

# Italian pilot version of DEMOQL-PROXY: Content and Face validity: a methodological bridge for a future Italian validation

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**Abstract.** *Background and aim of the work.* The assessment of Quality of Life through validated tools allow to improve level of assistance for people suffering from Dementia. To our Knowledge in Italian language seem to be absent a tool to evaluate mild and moderate dementia, consequently underestimating and underrating needs of this specific target. We show an Italian pilot version of the DEMQOL-PROXY (specific for mild and moderate Dementia) testing some psychometric properties as: back-translation, content validity and face validity in Italian language. *Method.* A back-translation by two bilingual authors was presented. Was enrolled an expert panel to test Content Validity composed by eight Medical Doctor and a panel of six participants was recruited to assess Face Validity (three professional caregivers and three family caregivers) related to patients with moderate Dementia (with 10 to 20 MMSE, mild and moderate Dementia). *Results.* Each item has a degree of agreement between experts of more than 70% and the Total CVI score is .90 (90% of agreement). So, in line with these results we can accept the version of items proposed. As regard Face Validity, the items of the instrument seem to be clear, without difficulty and there are no questions considered offensive or irritating. *Conclusion.* The Italian version of the DEMQOL-PROXY showed good psychometric properties: its structure and the results it leads to are similar to the original version and to the other translations produced so far. For this reason, we consider this paper as a methodological bridge for a future complete Italian Validation. ([www.actabiomedica.it](http://www.actabiomedica.it))

**Key Words:** Quality of Life; Dementia; Content Validity; Face Validity; Back-translation

## Introduction

Dementia can be considered one of the major causes of disability and dependency among the elderly around the world, that affects memory, cognitive and behavioural abilities and ultimately interferes with the ability to perform daily activities. Dementia represents substantial human costs for the country, society, family and individuals (1).

Dementia is a domain particularly relevant, for many reasons: (a) entails serious consequences in the affected persons, in the family and in general in the

socio-economic context; (b) so far it is not treatable and is recognized by the World Health Organization (WHO) as a public health priority; (c) it affects a growing number of people and represents the first cause of lowering the Quality of Life (QoL) among neurodegenerative disorders and the first cause of institutionalization (2).

The construct of Quality of Life (QoL) has constantly evolved over time, represented by a lot of definitions. In literature, despite we found a lot a consideration about QoL, it's universally recognized that it's a subjective and multidimensional concept, which is not limited

to physical contexts, but involves psychic, spiritual and socio-economic spheres and the surrounding environment (3). The QoL has become a fundamental and relevant health indicator; in the next years, the growth and social development policies must be designed with a view of improving and/or maintaining it (4). At the same time, one of the most relevant data of western societies is the aging of population and the consequent spreading of all age-related and loss of autonomy diseases, which is forcing many countries to finding suitable solutions. In the world, there are 46.8 million people suffering from a form of dementia; The WHO estimates that in 2050 it will be three times higher, with 7.7 million new cases per year and a survival from diagnosis of 4-8 years (5). Consideration of QoL in dementia could be directly related to quality care provided, so probably deterioration depends also on the poor quality of care received but improve QoL is a realistic achievable result in people with dementia (6).

The assessment of QoL through reliable and validated tools should represents both the objective and the parameter through which verify the effectiveness and efficiency of assistance.

In the last 20 years in the international context, many tools have been developed to evaluate the QoL in dementia (7).

In Italy, over one million people are affected and 600,000 have Alzheimer's disease: it means that around 400,000 people (the number is expected to grow) (5) are affected by dementia in different forms and severity and we don't have any tools to evaluate the QoL. There are few tools and are not indicated in the less advanced phases of dementia, leaving therefore many people uncovered.

To our knowledge in Italian language, there are only two validated instruments: the QOL-AD scale (8), indicated for people with Alzheimer's disease and the QUALID scale, indicated for people who suffer from severe and/or terminal dementia (9). In Italian language to our knowledge, tool to assess mild and moderate dementia seem to be absent, consequently, underestimating and underrating need of this specific target.

Among the International instruments considered, Smith and collaborators have devised an evaluation scale called Dementia Quality of Life-DEMQOL (10), dedicated from mild to moderate dementia (with

10 to 20 MMSE), whose psychometric properties (reliability and validity) have been re-confirmed in both English and Spanish version (10; 11). This tool has some efforts: firstly, the theoretical framework to which it refers, that includes many different aspects of the holistic conception of person, like personal autonomy, health, well-being, cognitive functioning, social relations and self-image. Secondly for the existence of the Proxy form (DEMQOL-PROXY), that assigns the evaluation of the QoL to the reference caregiver and can be applied in many contexts: specialized medicine wards, hospices, home contexts and long-term care settings. We have selected this scale for the gap in Italian language and for the two reasons aforesaid.

## Aim

No Italian version of DEMQOL-PROXY has been validated in Italian language thus far. In line with this gap, we have tested in this paper a pilot version. We show some psychometric properties of the Italian version of the DEMQOL-PROXY: back-translation, content validity and face validity in Italian language, as a methodological bridge for a future complete Italian validation.

## Materials and methods

The study was approved by Ethics Committee of the Santa Maria Nuova Hospital of Reggio Emilia (protocol no. 2018/0141634; approved on 19/12/2018). The first step was the back-translation of the DEMQOL-PROXY in Italian. The translation was made by bilingual authors according to existing guidelines (12;13) and back-translations (Table 1) were made to guarantee the maximum adherence to the original version (10). Written informed consent was obtained from subjects after a detailed explanation of the purpose of the study.

We recruited Content Validity Panel of Experts and Face Validity Panel Group, both between January 2019 and February 2019.

To test *Content Validity*, we enrolled an expert panel composed of 8 experts. We have recruited two

**Table 1.** Original version and Italian translation of the first six items of DEMQOL-Proxy

Question	Original version	Italian version
	In the last week, would you say that your relative has felt:	Nell'ultima settimana, può dirti quanto il/la suo/a assistito/a si è sentito/a:
1	Cheerful	Allegro/a
2	Worried or anxious	Preoccupato/a o ansioso/a
3	Frustrated	Frustrato/a
4	Full of Energy	Pieno/a di energie
5	Sad	Triste
6	Content	Soddisfatto/a
7	Distressed	Angosciato/a
8	Lively	Vivace
9	Irritable	Irritabile
10	Fed-up	Annoiato/a
11	That he/she has things to look forward to	In grado di guardare avanti
	In the last week, how worried would you say your relative has been about:	Nell'ultima settimana, pensa che il/la suo/a assistito/a si sia preoccupato rispetto a:
12	His/her memory in general	Alla sua memoria in generale
13	Forgetting things that happened a long time ago	Dimenticare cose accadute molto tempo fa
14	Forgetting things that happened recently	Dimenticare cose accadute recentemente
15	Forgetting people's names	Dimenticare il nome di alcune persone
16	Forgetting where he/she is	Dimenticare dove si trova
17	Forgetting what day is it	Dimenticare che giorno è
18	His/her thoughts being muddled	Iniziare ad avere pensieri confusi
19	Difficulty making decisions	Avere difficoltà nel prendere decisioni
20	Making him/herself understood	Farsi capire dagli altri
21	Keeping him/herself clean	Mantenersi pulito/a
22	Keeping him/herself looking nice	Mantenere un aspetto gradevole
23	Getting what he/she wants from the shops	Procurarsi le cose di cui ha bisogno dai negozi
24	Using money to pay for things	Usare i soldi per pagare le cose necessarie
25	Looking after his/her finances	Gestire le sue finanze
26	Things taking longer than they used to	Cose che richiedono più tempo in confronto al passato
27	Getting in touch with people	Mettersi in contatto con altre persone
28	Not having enough company	Non avere abbastanza compagnia
29	Not being able to help other people	Non essere in grado di aiutare altre persone
30	Not playing a useful part in things	Non avere un ruolo importante nelle vicende
31	His/her physical health	La sua salute fisica

Medical Doctor for each domain in which DEMQOL-PROXY can be used:

- Two Medical Doctor working in geriatric ward of Hospital
- Two Medical Doctor working in Hospice
- Two Medical Doctor working in residential structure

- Two Medical Doctor working in Home setting

The methodology for panel of expert's construction enrolled to evaluate content validity was adopted considering literature (14;15;16)

We prepared a questionnaire build *ad hoc* for the Content Panel of Experts. In this questionnaire, we asked to the experts to give a judge on Relevance and

Exhaustively for each items of DEMQOL-PROXY. Quantitatively, experts were required to rate item on a 4-point Likert scale in terms of its relevance to the instruments aim using a specifically designed form: 1=not relevant, 2= relevant with item revision, 3= relevant with minor item revision, 4 = very relevant, experts give also a qualitatively suggestion (Table 2). Then the medium of percentage score was the Content Validity Index (CVI). Content Validity Index consists in the medium percentage of experts' s answers. The acceptability cut-off of CVI is > 70% and in line with this cut-off we have considered no changing in the tool.

To explore *Face validity*, we enrolled 6 participants:

- Three professional-care giver (Medical Doctor and Nurses)
- Three family caregivers

To assess Face Validity, we administered an *ad Hoc grid* to the six experts to rate the 32 items of DEMQOL-PROXY on a two-level point scale (YES/NOT) about: difficulties, clarity, offensiveness. The answer of experts was considered on a qualitative way, to detect any request in line with a changing of the item. For any YES answer expert was required to give explanation.

All participants recruited to test content and face validity, were able to perfectly read and understand Italian and to fill out the questionnaires by themselves. The DEMQOL-PROXY were administered to caregivers during their permanence in structures for visiting their relatives or working.

*Statistical analysis*

The statistical analysis was performed by using SPSS Version 25,2019. To evaluate Content Validity,

**Table 3.** Quantification of Item Content Validity on Italian version of DEMQOL-Proxy

<i>Item number of the Italian version of DEMQOL-Proxy</i>	<i>CVI</i>	<i>Action</i>
1	1.00	Retain
2	1.00	Retain
3	0.88	Retain
4	0.88	Retain
5	1.00	Retain
6	1.00	Retain
7	1.00	Retain
8	0.75	Retain
9	0.88	Retain
10	1.00	Retain
11	0.75	Retain
12	1.00	Retain
13	0.88	Retain
14	1.00	Retain
15	0.88	Retain
16	1.00	Retain
17	0.88	Retain
18	1.00	Retain
19	0.88	Retain
20	0.88	Retain
21	0.88	Retain
22	0.88	Retain
23	0.75	Retain
24	0.88	Retain
25	0.88	Retain
26	0.75	Retain
27	0.88	Retain
28	1.00	Retain
29	0.75	Retain
30	0.75	Retain
31	1.00	Retain

CVI, Content Validity Index

**Table 2.** Example of Content Validity Rating Form for Expert Reviewers

Instruction:

Items listed below were included in the preliminary version of DEMQOL-Proxy. Please review the tool and rate each item for relevance in assessing the Quality of Life in patients with Dementia, using a 4 point Likert Scale (from 1=not relevant to 4=very relevant). Please provide any suggestion or recommendation for necessary item revision or deletion.

In the last week, would you say that _____ (your relative) has felt:	Do you think this item is relevant in the measurement of the <u>Quality of Life</u> in patients with Dementia?				Suggestions and comments
	1	2	3	4	
1. Cheerful					
2. Worried or anxious					

Score 1=not relevant, 2= relevant with item revision, 3= relevant with minor item revision, 4 = very relevant

we have performed CVI-*Content Validity Index* (17). Content Validity was carried out using the Scale for CVI-*Content Validity Index* (17), a 4-points Likert Scale which provides for .70 value as acceptability value.

To test Face Validity, we considered answer in a qualitative way, just considered YES answer.

## Results

Table 1 shows the Italian version of the DEMQOL-PROXY confronted with the original one in English. Table 3 reports the results for content validity. All the 8 recruited experts completed the grid. The analysis shows that each item has a degree of agreement between experts of more than 70% and specifically the scores obtained from each item are presented below in Table 1. The Total CVI score is 90 (90% of agreement). In addition, it is noted that of the 32 Items 12 obtained a total consensus from all experts. The detection of Content Validity through the administration of the Scale for the CVI provided an adequate degree of agreement between experts to proceed to the subsequent phases expected for pre-validation; furthermore, the fact that most of the items in the questionnaire obtained a total consensus from all the experts represented a very important positive predictive factor. This results did not require changing of the items proposed.

Also for the Face Validity; the 6 participants completed the *ad Hoc grid* but none give YES answer. So, the qualitative results did not require any changing of the instrument. Our results point out that DEMQOL-PROXY seems to be sufficiently understandable and clear in its formulation. In general, the items of the instrument seem to be clear, there is no difficulty in answering questions and there are no questions that are offensive or irritating.

## Discussion

We present the back-translation (12,13) and some psychometric features as content validity and face validity (14;15;16) for a pilot Italian version of the DEMQOL-PROXY. Our pilot version must be considered as methodological bridge for a future complete

Italian validation. Smith and collaborators, have devised an evaluation scale called DEMQOL-PROXY (10), dedicated from mild to moderate dementia (with 10 to 20 MMSE), another group or researcher (11) have validated also the instrument in Spanish language. The assessment of content validity in our research can be useful to verify thanks to the judgement of the panel of experts if the use of the instrument could be appropriate in Italian Context (14;15;16).

We first produced a back-translation of the DEMQOL-PROXY and then we administered it to the caregivers. Content Validity Index shows that this instrument seems to satisfy the content validity pre-requisite. In our research, the use of DEMQOL-PROXY seems to be appropriate to the Italian context. The total CVI score is .90 and this result points out that, experts evaluate this instrument able to assess in a relevant and exhaustive way the QoL domains for the specific target of people affected by mild or moderate dementia (with 10 to 20 MMSE).

The evaluation of Face Validity confirm that tool was clear, easy to fill and without offensive word. Our results point out that psychometric properties of the Italian pilot version of the DEMQOL-PROXY as back-translation, content validity and face validity in Italian language was verified and allow to consider the Italian version proposed as a valid methodological bridge for a future complete Italian validation.

## Conclusions

The DEMQOL-PROXY could be in Italy an important tool dedicated from mild to moderate dementia (with 10 to 20 MMSE), in order to assess the QoL from the caregiver perspective. Our proposed pilot Italian version of the DEMQOL-PROXY showed good psychometric properties: its structure and the results it leads to are similar to the original version (10) and to the other translations produced so far (11). For this reason, we consider that in future it could be useful to implement a complete Italian Validation of this tool. Moreover, it could be relevant to assess in the future this pilot version for: structural validity, convergent and divergent validity.

DEMQOL-PROXY in fact, is a simple and reliable questionnaire which can be completed in a few

minutes. Its capacity to explore QoL for patients from mild to moderate dementia is a fundamental characteristic so that caregivers of specialized medicine wards, hospices, home contexts and long-term care settings can understand how to improve patient's experience (18). DEMQOL-PROXY application could be helpful to better manage patients with a level of dementia from mild to moderate (with 10 to 20 MMSE).

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