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Translation and cultural adaptation of the scored Patient-Generated Subjective Global Assessment (PG-SGA®)

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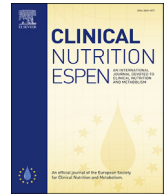
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Translation and cultural adaptation of the scored Patient-Generated Subjective Global Assessment (PG-SGA®)



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SUMMARY

Background and aim: The Patient-Generated Subjective Global Assessment (PG-SGA®) is a globally used malnutrition screening, assessment, triage and monitoring tool. The aim of this study was to perform a linguistic and content validation of the translated and culturally adapted version of the PG-SGA for the Danish setting.

Method: The study was conducted according to the International Society of Pharmacoeconomics and Outcomes Research (ISPOR) Principles of Good Practice for the Translational and Cultural Adaptation Process for Patient-Reported Outcomes Measures. Cancer patients (n = 121) and healthcare professionals (HCPs, n = 80) participated in the cognitive debriefing. A questionnaire was used in the cognitive debriefing in which comprehensibility, difficulty, and content validity (relevance) were quantified by a 4-point scale. Item and scale indices were calculated using the average item ratings divided by the number of respondents for content validity (Item-CVI, Scale-CVI), comprehensibility (Item-CI, Scale-CI) and difficulty (Item-DI, Scale-DI). As pre-defined, item indices <0.78 required further analysis of the item, and scale indices ≥0.90 were defined as excellent and 0.80–0.89 as acceptable.

Results: The patient component of the PG-SGA was rated as excellent content validity (Scale-CVI = 0.95) by HCPs and easy to comprehend (Scale-CI = 0.97) and use (Scale-DI = 0.92) by patients. The professional component of the PG-SGA was rated as acceptable content validity (Scale-CVI = 0.80), but below acceptable for comprehension (Scale-CI = 0.71) and difficulty (Scale-DI = 0.69). The physical exam was rated the least comprehensible Item-CI = 0.51–0.70) and most difficult (Item-DI = 0.33–0.063).

Conclusion: The PG-SGA was successfully translated and culturally adapted to the Danish setting. Patients found it easy to understand and to complete. Except for the physical exam, HCPs rated the PG-SGA as relevant, comprehensive, and easy to use. Training of HCPs is recommended before implementing the tool into clinical practise.

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1. Introduction

Systematic and regular screening and assessment of malnutrition in patients is advocated by international nutrition societies

[1–6]. Malnourished patients are at risk of adverse clinical outcomes, including increased morbidity and mortality, functional impairment, and poor quality of life [7–11]. Consequently, the economic burden of malnutrition is high, as approximately 30% of hospitalized patients are considered malnourished [7–9,12–14]. For certain advanced or catabolic diseases or conditions, malnutrition can be higher than 60% [15–17]. Screening for malnutrition risk is an essential step in identifying patients who may benefit from nutritional intervention [1,2,18]. When identifying patients

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with or at risk of disease-related malnutrition, it is strongly recommended to make use of validated malnutrition screening tools [1,2,5,6]. Grading and monitoring the severity of malnutrition can be conducted by a range of malnutrition assessments, enabling triaging of and response to nutritional treatment [19,20].

In the context of malnutrition, the Patient-Generated Subjective Global Assessment (PG-SGA®; Copyright FD Ottery, 1996, 2001, 2005, 2006, 2015, 2020) is a validated and extensively used 4-in-1 tool covering screening, assessment, interventional triage, and monitoring of risk factors and response to intervention (or lack thereof) [19,21]. The PG-SGA is used in research and in clinical practice settings in a range of patient populations worldwide [19,21]. The PG-SGA has a patient component, often referred to as the PG-SGA Short Form (SF), which can be used for nutritional screening [19,22]. This patient component includes items of current and past weight, food intake, presence of nutrition impact symptoms (NIS), and activities and function. It is easy and quick to complete by the patient, relative, or carer, which is important in a clinical setting. The professional component of the PG-SGA includes five Worksheets: scoring of weight loss, disease and its relation to nutritional demands, metabolic requirements, physical exam, and a global category rating. Additionally, the professional component includes interventional triage recommendations based on the total PG-SGA point score. The PG-SGA thus allows categorical staging of the severity of malnutrition, guides the nutritional triage-recommended interventions, and facilitates monitoring of response to the treatment of malnutrition and its risk factors (e.g., presence of nutrition impact symptoms, NIS).

In research, as well as in clinical practice settings, validated instruments are key when screening or assessing several clinical and health-related issues to ensure internal and external validity of results. In non-English speaking countries, internationally acknowledged and validated instruments are not always available in the native language. Hence, a translation must take place before utilizing the instrument. In translating from one language to another, conceptuality and cultural equivalence may get lost in translation [23]. If conceptuality or cultural equivalence is compromised, the internal validity of the instrument becomes questionable in the local language.

The PG-SGA was originally developed in English but has been translated and culturally adapted into several other languages [24–28]. However, an official and validated Danish translation has not been available. A simple straightforward word only translation of the PG-SGA may lead to alterations in the meaning and purpose because of the differences that exist between different cultures no matter how similar they may seem (8). It is also important that the process includes healthcare professionals and patients so that medical, nutritional, and layperson nuances are not missed. To secure transparency and validation of the translation and cultural adaptation process, the globally recognised ISPOR Principles of Good Practice for the Translational and Cultural Adaptation Process for Patient-Reported Outcomes Measures is of critical value [29,30].

The aim of the study was to assess the linguistic and content validity of the systematic translation and cultural adaptation of the original English PG-SGA into a Danish language version, to ensure conceptual, semantic, and operational equivalence to the original instrument.

2. Methods

The Danish version of the PG-SGA was developed between September 2016 and March 2018, according to the ten steps of the

International Society of Pharmacoeconomics and Outcomes Research (ISPOR) Principles of Good Practice for the Translation and Cultural Adaptation Process for Patient Reported Outcomes Measures [29].

2.1. Step 1, preparation

Authorization to translate the original English PG-SGA into Danish was granted from the developer and copyright holder of PG-SGA (FDO). The cognitive debriefing study was approved by the Ethics Committee of Region North Jutland (VEK, 2017). Key persons within the global PG-SGA network, including FDO and an international expert on the translation and cultural adaptation of the PG-SGA (HJW), participated actively in the cultural translation, cultural adaptation, and validation process. Explanation of concepts of the instrument was developed in order to strengthen the conceptual equivalence of the forward translation and to minimize misinterpretations of the items and concepts of the original instrument.

Steps 2 through 6 were conducted at two separate phases. First, the patient component (also known as the PG-SGA Short Form) was forward translated, reconciled, backward translated, reviewed, and harmonized in September to November 2016. Second, Steps 2 to 6 for the professional component of the PG-SGA were performed accordingly from February to April 2017.

2.2. Step 2 & 3, forward translation and reconciliation

A total of five individuals conducted Steps 2 and 3. The PG-SGA was forward translated by three translators for the patient component (Boxes 1–4 or PG-SGA Short Form) and two translators for the professional component (Worksheets). All translators were native Danish speaking clinical dietitians with knowledge of malnutrition and the English language. Reconciliation was subsequently conducted by the three translators for the patient component and the two translators for the professional component, where the individual forward translations were compared and merged into one single forward translation. Any discrepancies in the conceptual and semantic translations were discussed until consensus was reached.

2.3. Step 4, back translation

Two novel-to-the-project translators, i.e., both native Danish speaking clinical dietitians with knowledge of malnutrition and the English language, independently performed the back translation of the reconciled Danish PG-SGA version (from Step 3) into English. The back translators were blinded to the original English version.

2.4. Step 5 & 6, back translation review, and harmonization

Review of the back translation and harmonisation was performed simultaneously by the project coordinator (RT) together with a key persons and expert in the translational and cultural adaptation process within the global PG-SGA network (HJW, FDO). The two back translated versions of the PG-SGA instrument were used to highlight and investigate any discrepancies between the back translated reconciled Danish version and the original English version, acting as a quality control. Any discrepancies were discussed to ensure the conceptual and semantic equivalence and to ensure inter-translational validity.

2.5. Step 7, cognitive debriefing

The cognitive debriefing took place between July to October 2017, at two Danish hospitals: Aalborg University Hospital and Zealand University Hospital (Roskilde). The cognitive debriefing consisted of two questionnaires. Patients were asked to address perceived comprehensibility and difficulty of the patient component of the PG-SGA. HCPs were asked to address perceived content validity (i.e., relevance) of the PG-SGA, as well as perceived comprehensibility and difficulty of the professional component of the PG-SGA.

To quantify the content validity, HCPs were asked to rate each item of the Danish PG-SGA as relevant or not (perceived content validity). HCPs were further asked to rate each item of the professional component of the PG-SGA as clear or not clear to comprehend (perceived comprehensibility) and easy or difficult to understand (perceived difficulty). Likewise, patients were asked to rate comprehensibility and difficulty of the patients component of the PG-SGA. Additional details regarding content validity are described by Sealy et al. [24].

Patients (n = 130) were informed of the study, both in verbal and written form, and invited to participate. A total of 121 patients agreed to participate. As no personal information was collected, no ethical approval was needed (waiver was confirmed by the North Jutland Ethical Committee, 20th of February, 2017). Criteria for patient invitation to participate included those receiving oncologic treatment (chemo-, immune- and targeted therapy). No additional exclusion criteria were used. In order to ensure that patients were not asked to participate more than once, patients were approached during their 2nd therapeutic cycle.

A total of 80 HCPs participated in the study and included clinical dietitians, nurses, medical doctors, interns, occupational therapists and medical students. Clinical dietitians were included from the two hospitals and within the local municipality. Other HCPs were affiliated with the oncologic departments at the two hospitals. The study was described verbally and written material was made available for additional review.

Both patient and HCP questionnaires were completed in paper format.

The patient questionnaire consisted of 53-items including 44 items on a four-point scale regarding comprehensibility and difficulty of the items of the patient component of the PG-SGA [24]. The remaining nine items of the questionnaire concerned information about patient gender, age, and profession, as well as open-ended questions for the patient to make suggestions regarding possible improvements.

The HCP questionnaire consisted of 134-items including 114 items on a four-point scale regarding content validity of the full PG-SGA, as well as on comprehensibility and difficulty of the professional component. Four questions addressed information about the healthcare professional's current profession, years of experience, familiarity, and experience with PG-SGA. The remaining 16 questions included open-ended questions to identify potential barriers concerning operational aspects of the PG-SGA, as well as barriers concerning content validity, comprehensibility, and difficulty.

2.6. Step 8, review of cognitive debriefing results and finalisation

The project coordinator (RT) and key persons from the global PG-SGA network (HJW, FDO) reviewed the results from the questionnaires from the patients and healthcare professionals. Modifications in the Danish PG-SGA prototype were conducted based on the results from the cognitive debriefing. The order of the NIS, situated in Box 3, were changed in order to correspond to the original English version. This correction regarding order of the

NIS was done to safeguard operational equivalence with the original version.

2.7. Step 9 and 10, Proofreading and final report

The final version of the Danish language version of the PG-SGA was reviewed in order to highlight and correct any typographic, grammatical, or other errors.

2.8. Statistical analysis

The statistical methods used to assess content validity, comprehensibility and difficulty were conducted as previously described by Sealy et al. [24]. In order to calculate item and scale indices, the four-point scale was quantified as follows: 1 = very irrelevant/very unclear/very difficult, 2 = irrelevant/unclear/difficult, 3 = relevant/clear/easy, and lastly 4 = very relevant/very clear/very easy. According to the study conventions, low scores (score 1–2) were recoded as 0, indicating not relevant/not comprehensible/difficult. High scores (score 3–4) were recoded as 1, indicating relevant/comprehensible/not difficult. The item indices (I-CVI, content validity; I-CI, comprehensibility; I-DI, difficulty) are proportional scores ranging from 0 to 1, calculated by dividing the number of high scores by the total number of respondents. The Scale-CVI was calculated by averaging the I-CVI scores for the full PG-SGA. The Scale-CI and Scale-DI of the patient component of the PG-SGA were calculated by averaging I-CI scores and I-DI scores of Boxes 1 to 4. The Scale-CI and Scale-DI of the professional component of the PG-SGA were calculated by averaging Item-CI scores and Item-DI scores of Worksheets 1 to 5. A predefined item index greater than 0.78 was considered excellent, while less than 0.78 required further analysis of the item [31]. A scale index of 0.80–0.89 was considered acceptable, while 0.90 or higher was considered excellent [31].

3. Results

A total of 80 HCPs completed the questionnaire, including medical doctors (n = 13), nurses (n = 44), clinical dietitians (n = 14), medical students (n = 5), and others (n = 4), as shown in Table 1. Sixteen out of 80 HCPs were familiar with the PG-SGA, primarily from scientific literature, with three healthcare professionals reporting previous experience with the PG-SGA. Among

Table 1
Characteristics of healthcare professionals (n = 80).

Demographics	n
Profession	
Medical doctor	13
Nurse	44
Registered clinical dietitian	14
Medical interns	5
Other	4
Years of experience, mean (SD)	13.1 (10.4)
Familiar with PG-SGA	
Yes, from scientific literature/meetings	8
Yes, from PG-SGA training/clinical practice	4
Yes, from internet	3
Other	1
No	64
Experience with PG-SGA	
Yes, from use in clinical practice	1
Yes, others	2
No	77

PG-SGA: Patient-Generated Subjective Global Assessment.

the patients, a total of 121 (93%) participants completed the questionnaire. Patient characteristics are described in Table 2.

The HCPs found the overall content validity of the PG-SGA as being acceptable (S-CVI = 0.87), reflecting the instrument as being relevant in screening and assessing malnutrition (Table 3). The PG-SGA Short Form was rated as excellent (S-CVI = 0.95), while the professional component of the PG-SGA was rated just at the acceptable level (S-CVI = 0.80). Further analysis of the professional component of the PG-SGA showed that the I-CVI scores for Worksheet 4 (physical exam) were below 0.78. In contrast, all other components of the professional scored excellent (I-CVI > 0.78), with I-CVI ranging from 0.80 to 0.94.

The overall scores for comprehensibility and difficulty of the professional component of the PG-SGA were below acceptable (S-CI = 0.71 and S-DI = 0.69). Further analysis of comprehensibility of the professional component revealed that every item in Worksheet 4 (physical exam) scored below 0.78, while all other items in the professional component were above the pre-specified criteria for excellent ranging from 0.81 to 0.92. Analysis of the difficulty of the professional component of the PG-SGA showed that each single item in Worksheet 4 (physical exam) scored below acceptable (I-DI = 0.33–0.63). The explanatory text of Worksheet 3 (metabolic demand) scored below acceptable (I-DI = 0.74) for difficulty, whereas the remaining items of Worksheet 3 reached acceptable scores (I-DI = 0.86–0.89). The remaining items of the professional component, including Worksheet 1, 2, 5, and the Nutritional Triage Recommendations were considered acceptable or excellent, with scores ranging from 0.78 to 0.95.

Table 2
Characteristics of patients (n = 130).

Demographics	N	%
Gender		
Male	45	37
Female	76	63
Age, mean (SD)	64.1 (10.7)	
Education		
University level	48	40
Upper secondary school	3	3
Vocational education	39	32
Primary school	22	18
Other	8	7

SD: standard deviation.

Table 3
Item and scale indexes for content validity, comprehensibility and difficulty for the Danish PG-SGA prototype as perceived by Danish patients and healthcare professionals.

	Content validity (CVI)	Comprehensibility (CI)		Difficulty (DI)	
	Healthcare professionals	Healthcare professionals	Patients	Healthcare professionals	Patients
Item indexes of the PG-SGA Short Form					
Box 1 – Weight history	0.95		0.98		0.96
Box 2 – Food intake	0.96		0.96		0.89
Box 3 – Nutrition impact symptoms	0.95		0.98		0.92
Box 4 – Activities and function	0.93		0.98		0.91
Item indexes of the professional component of the PG-SGA					
Worksheet 1 – Scoring weight loss	0.91	0.85		0.81	
Worksheet 2 – Disease and nutritional requirements	0.89	0.89		0.93	
Worksheet 3 – Metabolic demand	0.86	0.88		0.74 ^a	
Worksheet 4 – Physical exam	0.66	0.59 ^a		0.47 ^a	
Worksheet 5 – Global Assessment Categories	0.91	0.87		0.85	
Nutritional triage recommendations	0.90	0.86		0.84	
Scale indexes of the PG-SGA Short Form	0.95		0.97		0.92
Scale indexes of the professional component of the PG-SGA	0.80	0.71 ^a		0.69 ^a	
Scale indexes of the full PG-SGA	0.87	0.71^a	0.97	0.69^a	0.92

^a Score below cut-off for 'acceptable'.

Patients found that the PG-SGA SF met the pre-specified criteria of excellent comprehensibility (S-CI = 0.97) and level of difficulty (0.92).

Based on comments from HCPs, a total of eight modifications were made to the Danish version of the PG-SGA. Proofreading resulted in correction of 13 grammatical and spelling errors. The finalised Danish PG-SGA version was published 14th of September 2018 and can be retrieved from <https://pt-global.org/>.

4. Discussion

The Danish version of the PG-SGA has been systematically translated, culturally adapted, and validated for linguistic and content by patients and multidisciplinary healthcare professionals. This multidimensional approach serves to safeguard the conceptual, semantic, and operational understanding correspond to the original English version. The finalized Danish PG-SGA (Danish 18–009 v09.14.18) is available for clinicians and researchers to access and download at no charge from the Pt-Global website (<https://pt-global.org/>).

The use of the ISPOR based principles enabled robust understandings of the patient and professional components of the PG-SGA. The patient component of the Danish version of the PG-SGA, i.e., the PG-SGA SF, received excellent ratings in content validity as assessed by HCPs. The patients considered the PG-SGA SF easy to comprehend and to use. Overall, the professional component of the PG-SGA received adequate ratings for the content validity, comprehensibility and difficulty. However, the physical exam of the professional component of the PG-SGA received the lowest score on relevance and was found to be difficult to understand and use by HCPs.

The study results are consistent with findings from similar ISPOR-based translations and cultural adaptations of the PG-SGA for Norwegian, Dutch, German, Greek, and Japanese languages [24,25,27,28,32]. Similar to the Danish results, the patient component consistently received high ratings, indicating high content validity (S-CVI = 0.89–0.99), ease of comprehension (S-CI = 0.90–0.99), and low level of difficulty (S-DI = 0.90–0.97) [24,25,27,28]. In addition, content validity of the professional component was rated excellent in all translated and culturally adapted language versions [24,25,28,32]. In contrast, comprehensibility of the PG-SGA reached below acceptable in Norwegian

(S–CI: 0.78) as in Danish, acceptable in German, Dutch and Japanese (S–CI: 0.81–0.88), and excellent in Greek [24,25,27,28]. As for perceived difficulty of the PG-SGA, the Danish, Dutch, Norwegian, German, and Japanese version was rated below acceptable (S-DI: 0.55–0.72), whereas the Greek reached excellent results [24,25,27,28,32]. Comparable to the Danish results, the physical exam (Worksheet 4) was rated as the least comprehensible (S–CI: 0.61–0.70) and most difficult to complete (S-DI: 0.26–0.47), while the metabolic demand (Worksheet 3) was the least comprehensible and most difficult in the Norwegian, German and Japanese studies (S–CI: 0.69–0.74; S-DI: 0.67–0.70) [25,27,32].

With the availability of the validated Danish version of the PG-SGA at www.pt-global.org, Danish patients have the opportunity to be screened and assessed by an instrument found to have high ability to predict clinical, oncologic, and economic outcomes [7–13,19]. Access to the linguistic and content validated Danish PG-SGA is essential to ensure internal and consistent validity globally [29]. As a result, Danish data regarding malnutrition screening and assessment can contribute to global reporting and pooling of data in global databases [30].

Based on the study results combined with the large sample size, the patient component of the PG-SGA is ready to be implemented in clinical practice. Results confirm that no training is needed for patients to complete their component. The PG-SGA SF is the equivalent to a patient reported outcome (PRO) instrument. In Denmark, inclusion of PROs has made its entry into the expanding use of telemedicine where patients report various PROs prior to hospital visits. In the growing use of telemedicine, implementation of the PG-SGA SF will enable identification of patients with nutritional deficit or risk of malnutrition. As a result, this frees up time for HCPs to focus on actual nutritional assessment and intervention.

Feedback from the open-ended questions identified differences in perspectives between professions. Nurses found the physical exam to be outside the scope of their role as nurses and identified themselves as unqualified to conduct the physical exam. In contrast, medical doctors and clinical dietitians emphasised lack of time and magnitude of comprehensibility. Physical examination of nutritional status is rarely conducted systematically in clinical practice at Danish hospitals. In daily practice, in Denmark, malnutrition assessments are often based on objective assessments, such as degree of weight loss, low BMI, and nutrient intake. This is reflected by the results were less than 5% of the HCPs had previous experience with the PG-SGA and frequent reports of lack of training or skills by the healthcare professionals in the open-ended questions.

Awareness of the importance of routine nutritional examination, including physical assessment, as well as relevant training is recommended in order to increase comprehension and use of the professional component of the PG-SGA. Education most appropriately needs to target the physical examination from a nutrition or body composition perspective (Worksheet 4) and metabolic demands associated with fever and catabolic steroids (Worksheet 3). Previous research has found that the comprehension of the individual items of physical examination increased from 0.41 to 0.50 pre-training to 0.91–0.97 post-training after a single session of training [33]. Additionally, the level of difficulty improved from 0.13 to 0.17 pre-training to 0.53–0.71 post-training ($p < 0.001$), indicating that comprehension and ease of use significantly improved after receiving the one single session of training with the PG-SGA [33].

A major strength to this study is that the developer of the PG-SGA was involved in the translation and cultural adaptation process which guarantees equivalence to the original instrument. Additional strength to the study was the large sample of HCPs and patients in the cognitive debriefing. Patients with cancer are considered to be a heterogeneous patient group, which required a

large sample size in order to ensure sufficient depth and breadth to reach representativeness of the cancer population as a whole. Patients and the majority (96%) of HCPs had no previous experience with the PG-SGA instrument which minimize the impact of biased perception of content validity, comprehensibility, and difficulty. However, this likely has affected the results of the cognitive debriefing, especially the time needed to complete the questionnaire and the lack of experience in performing a physical exam. Especially HCPs who are not experienced in assessing a subjective evaluation of body composition in the context of nutritional status found this section to be the most difficult. However, both comprehensibility and difficulty improve with training [33]. The major limitation of the study is that study population was limited to cancer patients only, which can impact the generalizability of use beyond cancer patients.

In conclusion, a culturally adapted and linguistic and content validated Danish version of the PG-SGA (Danish 18–009 v09.14.18) is now available, securing conceptual equivalence to the original English version. HCPs found the Danish version of the PG-SGA relevant in screening and assessing malnutrition. The professional component of the PG-SGA was found understandable and easy to complete, with the exception of the physical exam and the explanatory text to the metabolic demand. Training of Danish HCPs is indicated before implementing the professional component into clinical practice and research, as training has shown to increase comprehension and ease of use. Importantly, patients found the patient component, i.e., the PG-SGA SF, understandable and easy to complete, indicating the instrument can be implemented into clinical practice and research without further action.

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Authorship

RT, HJW and FDO contributed to the conceptualization, design, and methodology. RT, JS, PS, PS, and LHPK collected data. RT, HJW and FDO analysed and interpreted the data. RT drafted the manuscript, which was critically reviewed by all authors. All authors approved the final manuscript.

Declaration of competing interest

All PG-SGA tools and derivatives were developed or co-developed by FDO and are copyrighted by FDO, with pro bono support to researchers and with availability at no cost to clinicians for patient care. HJW was co-developer of the PG-SGA-based Pt-Global web tool. None of the remaining co-authors have any conflicts of interest to declare.

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