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Health status in patients with limited health literacy; development and validity of the Clinical COPD Questionnaire graphic (CCQg)

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Patients with Chronic Obstructive Pulmonary Disease (COPD) often experience limited health literacy, hampering health status assessment via standard questionnaires like the Clinical COPD Questionnaire (CCQ). We aimed to develop and validate a modified, literacy-sensitive version, the CCQgraphic (CCQg), for all patients with COPD co-designed with a large stakeholder group. CCQ items were rephrased and complemented with graphics, followed by optimization through semi-structured interviews with patients with limited health literacy. In adequate health literacy ($n = 64$) concordance of CCQg and CCQ was 0.88 (95% CI: 0.82–0.92). Correlation with the COPD Assessment Test (CAT) was 0.81 (95% CI: 0.70–0.88). Agreement showed a mean bias of 0.22 (95% CI: 0.10–0.34, $P < 0.001$) with higher scores on mental and functional domains compared to the original CCQ. Test-retest reliability in limited health literacy ($n = 25$) was high, CCC = 0.93 (95% CI: 0.86–0.97). The majority (88%) rated the CCQg as equal or better to the original. The CCQg offers a validated, literacy-sensitive tool, narrowing the gap in health status assessment for patients with COPD with varying literacy skills.

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INTRODUCTION

Chronic Obstructive Pulmonary Disease (COPD) is a heterogeneous lung condition characterized by chronic respiratory symptoms due to abnormalities of the airways (bronchitis, bronchiolitis) and/or alveoli (emphysema) that causes persistent, often progressive, airflow obstruction^{1,2}. The disease course is unpredictable: medical management is based on current health status and exacerbation severity and frequency. The GOLD strategy document suggests four tools to assess symptom status in daily clinical practice, including the Clinical COPD Questionnaire (CCQ)².

The Clinical COPD Questionnaire (CCQ) is a multidimensional questionnaire and is used to measure health status^{2–4}. The CCQ comprises ten items in three domains (symptoms, mental status, functional status, and shows the disease course over time when completed on a regular base³. The patient is assumed to possess a certain level of (health) literacy in order complete this, or any other questionnaire measuring COPD health status. The CCQ is worldwide used and available in more than 80 languages. (<https://www.ccq-questionnaire.org>)

Health literacy is the ability of individuals to obtain, understand, appreciate and use information when making health related decisions⁵. The numbers of low and limited health literacy vary internationally between 29–62%^{6–8}. The definition of health literacy is a broad concept and developing at a fast pace. It is multidimensional and comprises patient characteristics, but has an overlap with socio-demographic characteristics.

Patients with COPD with low and limited health literacy suffer from a higher burden of disease, more frequent hospital admissions, more emergency department presentations are less likely to finish pulmonary rehabilitation and have poorer disease control compared to patients with COPD with adequate health literacy levels^{9–11}.

19.7% of all adults had a low level of reading skills, according to the latest program for international assessment of adult competencies (PIAAC) survey executed in all Organization for Economic Cooperation and Development (OECD) countries. In the Netherlands, this percentage was 13.2%¹² and is a growing problem¹³.

Patients with limited health literacy have less consistent test results in questionnaires. A large study among 1000 participants showed an internal inconsistency in previous validated questionnaires for key psychological instruments in subjects with limited health literacy in comparison to adequate health literacy and could lead to incorrect conclusions and subsequent treatment¹⁴. Low or limited health literacy is related to response to questionnaires with missing data and discrepancies between verbal and written assessments on a visual analogue scale in patients with rheumatic disease^{15,16}.

Not only adjustment of text into plain language in short sentences, but also the use of visual aids in health education materials is proven to be helpful for patients with low literacy¹⁷. A checklist provided by the American Agency for Healthcare Research and Quality to assess the accessibility and

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comprehensibility of patient education material comprises visual aids as one of the items that contribute positively to usability¹⁸.

In 2016, the international consensus on COPD self-management stated that interventions should be literacy sensitive to enhance comprehensibility¹⁹. Fully in line with this agreement, the aim of this study is to develop a questionnaire that can be used by all patients with COPD, hence reducing the gap between patients with COPD with limited and adequate health literacy. To that end, we adapted and validated the Clinical COPD Questionnaire graphic (CCQg) based on the original CCQ, complying with the FDA recommended validation steps²⁰.

MATERIALS AND METHODS

Design of the CCQgraphic

First, a multidisciplinary meeting with relevant stakeholders and experts (the CCQ developers and researchers, two pulmonologists, a representative of the Dutch COPD and Asthma General Practitioners Advice Group (CAHAG), a nurse practitioner, a representative of the Dutch National Expertise Center for low health literacy (Pharos), a medical sketch artist and two language ambassadors took place. Language ambassadors are volunteers with expert experience in low literacy, specifically trained to evaluate medical information and identify barriers to healthcare accessibility for individuals with limited (health) literacy.

The limitations of the CCQ for patients with low health literacy were addressed and discussed and a new CCQg was designed with the input of the above-mentioned group. Different versions of the CCQg were frequently checked with the expert group and adjusted until consensus was reached.

Cognitive debriefing and adjustment of initial design

A preliminary version of the CCQg was evaluated through semi-structured interviews with the target population²¹. Patients with COPD and low or limited health literacy were asked to participate by their treating pulmonary physician. After the clinic visit, low (functional) health literacy was confirmed through a set of predefined screening questions: the "Pharos Quickscan". This quickscan assesses the ability of patients to use, interpret and assess written information²². Eligibility for participation was determined by the identification of low health literacy in one or more domains based on the answers on these questions. We did not predetermine a fixed number of interviews; instead, data collection was concluded once no new information or insights emerged.

One of the authors (ETG) performed the interviews. Feedback from patients collected during the semi-structured interviews was systematically analyzed and communicated to the stakeholders group for further evaluation. Upon validation, modifications to the text or graphical elements were implemented, followed by subsequent rounds of testing in debriefing sessions to ensure the revisions effectively addressed comprehension challenges.

Study design

Patients with COPD from both primary and secondary care were included for validation and reliability assessment of the CCQg, to assess respectively the accuracy and stability of the CCQg. We aimed to include 100 patients with COPD and adequate health literacy, and 40 patients with COPD and limited health literacy. Recruitment was conducted in two ways. First, the database of the General Practice Research Institute (GPRI), consisting of patients who had previously participated in studies and had expressed willingness for future participation, was utilized. Second, in a secondary care center, patients were directly approached for participation by their primary treating physician.

All data was collected by postal mail and analyzed by GPRI, Groningen, The Netherlands.

Patients were grouped based on self-reported health literacy scores measured with the Health Literacy Survey Europe with 16 questions (HLS-EU-16)²³. Based on HLS-EU-16 scores were classified between adequate health literacy group (≥ 13) or limited health literacy group (< 13). After consulting the group that validated the HLS-NL of the HLS-EU-16, we included the patients with missing data in the HLS-EU-16 in the group with limited health literacy (personal communication with Prof. dr. JJ Rademakers, Maastricht, the Netherlands). Since not being able to complete a questionnaire is an indication for impaired health literacy.

The Medical Ethics Committee of the Franciscus Gasthuis&Vlietland Hospital declared that this study was outside the remit of the Medical Research Involving Human Subjects Act (in Dutch: WMO). Study participants gave oral consent for cognitive debriefing sessions and written consent for the validation studies.

The correlation between the graphical and original versions of the CCQ was assessed exclusively among participants with adequate health literacy. The underlying assumption is that individuals with limited health literacy may not complete the original version accurately. Therefore, to ensure the validity of the correlation, only data from those known to have adequately understood the original questionnaire were included in this analysis. At day 0, these patients completed the CCQg, COPD Assessment Test (CAT)²⁴, HLS-EU-16²³, and a general questionnaire containing demographical and disease related questions. At day 14, patients received the original CCQ, Global rating of change scales (GRC)²⁵ for their state of health compared to day 0, and a general questionnaire. At day 28, patients completed the CCQg, GRC for their state of health compared to day 14, and a general questionnaire (Fig. 1).

Patients with low and limited health literacy received the CCQg at day 0 and day 14 in. At day 0, HLS-EU-16, CAT, CCQg and a general questionnaire were completed. At day 14, patients completed again the CCQg, Global rating of scale for their state of health compared to day 0, and a general questionnaire was completed.

A satisfaction questionnaire for the CCQg was designed with statements, a 5-point Likert scale with smileys (totally disagree, disagree, neutral, agree and totally agree), and a text box for comments. The satisfaction questionnaire was sent to all participants. The adequate health literacy group received the questionnaire at day 28, and the limited health literacy group at day 14.

After designing, validation and measuring the reliability of the CCQg in Dutch, forward and backward translation in English was performed by independent translators. Next, the developer of the original CCQ (TvdM) executed cognitive debriefing/ cultural adaptation sessions with COPD rehabilitation participants of the Haringey Breathe Easy programme, London, UK.

Statistical analysis

Patients with stable disease state (GRC score of -1, 0, or 1), and fully completed CCQ questionnaires within the timeframes (first round within 21 days, and second round within 35 days) were selected for data analysis for validation and reliability of the CCQg. Next to GRC stability, clinically unstable patients, as indicated by change in medication or exacerbations in the last six weeks, or in between the rounds, were excluded ($n = 28$).

All data are presented with mean and 95% confidence intervals. Test-retest reliability and validation was examined by Lin's concordance correlation coefficient (CCC)²⁶. One-sample Wilcoxon signed rank test is used for significant differences. A p-value of < 0.05 was considered statistically significant. Data analysis was performed using R version 2021.09.0²⁷.

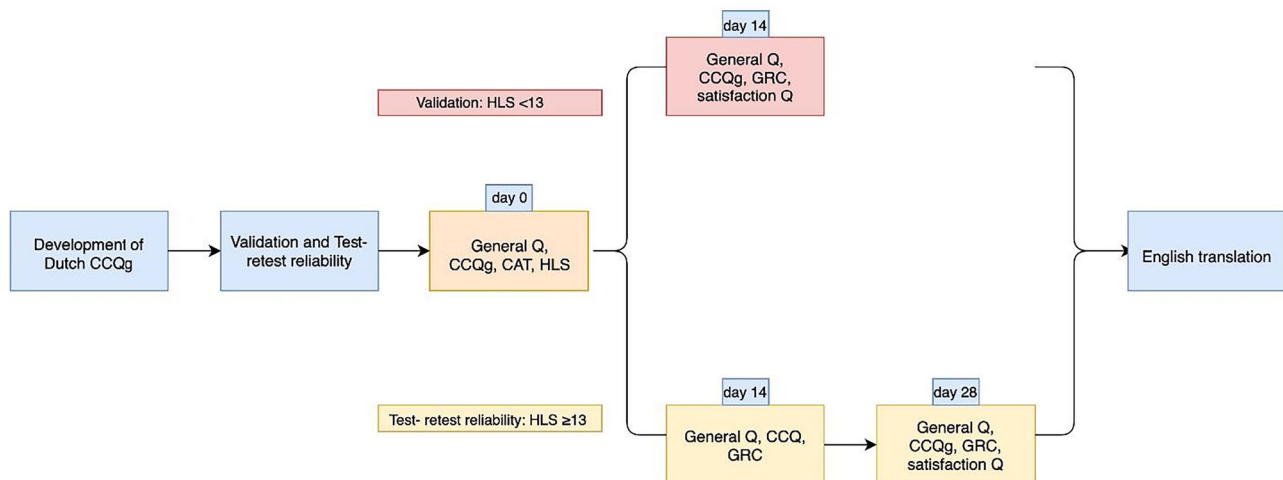


Fig. 1 Study design of validation and reliability of Dutch CCQ graphic (CCQg) version. Adequate health literacy is indicated by an HLS score of ≥ 13 . Limited health literacy is indicated by an HLS score of <13 . CAT = COPD Assessment Test. Q = questionnaire. HLS = European Health Literacy Survey. GRC = Global Rating of Change.

In general, during the past week, how much of the time:

5. Did you cough?



5. How often did you COUGH?

never	hardly ever	a few times	several times	many times	a great many times	almost all the time
0	1	2	3	4	5	6
0	1	2	3	4	5	6
0	1	2	3	4	5	6



0 never 1 almost never 2 some-times 3 regularly 4 often 5 very often 6 always

Fig. 2 The original CCQ presented items with hyphenated sentences arranged both horizontally and vertically, resulting in lengthy statements and a Likert scale that was challenging to interpret. The stakeholder group reached consensus that the reading direction should be unidirectional and horizontal, sentences should be shortened, font size should be increased, and illustrations should be incorporated to support textual information.

RESULTS

Design of the CCQgraphic

During development, difficult to comprehend words by the language ambassadors in the original CCQ were replaced with synonyms that are more common. The sentences were shortened, to comprise seven words at maximum. The hyphenated sentences with vertical reading direction were replaced by complete sentences and statements to understand readability and completing every statement as a rounded whole. To support the statements, drawings of simple figures, designed to be unisex, without ethnic identity were added. Smileys support the Likert scale. Font size and readability were carefully changed with the target audience in mind (Fig. 2). The CCQg covers two pages instead of one page in the original CCQ, due to these adjustments. The readability when printing and copying multiple times in grayscale was checked and approved. The grading of severity in

smileys in colors were checked and approved by two persons who are color-blind.

Cognitive debriefing and adjustment of initial design

A total of 13 interviews were conducted. Two individuals demonstrated adequate health literacy as determined by standardized assessment criteria. During the interviews, we received feedback on multiple levels. Patients felt acknowledged and they were able to understand the questions without help. It gave them a feeling of empowerment. In this dynamic process the feedback led to alterations in the drawings and adjustments of the text. The fonttype and was adjusted after several recommendations during the interviews to improve readability to *Futura*²⁸. The patients observed that the sequence of the final four questions was illogical and caused confusion. In response to this feedback, questions 7 and 9 were interchanged in the CCQg.

COPD questionnaire

These questions are about the past week 

- How often did you feel short of breath while RESTING?

- How often did you feel short of breath during PHYSICAL ACTIVITY?

- How often were you AFRAID of becoming short of breath?

- How often did you feel DEPRESSED about your lungs?

- How often did you COUGH?

- How often did you cough up PHLEGM?


0 never 1 almost never 2 some-times 3 regu-larly 4 often 5 very often 6 always

Go to the next page 

COPD questionnaire

These questions are about the past week 

- How often did you feel limited during DAILY activities because of your lungs?

- How often did you feel limited during MODERATE activities because of your lungs?

- How often did you feel limited during HEAVY activities because of your lungs?

- How often did you feel limited during SOCIAL activities because of your lungs?


0 never 1 almost never 2 some-times 3 regu-larly 4 often 5 very often 6 always

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Fig. 3 English version of the CCQ graphic (CCQg). The CCQg is copyrighted, For more information visit <https://www.ccq-questionnaire.org/>.

In the final interviews, no additional input was provided and consensus on the final design of the CCQg was achieved (Fig. 3).

Validation

The study population for the data analysis included 64 patients with COPD and adequate health literacy, and 25 patients with COPD and limited health literacy. Patient characteristics are described in Table 1. Initially 4 respondents (2.9% of 138 eligible patients) did not fully or correctly fill out the HLS-EU-16 and were included in the limited health literacy group. 1 of these respondents did not meet criteria for stable disease and was excluded for further analysis.

Of the 138 eligible patients, four respondents (2.9%) did not fully or correctly complete the HLS-EU-16 and were therefore categorized within the limited health literacy group. Among these four, one respondent did not fulfill the criteria for stable disease and was excluded from further analysis.

In the limited health literacy group 62.5% had an International Standard Classification of Education (ISCED) level of 0–2 (lower secondary education and less) and 16.7% of 3 or higher (upper secondary education and up)^{29,30}. In the adequate health this distribution was respectively 44.3 and 33.3%.

86 patients met our inclusion criteria and had a stable situation according to the global rating of change (GRC) (Fig. 4). In 64 patients with adequate health literacy, the mean (SD) CCQg total score was 1.7 (1.1). The mean (SD) CCQ score was 1.5 (0.9). In general, patients with adequate health literacy scored significantly higher on the CCQg compared to the CCQ with a mean bias of 0.22 (95% CI: 0.10–0.34), $p < 0.01$ (Fig. 5). The correlation between

CCQg and CCQ scores were strong ($r = 0.88$ (95% CI: 0.82–0.92)). The CCQ and CCQg correlated strong with the CAT (resp $r = 0.76$ (95% CI: 0.64–0.84) and $r = 0.81$ (95% CI: 0.70–0.88)).

Both the CCQg mental status and functional status scored significant higher as compared to original CCQ (resp. mean bias = 0.38 (95% CI: 0.21–0.56), $p < 0.01$), mean bias = 0.37 (95% CI: 0.21–0.53), $p < 0.01$) (Supplementary fig. 1), there was no significant bias in the symptom domain. Results from individual items can be found in Supplementary Table 1.

Reliability of CCQg was assessed by completing the questionnaire twice within 14 days in stable patients with COPD with limited health literacy.

The mean (SD) CCQg scores were 2.1 (1.1) at day 0 and 2.1 (1.2) at day 14. The scores for self-completed CCQg at the two timepoints demonstrated a high degree of correlation ($CCC = 0.93$ (95% CI: 0.86–0.97)), and showed no significant bias (mean bias = 0.08, 95% CI: –0.09–0.24) as shown in Fig. 6. Similarly, the CCQg scores displayed a strong correlation with the CAT scores ($CCC = 0.84$, 95% CI: 0.73–0.91).

Reliability of CCQg was also assessed in stable patients with COPD with adequate health literacy, a test-retest was performed after 28 days. The CCQg at day 0 and day 28 had a mean bias of –0.03 (95% CI: –0.18–0.12) ($n = 56$).

Satisfaction with the CCQg

We measured the satisfaction of the CCQg with a self-designed Likert scale questionnaire. In patients with limited health literacy, as well in patients with adequate health literacy the response was positive, the drawings were clear for both groups (Fig. 7). In the

Table 1. patient characteristics.

	Validation: Adequate health literacy	Test-retest reliability: Limited health literacy
Sex (n (%))		
Male	29 (45.3)	9 (36.0)
Female	35 (54.7)	16 (64.0)
Age (Mean (sd))	68.9 (6.9)	69.5 (7.5)
Education (n (%))		
Low education	26 (44.3)	15 (62.5)
Medium education	14 (23.3)	5 (20.8)
High education	20 (33.3)	4 (16.7)
Smoke status (n (%))		
Current smoker	9 (14.1)	6 (24.0)
Ex-smoker	52 (81.3)	17 (68.0)
Never smoker	3 (4.7)	2 (8.0)
Smoke years (Mean (sd))	35.4 (13.4)	35.8 (12.5)
Work status (n (%))		
Yes	13 (20.0)	4 (16.0)
No	25 (39.1)	11 (44.0)
No work due to COPD	2 (3.1)	2 (8.0)
Retirement	24 (37.5)	8 (32.0)
COPD medication use (n (%))		
Triple therapy (%)	25 (39.1)	12 (50.0)
ICS/LABA (%)	18 (28.1)	7 (29.2)
LAMA/LABA (%)	5 (7.8)	2 (8.3)
ICS/LAMA (%)	0	1 (4.2)
LABA (%)	3 (4.7)	1 (4.2)
LAMA (%)	7 (10.9)	0
Short-acting BD only (%)	1 (1.6)	0
None/unknown (%)	5 (7.8)	1 (4.2)

ICS inhalation corticosteroid, LABA long-acting beta-2-agonist, LAMA long-acting muscarinic antagonist, Short-acting BD only short-acting bronchodilator only.

group with limited health literacy, 51% of patients expressed a preference for the CCQg compared to the original CCQ. Among those with adequate health literacy, 44% indicated a preference for the CCQg. In each group, respectively, 39 and 44% did not express a preference. In the open comments section, only a few patients mentioned that the drawings had no added value, while others found them clarifying.

Translation

For the translation process, one of the authors (TvdM) attended the Haringey Breathe Easy Group, a peer support group for patients with COPD. Here, semi-structured interviews were conducted with ten patients representing a range of health literacy levels, as well as the volunteer facilitator of the group. Overall, the respondents feedback concerning the choice of words were incorporated. The term “depressed” in question 4 prompted concerns about the accessibility for individuals with low health literacy. While “feeling down” was considered clearer, it lacks clinical precision and reflects American English. This highlights the challenge of balancing clarity and accuracy in patient

communication. In addition, the illustration depicting social activities was modified to align with the cultural context of the UK.

DISCUSSION

In this study we adapted a well known health status questionnaire, the CCQ, to the CCQgraphical in order to make it more understandable for patients with low (health) literacy. The lack of previous studies in this field forced us to develop new methods.

We have defined the process, based on the FDA guidance on Patient Reported Outcomes Development, in collaboration with the patient group and involved clinicians and developers. We designed and validated a modified version of the CCQ that is suitable for the majority of patients with COPD by adjustments in language, re-arrangement of the questions and the support of drawings. The CCQgraphical (CCQg) is reliable, and well accepted by patients both with limited and adequate health literacy. One key consideration is sample size, however, there is no consensus on the number of inclusions for validation of a translation of a questionnaire³¹, but a sample size of 10–40 participants is suggested for a validation studies^{32,33}.

Our study is in line with the growing awareness of the role of health literacy in health care. Limited health literacy is frequently pointed to as a patient-related factor, but in fact represents a shared concern that impacts patients, healthcare providers, and the broader healthcare system. Over the past years, many studies were performed regarding the impact of low socioeconomic status and limited health literacy skills on outcomes of COPD^{34,35}. Patients with COPD and limited health literacy encounter difficulties in accurately completing questionnaires or following medical instructions, which can compromise the assessment of their symptoms and adherence to treatment regimens. These challenges not only increase the burden of disease for patients but also impede clinicians' ability to deliver optimal care.

Patient education on disease specific materials and medication use has locally been adapted to meet the needs of limited health literacy with written, drawn, verbal instructions and videos³¹.

While management recommendations are guided increasingly by ehealth and questionnaires, questionnaires have not yet been adjusted to the large (COPD) patient population with limited health literacy. To the best of our knowledge, this study is the first to adapt and validate an existing COPD questionnaire to address patients with limited health literacy skills.

CCQg scores were in general 0.2 point higher, while the patients' complaints were stable over time. A consequent higher score in the mental and functional status domain in the CCQg explains this difference. The drawings and altered text of the CCQg could have influenced these scores. We hypothesize that patients are able to better associate the drawings and statements with their complaints, especially in the mental health status domain. The Minimal Clinically Important Difference (MCID) of the CCQ is 0.4, hence the difference of 0.2 points between CCQg scores and the CCQ scores fall well within this range³⁶. Although the effect of the difference on the MCID is unknown, we currently have no reason to expect that the MCID will change with the adaptation, but this is in need of further validation in the future.

Another major change was the order of the questions. The altered order of questions 7 and 9 makes more sense for patients. Although there was strong correlation between CCQg and CCQ, it is therefore not possible to use the questionnaires interchangeably.

This study focused on health literacy skills and patients with low literacy. An interesting next step would be to extend the study to illiterate patients and non-native speakers and measure validity of the CCQg in these groups.

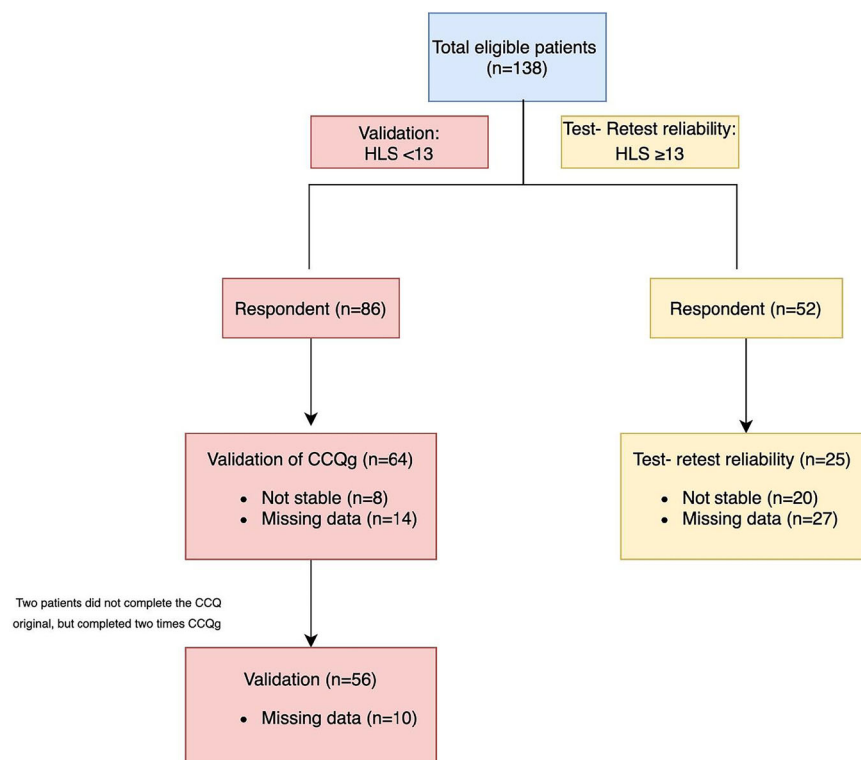


Fig. 4 Flow chart showing patient selection for validation and test-retest reliability of the Dutch CCQg. HLS = European Health Literacy Survey. Adequate health literacy is indicated by an HLS score of ≥ 13 . Limited health literacy is indicated by an HLS score of <13 .

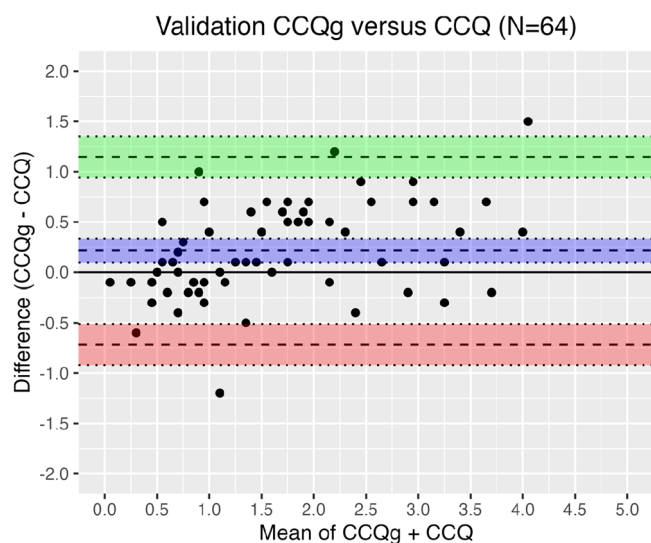


Fig. 5 Bland-Altman plot showing validation of CCQgraphic (CCQg) versus CCQ in participants with limited health literacy (HLS < 13) and stable COPD. Adequate health literacy is indicated by an HLS score of ≥ 13 . Limited health literacy is indicated by an HLS score of <13 .

Strengths and limitations

Strength of our studies is that we have included both primary and secondary care patients.

The severity of COPD was not an inclusion criterium. By encompassing a broad spectrum of patients with COPD, our findings demonstrate that the CCQg can be used by all patients, regardless of severity of COPD or health care provider. This strengthens the generalisability and relevance of our results.

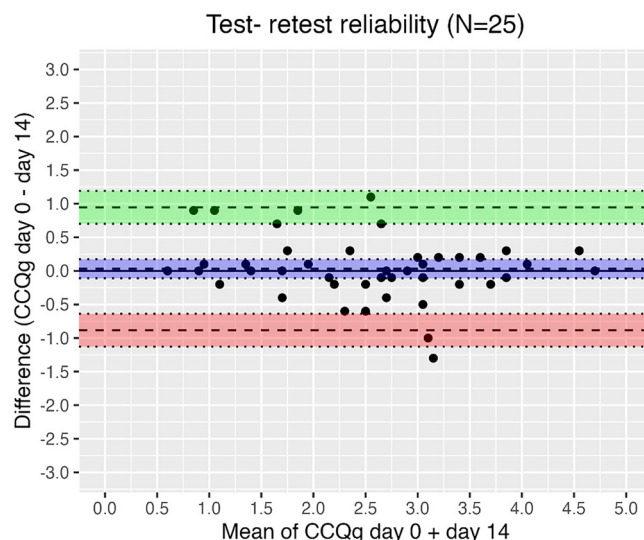


Fig. 6 Bland Altman plot showing Test- retest reliability of CCQg at day 0 versus day 14 in participants with adequate health literacy (HLS ≥ 13) and stable COPD. Adequate health literacy is indicated by an HLS score of ≥ 13 . Limited health literacy is indicated by an HLS score of <13 .

While developing the CCQg, we designed the drawings as neutral as possible and relatable for majority of European inhabitants. During interviews in the UK though, one set of drawings (question 10, social limitation) were not applicable for their cultural frame of reference and needed adjustment. This emphasizes that, although the drawings will be relatable for the majority of people living in a western society, when translating the

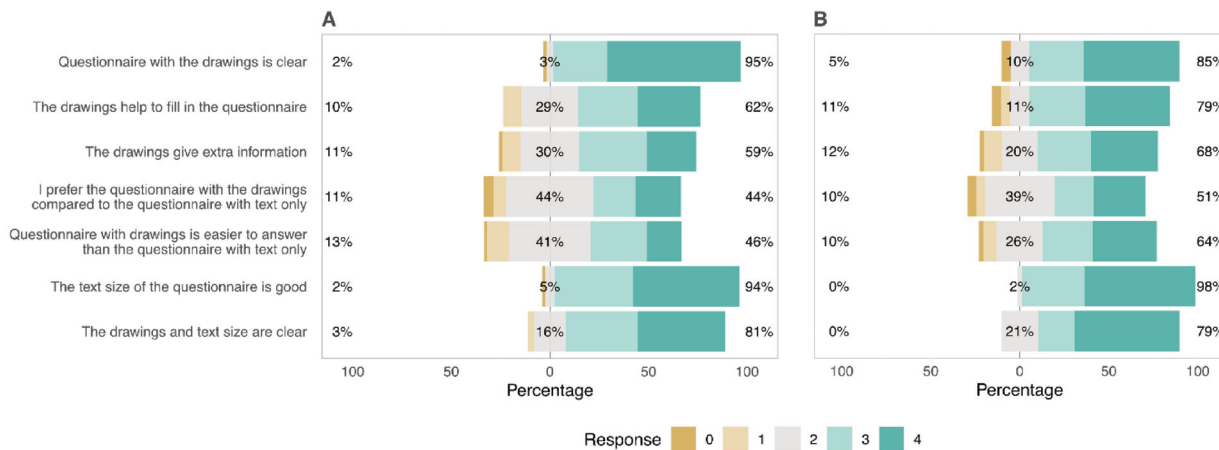


Fig. 7 Satisfaction questionnaire in patients with adequate health literacy and limited health literacy. **A:** patients with adequate health literacy ($n=25$); **B:** patients with limited health literacy ($n=56$); 0- brown = unsatisfied; 1-beige = little unsatisfied; 2-grey = neutral; 3-turquoise = little satisfied; 4-green = very satisfied.

CCQg in another language or for another language area, both the text and the drawings need reassessment for cultural adaptation.

CCQ and CAT have been used next to each other for years, although patients expressed a slight preference for the CCQ³⁷. Previous studies have shown that the CCQ and CAT correlated similar as in our study^{36,38,39}. An interesting bycatch of our study is the even stronger correlation between the CCQg and the CAT. This is in need of further validation. It will be of additional value to extend the study to applicability in ehealth.

The results of the satisfaction questionnaire showed that patients with both limited and adequate health literacy are either neutral or prefer the CCQg over the CCQ. Patients appreciated overall appearance of the CCQg, only a few gave feedback that the drawings in the CCQg did not add value. The benefits of many of the patients with limited health literacy being able to use the CCQg outweighs this feedback.

A weakness of the current study is that the number of patients with limited health literacy involved in the validation was limited, recruitment of these patients for a study proved to be difficult. The underlying reasons for difficulties in recruiting patients with limited health literacy are likely multifactorial. Firstly, we suspect that stigma continues to play a significant role for individuals with lower health literacy; feelings of shame may have contributed to non-response among potential participants. Secondly, the nature of the study—specifically, the use of questionnaires—may itself present challenges for this patient group, which could account for the observed missing data during the validation process. Additionally, the study design, which relied on postal distribution of questionnaires, may not have been ideally suited to engaging patients with limited health literacy. An alternative approach with more direct guidance might have resulted in greater participation from this group. On the other hand, this methodology does reflect the real-world conditions under which such questionnaires are typically administered.

There is no consensus on the number of inclusions for validation of a translation of a questionnaire³¹, a sample size of 10–40 participants is suggested for a proper validation³³, we therefore are on the lower end of the participants with low health literacy. A larger number of participants would have enabled us to look into more details on how patient characteristics, inhalers and COPD severity influence would have impacted scoring and agreement between the original and CCQg.

CONCLUSION

With high numbers of limited health literacy and digitization of health care, there is the risk for (digital) divide. It is of great importance that these patients are able to use the tools we provide.

This study is a first step in the process of reducing system bound factors of low and limited health literacy. Although the CCQ and CCQg, should not be used interchangeably within the same patient we suggest that both questionnaires are valid in patients with COPD where the CCQg is better understood by patients with low health literacy.

DATA AVAILABILITY

No datasets were generated or analysed during the current study.

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AUTHOR CONTRIBUTIONS

ETG wrote the main manuscript text. BS wrote part of material and methods and was responsible for the statistical analysis. IGP prepared the figures and tables. EvH designed the drawings of the CCQg. BS, IGP, AM, KK, MK collected data and prepared database. ETG, NHR, CL, EvH, TvM, MZ, Jiv and JK formed the expert group. All authors reviewed the manuscript.

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