (62), but did not observe these side effects in over 500 patients. The therapy was found to be safe, (estimated from this: NNH>500). We then could present the NNtH/NNtB as 500/(1.41<NNT<2.31). As we for medical-ethical reasons need to use the most pessimistic number for the calculation we find NNtH/NNtB/NNtH=500/2.31= 216.5.

We can compare this with the treatment of mentally ill schizophrenic patients with Clorpromazine (63): *Number Needed to Treat:* Prevents relapse, longer term data: NNT 4 CI 3 to 5. Improves symptoms and functioning NNT 6 CI 5 to 8. *Number Needed to Harm:* Sedation: NNH 5 CI 4 to 8. Acute movement disorder NNH 32 CI 11 to 154. Need for antiparkinson drugs NNH 14 CI 9 to 28. Lowering of blood pressure with accompanying dizziness NNH 11 CI 7 to 21. Considerable weight gain NNH 2 CI 2 to 3. Thus we find NNtH/NNtB=2/5=0.4. If we treated schizophrenics only, our treatment would have been 543.5 times more valuable than the treatment with chlorpromazine, but we did not as our group was an undiagnosed, mixed group of patients feeling mentally very ill.

Conclusions

The QOL10 combined with the Square Curve Paradigm data collecting procedure seems to be an extremely efficient, fast, in-expensive and valid method of documenting treatment effect and securing quality of a treatment facility. Self-rated health seems to be the most important health measure we have. It is simple to use and eminent for documenting treatment effects and securing quality of a clinical practice.

The use of QOL10 and its 10 key questions makes it possible to group the patients into treatment groups according to their health/QOL/functional problems, and follow the development of each group to see how well they are helped in the clinic. We found the following dimensions to be of primary interest in quality assurance and documentation of treatment effect:

- Health: Self-assessed physical health, self-assessed mental health,

- QOL: Self-assessed QOL, QOL measured with a small questionnaire like QOL5
- Ability: Self-assessed sexual ability, self-assessed self-esteem (relation to self), self-assessed social ability, and self-assessed working ability.

Also important are the self-rated quality of relation to partner, self-rated quality of relation to friends, and self-assessed I-strength (ability to love). We thus recommend the QOL10 (see appendix 1) measuring the global quality of life, self-rated physical and mental health, and self-rated ability for inexpensive, fast and reliable clinical quality-assurance and for research in treatment-efficacy in biomedicine, complementary and holistic medicine.

Appendix 1

The QOL10 – a 10 item questionnaire on health, QOL and ability including the validated QOL5 and QOL1

Q 1 How do you consider your **physical health** at the moment?

1 very good
2 good
3 neither good nor bad
4 bad
5 very bad

Q 2 How do you consider your **mental health** at the moment?

1 very good
2 good
3 neither good nor bad
4 bad
5 very bad

Q 3 How do you **feel about yourself** at the moment?

1 very good
2 good
3 neither good nor bad
4 bad
5 very bad

Q 4 How are your relationships with your **friends** at the moment?

1 very good
2 good
3 neither good nor bad
4 bad
5 very bad

Q 5 How is your relationship with your **partner** at the moment?
1 very good
2 good
3 neither good nor bad
4 bad
5 very bad
6 I do not have one (This is scored like "5" very bad)

Q 6 How do you consider your ability to **love** at the moment?

1 very good
2 good
3 neither good nor bad
4 bad
5 very bad

Q 7 How do you consider your **sexual functioning** at the moment?

1 very good
2 good
3 neither good nor bad
4 bad
5 very bad

Q 8 How do you consider your **social functioning** at the moment?

1 very good
2 good
3 neither good nor bad
4 bad
5 very bad

Q 9 How is your **working ability** at the moment?

1 very good

2 good
3 neither good nor bad
4 bad
5 very bad

Q 10 How would you assess your **quality of your life** now?

1 very high
2 high
3 neither low nor high
4 low
5 very low

The Endpoints you collect are:

QOL1: Self assessed (global) quality of life[]
QOL5: Measured global quality of life[]
QOL10: QOL+Health+Ability/3

To calculate QOL1: Q10

To calculate QOL 5: ((Q1+Q2):2+Q3 + (Q4+Q5):2):3

To calculate QOL 10 "Health-QOL-Ability":

([Health] ((Q1 + Q2).2) + [QOL] ((Q10)+(Q3+Q4+Q5):3):2)+ [ability] ((Q6+Q7+Q8+Q9):4)):3

The result is comparable to a five point Likert scale of global QOL but more informative. QOL10 is a "global life status", we like to think of this measure as a "subjective sense of coherence(SOC)" measure. We just call the measure "Health-QOL-Ability".

The normal values for Danes for QOL1, QOL5 and QOL10 are around "2" [Ventegodt, S. (1995) *Livskvalitet I Danmark. Quality of life in Denmark. Results from a population survey.* [partly in Danish] Copenhagen: Forskningscentrets Forlag.] (you will see that "2" equals "70%" in the Table if you transform the result to "percent of maximum" as described in [Ventegodt, S. (1996) Measuring the quality of life. From theory to practice. Copenhagen: Forskningscentrets Forlag.].

To keep it simple we recommend the use of this scale for comparison:

Q 10 Measured quality of your life:

1 very high
2 high
3 neither low nor high
4 low
5 very low

Interpretation: 1 is great, 2 is normal, 3 is bad for QOL1 and very bad for QOL5 and QOL10; 4 is very bad for QOL1 and deadly for QOL5 and QOL10; 5 is dying for QOL1, QOL5 and QOL10 - you cannot survive for very long with this low rating.

I would say; if your patients in average are doing worse than QOL1=3 and QOL5= 2.7.5 and QOL10 =2.5 then a significant number of your patients might have severe existential problems and significant suffering.

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