

# The Danish Translation of the Medicines-related Quality of Life (MRQoL) Scale From the Patient Perspective

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## Research Article

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# Abstract

**BACKGROUND:** Pharmacist interventions (PIs) have shown varying effect on Health-Related Quality of Life (HRQoL). However, the instruments used to measure HRQoL also lack sensitivity in detecting the effect in relation to PIs. In 2017 the Medicines-Related Quality of Life (MRQoL) scale was translated from Chinese into Danish, but the Danish MRQoL scale showed marked ceiling effects.

**OBJECTIVE:** To evaluate the Danish MRQoL scale from a patient perspective using cognitive interviewing.

**SETTING:** Polypharmacy patients in the capital region of Denmark.

**METHODS:** Semi-structured cognitive interviews with patients ( $\geq 18$  years) taking  $\geq 5$  medicines regularly were conducted. A purposive sampling strategy was applied recruiting from different locations in the Greater Copenhagen Area. Interviews were recorded, transcribed, and analysed thematically.

**MAIN OUTCOME MEASURE:** Patients' thought processes when responding to the Danish MRQoL scale.

**RESULTS:** Eight patients were interviewed. Two major themes emerged from the interviews: The role of the medicines in everyday life and Understanding and filling in the scale. The latter theme consisted of three sub-themes: Interpretations of the items, Recall period and Interpretation and use of scale possibilities. The patients did not think about their medicines when answering the scale. Several items were interpreted differently by the patients and they used different recall periods. Some patients used the scale possibilities incorrectly, either by overstating or understating their answers, or simply to create variation in responses.

**CONCLUSION:** Several reliability and validity issues were identified based on the interviews and further research is needed to develop more reliable and valid measurement tools to detect the effect of PIs on HRQoL.

## Impacts On Practice Statements

- Since the participants did not distinguish between MRQoL, HRQoL and QoL it is challenging to find an outcome measure that can measure how patients see their medicines taking in relation to quality of life
- Further development of scales intended for this purpose may either build on the MRQoL scale or other developed scales, using both qualitative and quantitative methods to ensure reliability and validity.

## Introduction

The term 'polypharmacy' refers to the use of multiple medicines and is typically defined as the use of  $\geq 5$  medicines (1, 2). Polypharmacy is related to an increased risk of drug-drug interactions and side-effects and it is important to ensure optimal treatment to minimize these risks (3, 4). Polypharmacy is often

managed in the clinic by the general practitioner, who conducts the assessment of appropriate medicines to treat the disease, but in recent years also pharmacists have begun contributing (5, 6).

A pharmacist intervention (PI) is an intervention where the pharmacist is involved in the assessment of a patient's medicines. The intervention can involve several inputs such as a medication review (7), medication history taking (5), patient counselling, or a combination (8, 9). Several studies investigating the effects of PIs in either the hospital or community setting revealed non-rational pharmacotherapy and drug-related problems among the patients, but the studies also reported variable effect on clinical outcomes (5, 8–12).

The effects of PIs have also been studied on patients' Health-Related Quality of Life (HRQoL). HRQoL and Quality of Life (QoL), terms that are often used indistinguishably (13).

PI studies measuring HRQoL outcomes vary regarding the measured effects or the methods used (10). Some studies found no significant change in patients' HRQoL after receiving a PI (11, 12) while others found a significant change or effect (14, 15). These studies used different methods and scales when investigating the patients' HRQoL.

As a growing number of studies could not find a clear significant change in patients' HRQoL, it is questionable if the existing measurement tools are sensitive enough to measure the effect of PIs, where the clinical intervention focuses on medicines. The HRQoL instruments are designed to measure HRQoL in relation to disease and treatment and no or only a limited number of scale items directly concern medicines (16).

A number scales have been developed with the purpose of better measuring the subjective effect of medicine use, and in turn, of PIs in patients (17–23). One of these scales was the 14-item Medicines-Related Quality of Life (MRQoL)-scale originally developed in Taiwan, which is used for polypharmacy patients (17). The MRQoL-scale has recently been translated from Chinese to Danish, where the psychometric validation yielded high ceiling effects questioning the scale's sensitivity in a population of Danish polypharmacy patients (24).

## **AIM OF STUDY**

The aim of this study was to evaluate the Danish MRQoL scale from a patient perspective using cognitive interviewing.

## **Methods**

### **Design**

The cognitive interview approach was chosen because it is the method most used to investigate how participants think while answering a scale. The method shows the thought process of a participant when answering a scale, which is very close to the real-world way of answering, where the participant sits alone

with the scale (25, 26). The method has also been used in evaluating other scales regarding the medicines' impacts on the patient's life (19, 21).

## **Participants and Setting**

A purposive sampling strategy was chosen to ensure variation in age, gender and number of used medicines (27). Inclusion criteria for participating in the interview were adults with polypharmacy, defined as the use of 5 or more medicines regularly. Exclusion criteria were persons under 18 years of age and persons with any cognitive impairment which could reduce the ability to be interviewed. Patients were included or excluded by IVR. The face-to-face recruitment took place in four different locations; a housing association, an activity centre (for persons  $\geq 65$  years old), a community pharmacy and a high school - all located in the Greater Copenhagen Area.

## **Interviews**

The interviews were carried out by IVR using a cognitive interviewing approach where the two main approaches 'think aloud' and 'verbal probing' were combined (28). A semi-structured interview guide was designed using the Danish MRQoL scale as the starting point. Each item was examined to discover probable misunderstandings. Possible probes were made for each item and they were to be used if deemed appropriate. Some general probes were also made which could be used throughout the interview if necessary. The interview guide was piloted, and no changes were necessary after piloting.

The interviews were performed in a location chosen by the participant. The participant was handed the Danish MRQoL scale at the start of the interview and was asked to think aloud while answering the scale. Probes were used to investigate an item's anticipated pitfalls and follow-up questions were used to clarify answers. All interviews were carried out in Danish, audio recorded, and transcribed verbatim.

## **Analysis**

The transcribed interviews were analysed using inductive thematic analysis on a semantic level (29). The analysis followed the step-by-step guide to the thematic analysis as proposed by Braun and Clarke (29). The coding of the interviews was conducted by IVR. The initial coding of one of the interviews was conducted separately by IVR and ABA, and the results were compared and agreed upon. The resulting themes were discussed and agreed upon by IVR, ABA and LVJL. The cited quotes were translated from Danish to English by IVR and validated by ABA, and each participant was labelled numerically in the order of which the interviews were planned.

## **ETHICS APPROVAL**

Written information about the study was provided to patients at the time of recruitment. All participants signed an informed consent form at the beginning of the interviews. The study did not require ethics approval or registration by the Danish Data Protection Agency. The interview data were stored according to the EU rules of GDPR.

## Results

Eight interviews were carried out during March and April 2019. Five women and three men participated, ages from 33–87 years (average: 69.5 years, median: 75 years) and taking between five and ten medicines regularly (average: 7, median: 6). The interviews were performed in the participant's own home (N = 6), at an activity centre (N = 1), and in a café (N = 1).

From the eight interviews two major themes emerged: *The role of the medicines in everyday life* and *Understanding and filling in the scale*. *Understanding and filling in the scale* consisted of three sub-themes: *Interpretations of the items*, *Recall period* and *Interpretation and use of scale possibilities*.

Table 1

The Danish MRQoL scale in an English translated version. Below is an English translation of the Danish MRQoL scale. This English version is translated directly from Danish to reflect the Danish version of the scale as much as possible, but this version is not validated, and exclusively serves to provide an overview of items, scale possibilities and recall period as presented for the participants in the interviews.

<i>During the last month, in relation to taking medicines, did you feel that ...</i>							
Items	Question	Scale possibilities					
		Never	Seldom	Sometimes	Often	Very often	Always
1.	You have had less time for work or daily activities?						
2.	You have had less energy to do work or daily activities than you wanted to?						
3.	You have completed less work or daily activities?						
4.	You have had to make an effort, or it has been difficult to complete work or daily activities?						
5.	You have had difficulties participating in social gatherings with family and friends?						
6.	You have not had energy for your leisure activities, like sport or watching TV?						
7.	You have had difficulties concentrating in relation to work or daily activities?						
8.	You have been tired, exhausted or had difficulties doing work or daily activities?						
9.	You have had less days filled with energy?						
10.	You have been frustrated or sad?						
11.	You have been a burden to others?						
12.	You have been worried about disappointing others?						

<i>During the last month, in relation to taking medicines, did you feel that ...</i>	
13.	It has been necessary that you had to cancel an appointment or activity?
14.	You have had to stop work or a daily activity?

## Understanding and filling in the scale

The interviews revealed that the participants had several issues with the understanding and filling in the scale. Both items and scale possibilities had various interpretations by the participants and the participants seemed to apply a different recall period than described in the scale. Additionally, there seemed to be discrepancies between what the participants chose to answer on the actual scale item and their oral explanations.

## Interpretations of the items

The participants skimmed the scale introduction without necessarily reading it thoroughly. It did not cause issues in relation to their ability to complete the scales, but the items were many times rephrased by the participants so that they omitted the first part of the item, which is placed in the introduction at the top of the scale. It was therefore evident that the participants in their effort to respond to the scale did not make a connection between medication-related problems and the items but saw the items as being about their life and health in general. This was in concordance with what participants reported after they had completed the scale and gave more insights into their living with medicines.

Several items caused problems for the participants. These problems were mainly interpretation problems, i.e. the participants understood the items in various ways, but there were also difficulties with the wording of some items.

Items 1, 2, and 3 showed the same problems for all participants. They used the words 'time' and 'energy' when talking about these three items where they did not necessarily distinguish between these words and were more concerned with how they did not accomplish as many activities as they wanted to due to ill health.

*"[Item 1] It relates a lot to how much energy I have for my children and my wife and how my mood is ... if I have a short fuse." (Man, 33 y.)*

Items 4, 7, 9, and 13 revealed interpretation problems as the interviewees understood items in different ways. They defined 'effort', 'concentrate', 'filled with energy', and 'interrupt' in various ways. The varying interpretations of the items led to different responses to the items, even if the described situations were

similar. For instance, the term 'filled with energy' was interpreted by the majority as having the energy to do everything or more than usual.

*"[Filled with energy] That is when I am a little manic. Then I get a bucketload done. Often several things at once. Then I will super tidy up or wash a bucketload ... clean places that normally would not get cleaned. And then I am completely worn-out when the day is over." (Woman, 52 y.)*

Item 11 caused another interpretation problem. The item asks to the participant's feelings of being a burden to others due to the use of medicines, but most participants answered whether or not they were an actual burden to others in their daily lives.

*"I don't think I am. Not that I know of, I have taken care of myself in all sorts of things. Also, I have my own car if it ... I don't think there is anything to it." (Woman, 83 y.)*

In item 5 (Interfered with your social activities with family or friends) and 13 (Had to cancel scheduled appointments or meetings) the participants brought up new aspects of the items which had not been considered when formulating the items. In item 5 the transportation to social activities was considered a potential hindrance without reference to medicines, and in item 13 the participants had chosen not to plan any appointments if there was a chance of cancelling due to ill health.

*"Really, I do not have difficulties attending social activities with family and friends when I have a lift. "*  
*(Woman, 76 y.)*

Item 6 was difficult to understand for the participants and there were multiple interpretations of 'leisure activities'. The participants also used the two given examples provided and refrained from thinking of other leisure activities.

*"Oh dear, no, I can still watch TV. I also participate in a little exercise and such in [the activity centre] ..."*  
*(Woman, 83 y.)*

It was also revealed that the participants had difficulties to define 'daily activities' which was a frequently used term in the scale items. For some it was housekeeping, others thought it was time spent outside work or it was leisure activities.

*"It is doing the dishes after eating, cooking ..". (Man, 87 y.)*

*"Well, before I got this blood clot, I was ... went to physical exercises and did Nordic walking." (Woman, 83 y.)*

## **Recall period**

Throughout the interviews it was revealed that the participants were using other recall periods than the indicated one month. Conversely, during the interview some participants told long stories from their life stretching far back in time and used these stories to come up with an answer.

*“Well, what is less time? I suppose it is when you are under pressure. I would say, when I had my husband home – he died of cancer – I could have used more time then. That was round the clock work.” (Woman, 83 y.)*

Another approach was to compare their current life situation to before the disease emerged.

*“I think ... I definitely perceive that my ‘filled with energy’ today is not much bigger than 50 % of ‘filled with energy’ five years ago. “ (Man, 33 y.)*

## **Interpretations and use of scale possibilities**

During the interviews it was revealed that the participants did not always answer items on paper equivalent to their oral descriptions. All participants beautified one or more answers either by understating or overstating.

Understating was done by participants to indicate that they were ‘all right’ even if they had challenges with their health. This was shown either by participants saying, ‘it is not that bad’ and then choosing a response on the scale that did not agree much with the verbal explanation.

*“You have had to make an effort or had more difficult in accomplishing job assignments or daily activities? Often, yes, 4.” (Man, 87 y.):*

*Interviewer: “When do you have to make an effort?”*

*“When I finally get out of bed and get dressed and have taken a shower and so on ... taken care of myself. That demands a good deal of overcoming especially in my age.” (Man, 87 y.)*

Participants sometimes overstated and chose a category that was higher than pertained to today's feelings in order to take uncertainties into account. Some participants described not having cancelled any appointments in the past month, but still chose to tick off the response category *seldom*, and some described not being a burden to others, but still chose *seldom* instead of *never*.

*“No, I don't think so. At least nobody has said anything. But let's say number two because it may well be the case sometimes, that ..”. (Man, 68 y.)*

Three participants also mentioned that their answers should have some variation, indicating that they did not like always answering by ticking off the same response category.

*“Yes. Then we will write rarely. To make some variation. “ (Woman, 74 y.)*

## **The role of the medicines in everyday life**

After completing the scale, the participants were asked how they considered their medicines while answering the items. The participants said they did not think of their medicines while completing the scale.

*"I didn't think about it, not at all." (Woman, 83 y.)*

Other participants described similar thoughts, as they simply take the medicine but do not feel an improvement or worsening. The medicines are a part of their daily routine and it is not an aspect of life they put much thought to.

*"Well, the medicines and taking the medicines have not been a part of the answer. Well, it is a routine. "*  
*(Man, 87 y.)*

The participants also had difficulties estimating whether they experienced side-effects or not. It was difficult for the participants to determine if their feeling ill was caused by the disease or by side-effects. Some participants told they were bothered by tiredness, but they were all unsure whether it was caused by the drug or the disease. As explained by this participant.

*"I think it is damned difficult to say what is one and the other [disease or side-effects]. I merely take comfort in the fact that they say the same thing at the hospital, it is almost impossible to say what is one and the other." (Participant 10, man, 68 y.)*

The participants were asked about how many medicines they took regularly, and it was revealed that the participants did not agree on a definition of medicines. Four described their medicines as how many pills they take and four described the medicines as either brand name or pharmaceutical ingredient. For some, nutritional supplements were regarded as medicines while others were unsure.

*"I take ... six pills every morning. I also take some vitamin supplements on the side. But I don't know ... that's ... no one ... that's something I have figured out myself gradually." (Woman, 83 y.)*

The participants viewed their medicines as a representation of the disease. For some, the medicines were a noticeable part of their life partly because they do not function normally without medicines, either because of pain or mental stability.

*"All the time the alarm goes off and then I must go and take my medicines, so no matter what I'm doing there is always this reminder, that I must try to balance myself in an altogether unnatural way to prevent it all from tumbling down." (Man, 33 y.)*

## **Discussion**

According to the participants the Danish MRQoL scale was manageable and easy to use. They seemed to have no problems completing the scale, but the interviews revealed several concerns regarding the scale. The participants had difficulties understanding some items in the scale, they used wrong recall periods, and they tended to either understate or overstate their responses. It was also found that medicines did not influence greatly on the participants' lives. The medicines were necessary and important for a life without disease, but the participants would rather live without it if this was a possibility. This suggests that the medicines are merely seen as a necessity to avoid illness. This finding is also reported in other studies

(3). As the participants did not regard their medicines as important in everyday life, it affected the reliability and validity of the Danish MRQoL scale. The participants weighed other aspects of life higher and chose instead to answer in relation to these.

The validity of a scale is connected to the variation of item interpretation. If the participants did not interpret the item as intended, they answered either a different question or chose a score not suitable for their situation. A number of concepts in the scale caused varying responses on the scale in spite of them answering based on similar situations. This indicates low reliability and validity as the scale is self-administered to the patients. Variable interpretations of items is a common problem seen in evaluations of scales, and they should be minimized before scales are used in a large population (28).

During the interviews, the participants did not always read the introduction to the items before each item. This was only done if they were in doubt about the item's meaning. The item introduction is very important to secure that the participants answer the items validly, but if it is not read or remembered, the aspect of medicines will not emerge in the responses. However, the participants omitted the recall period and instead answered items with different time frames, which makes their answers non-comparable. It is common that survey participants do not always read the instructions of a scale (30). The participants might fail to include the introduction due to a substantial cognitive demand. Participants are supposed to do a thorough memory search to produce satisfying data, but the standard participant cuts corners. This is caused by satisficing, where the participant simply gives a reasonable answer after reading the item only superficially (31).

As the participants did not include medicines in their answers, it is difficult to claim that the Danish MRQoL scale measures MRQoL. The participants described troubles concerning their disease, old age, or general aspect of life, e.g. their families, and not specifically about their medicines, which seems to be merely a part of their everyday life and a routine. Therefore, it is uncertain if the participants were able to distinguish between QoL, HRQoL, and MRQoL, which has also been seen in the literature (13). All participants described joy when talking about their family, which suggest they are more focused on other QoL aspects than those regarding health and medicines. The difficulties with distinguishing between QoL and HRQoL are well described in the literature, as there is no golden standard or definition of QoL and HRQoL (32). Therefore, it can be argued that another concept, such as MRQoL, is merely adding to the confusion.

There are several instruments which measure the impact of medicines on patients' QoL or HRQoL (17–19, 22, 23). The methods all aim to measure the medicines' impact on the patient's life, but they vary in their definitions of QoL and HRQoL, theoretical foundations, and measurement parameters, and therefore they are not truly comparable, which also is seen in the literature (33).

## **Strengths and Limitations**

The data collection continued until saturation, as no new data was obtained after interview 6. As this study was qualitative, findings cannot be used to generalise to a larger population. However, the study

does provide an understanding of how the participants comprehend the scale. The interview setting mimicked a real-world way of administering the scale, and it is possible to assume that the same issues will arise when the scale is self-administered (25).

The cognitive interview methods were also used in the development of other similar scales (18, 19). Willis *et al.* describes verbal probing as the optimal way of conducting cognitive interviews, but the think-aloud version was used as it ensures more raw data (28).

## Conclusion

This qualitative evaluation showed that the Danish translation of the MRQoL scale does not seem to measure patients' MRQoL. Several items had reliability or validity issues. The participants did not include their medicines while completing the scale and apparently, they did not distinguish between their MRQoL and the more general QoL and HRQoL. The recall period varied, and interpretations of response categories were uncertain.

The Danish MRQoL scale is not optimal in its current state and future research should investigate possible improvements or use the findings of this study to develop a new scale.

## Declarations

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Non-applicable.

## CONFLICTS OF INTEREST

The authors declare that they have no conflicts of interest.

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